DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey and Certification Group

November 30, 2007

Dear Colleague:

This letter will serve to notify you that CMS is adjusting the scope and extent of the policy for "educational" Analytic Systems (QC) requirements with regard to the CLIA 2003 Final Quality System regulations. In addition, it will review the complaint policy and stress the importance of using special care regarding the handling of proficiency testing samples.

Adjustment to "Educational "CLIA QC Policies

In the 2004 release of our Surveyor Interpretive Guidelines, we stated that we would not cite certain deficiencies on a CMS survey report for requirements that were "new to the laboratory" unless there was real or potential harm to patients. Instead, we would provide the laboratory a letter that reflected our findings, with an explanation of the applicable regulation. This policy mainly impacted laboratories that conduct moderate complexity tests. The CLIA requirements included in the educational phase-in consist of:

- 493.1255--Calibration and calibration verification
- 493.1253--Test method verification
- 493.1254--Maintenance and function checks
- 493.1256--QC procedures

We are notifying you to alert your constituencies that we are going to limit what is included in the "educational" phase-in, effective December 31, 2007, to QC procedures. All the remaining Analytic Systems requirements must now be met or a deficiency will be cited. We are extending the QC Procedures due to our collaboration with the Clinical and Laboratory Standards Institute (CLSI) and the development of guidance documents for manufacturers and laboratories that will provide further information which will enable laboratories to develop customized QC protocols.

Our rationale for ending the educational period for the other requirements is that we believe laboratories have been educated on the requirements and have had ample opportunity to comply. We have educated laboratories during the previous 2 inspection cycles and distributed brochures to address most of these topics. Therefore, effective December 31, 2007, if any of these requirements are not met, the laboratory will receive a deficiency citation instead of a letter for all of the above except for QC procedures; i.e., those requirements under 493.1256. Those laboratories not performing 2 levels of external QC per day of testing or not successfully performing a CMS-approved Equivalent QC (EQC) option, will still receive a letter, unless no QC at all is being performed or there are serious concerns about the quality of the testing in that

laboratory. . In that case, the laboratory will receive a deficiency citation. Please refer to the Decision chart that is attached to this letter for details.

Attached you will also find the guidance and a copy of a revised "QC letter" for laboratories that we have sent to our State surveyors. Please note that this affects ***only CMS surveyed laboratories*.** If your laboratory receives its CLIA certification by virtue of accreditation by a CMS-approved accreditation organization, compliance is achieved by meeting your accrediting organization's QC standards.

Importance of Options for Filing Complaints and Without Fear of Retribution

In response to the May 2006 Government Accountability Office (GAO) report on laboratory quality and oversight, we are re-emphasizing the importance of having an open complaint process.

A component of CMS' mission is to provide for the public's heath and to ensure quality healthcare services. Toward that end, when anyone -- patient, employee, caregiver, etc. identifies concerns about the quality of a laboratory's testing, there should be simple, non-threatening mechanisms in place for reporting the concerns to the appropriate parties.

CMS now utilizes an automated tracking system to collect complaint information. Each complaint is investigated promptly and a determination is made whether the allegation has been substantiated. Every complaint is evaluated to the appropriate degree and every attempt is made to maintain the confidentiality of the complainant.

Complaints may be filed with the State agencies that conduct CMS' CLIA surveys, the CMS regional office CLIA consultants or to CMS' Central Office (CO), the Division of Laboratory Services, in Baltimore. Contact information for the State agencies and CMS regional offices is listed on the CMS/CLIA web site at: www.cms.hhs.gov/CLIA. Most State Departments of Health also have a general toll free number for filing complaints. CMS' CLIA CO can be reached at: 410-786-3531 or you may email Judy Yost at: judith.yost@cms.hhs.gov.

Additionally, CMS has placed complaint-related information in the updated Surveyor Interpretive Guidelines, that will be available on our CLIA web site at a later date. A special CLIA brochure regarding complaint filing will be published and distributed to all laboratories surveyed by CLIA surveyors and will be posted on our web site.

Refresher on CLIA Statute, Regulations & Policy for Proficiency Testing (PT) Referral

Proper handling of PT samples is one of the most important requirements of the CLIA program, with improper PT referral resulting in laboratory closure. When intentional PT sample referral or communications between laboratories with regard to PT results occurs, an automatic determination of immediate jeopardy to patient health and safety is made, followed by revocation of the laboratory's CLIA certificate, immediate loss of Medicare/Medicaid payment and the inability of the owners/operators of the laboratory to own/operate any laboratory for 2 years.

Many CLIA appeals are related to PT referral and in every instance CMS determination has been sustained. A detailed listing of these cases is in the ALJ/DAB database on the CLIA web site.

An important caution about PT referral is to alert you that it's critical to enhance laboratories' awareness about circumstances when a laboratory utilizes a PT program to meet the alternative assessment requirements (PT for analytes not listed in the regulations in Subpart I) at 493.1236. These non-regulated analyte PT samples must also be handled in the same manner as regulated samples. **Improper PT referral of non-regulated analyte samples will result in the same strong sanctions as for regulated analytes.**

PT samples, information and results/scores should not be used until the results of the PT samples have been returned to the laboratory from the PT provider. PT samples should not be used for other purposes, for example, training or competency testing, until after the results of the PT event have been returned to the laboratory.

This concludes our notifications and we thank you in advance for sharing them with your customers, constituencies and the public, as you feel necessary. If you have any questions or concerns, please feel free to contact me or my staff. We look forward to working with you now and in the future toward our mutual goal of improved laboratory quality and education.

Sincerely,

/s/

Judith A. Yost
Director,
Division of Laboratory Services
CMS