Attachment 1

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations

Ref: S&C-03-30

DATE: **August 14, 2003**

FROM: Director
Survey and Certification Group

SUBJECT: Clinical Laboratory Improvement Amendments (CLIA) Policy Letters for First Survey Cycle Following the Effective Date of CMS-2226-F

TO: Survey and Certification Regional Office Management (G-5)
State Survey Agency Directors

This memorandum presents two letters for use in certain first survey cycle (FY2004-FY2005) compliance situations involving CMS-2226-F ("Medicare, Medicaid, and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications,"
68 FR 3640).

For the most part, this final rule simply reorganizes portions of the prior CLIA regulations. However, the provisions outlined in Subpart K-Quality Systems for Nonwaived Testing at section 493.1250, Analytic systems requirements, now apply to all laboratories performing nonwaived testing. Prior to this rule, laboratories that performed moderate complexity tests using an instrument, kit, or test system cleared by the Food and Drug Administration through the premarket notification (510(k)) or premarket approval (PMA) process for in-vitro diagnostic use were not held to all of these requirements. In keeping with CMS' educational approach and the continued use of the outcome-oriented survey process, surveyors are to use the two attached letters when laboratories are not in compliance with the analytic systems provisions that are new to the laboratory.

Letter number 1 (first survey cycle letter without accompanying CMS-2567) is to be used when the laboratory's only deficiencies include analytic systems provisions that are new to that laboratory. Letter number 2 (first survey cycle letter with accompanying CMS-2567) will be used to accompany a survey report form (CMS-2567) when the laboratory has deficiencies in items that were required under the former rule as well as deficiencies in the analytic systems provisions of CMS-2226-F that are new to the laboratory.

If you have questions or would like further clarification, please contact Judy Yost at 410-786-3407 or Virginia Wanamaker at 410-786-7304. We appreciate your ongoing dedication to the effective administration of the CLIA program and your assistance during this upcoming survey cycle.

/s/
Steven A. Pelovitz

Attachments

Model Letter # 1

First survey cycle letter <u>without</u> accompanying CMS-2567

Date_____

[Laboratory Director]
[Laboratory's Name]
[Address]
[City], [State], [Zip Code]

Re: CLIA # _____
State ID #_____

Dear [Laboratory Director]:

A representative [or name of the surveyor] of the [State Survey Agency] surveyed your laboratory on [date] for the Centers for Medicare & Medicaid Services (CMS) for CLIA purposes. I hope the on-site survey was helpful to you and your staff.

During the exit conference, the representative [or the surveyor's name] discussed some items **needing** correction due to provisions contained in the newly effective revised CLIA regulations. (See 68 Federal Register 3640 that became effective April 24, 2003.) The majority of the material contained in this regulation was merely a reorganization of existing provisions, but there are a limited number of new provisions in the rule as well.

During this survey cycle, CMS is seeking to educate providers about the new regulatory requirements, and hopes to obtain voluntary compliance with these requirements. As such, these items are listed in this letter rather than the survey report. We encourage you and your staff to familiarize yourselves with these new provisions. Correction of the items listed below will improve the quality of care for your patients and will assist you in the future, when deficiencies in meeting these requirements will be included as part of the survey report and resolution process.

At the time of your survey on [date], your laboratory was not in compliance with the following new provisions contained in the revised CLIA regulations:

[List any of the following that are applicable]

- Section 493.1253: Establishment and verification of performance specifications
- Section 493.1254: Maintenance and function checks
- Section 493.1255: Calibration and calibration verification procedures
- Section 493.1256: Control procedures

[Include any pertinent specific information that will clarify the concern or help the laboratory understand how to comply here.]

The representative [or surveyor's name] will follow up in [x days] to determine if your laboratory has addressed the areas needing correction. In the meantime if you would like additional information or need further assistance, please contact [State Representative's name] at [phone number].

Sincerely,

State Agency Signature
Name and Title

Model Letter # 2
First survey cycle letter <u>with</u> CMS-2567

Date_____

[Laboratory Director]
[Laboratory's Name]
[Address]
[City], [State], [Zip Code]

Re: CLIA # _____
State ID #_____

Dear [Laboratory Director]:

A representative [or name of the surveyor] of the [State Survey Agency] surveyed your laboratory on [date] for the Centers for Medicare & Medicaid Services (CMS) for CLIA purposes. I hope the on-site survey was helpful to you and your staff.

During the exit conference, the representative [or the surveyor's name] discussed some items that appear on the survey report **requiring** correction by you/your staff. Details concerning those items are provided in the accompanying letter and survey report. Please note that the items listed on the survey report form are those items that were required of your laboratory both under the former CLIA rules and the newly effective revised rules. (See 68 Federal Register 3640 that became effective April 24, 2003.) These items **must** be addressed by the time frame specified in the accompanying letter in order to avoid any adverse actions by CMS.

The representative [or surveyor's name] also discussed some items **needing** correction due to provisions solely contained in the newly effective revised rules. During this survey cycle, CMS is seeking to educate providers abut the new regulatory requirements, and hopes to obtain voluntary compliance with these requirements. As such, these items are listed in this letter rather than the survey report. We encourage you and your staff to familiarize yourselves with these new provisions. Correction of the items listed below will improve the quality of care for your patients and will assist you in the future, when deficiencies in meeting these requirements will be included as part of the survey report and resolution process.

At the time of your survey on (date), your laboratory was not in compliance with the following new provisions contained in the revised CLIA regulations:

[List any of the following that are applicable]
- Section 493.1253: Establishment and verification of performance specifications
- Section 493.1254: Maintenance and function checks
- Section 493.1255: Calibration and calibration verification procedures

- Section 493.1256: Control procedures

[Include any pertinent specific information that will clarify the concern or help the laboratory understand how to comply here.]

Please note that the deficiencies listed above are in addition to any items listed on the survey report form. Both lists of deficiencies need correction before your laboratory will be in complete compliance with the CLIA regulations.

The representative [or surveyor's name] will follow up in [x days] to determine if your laboratory has addressed the areas needing correction that are listed on this letter. In the meantime if you would like additional information or need further assistance, please contact [State Representative's name] at [phone number].

Sincerely,

State Agency Signature
Name and Title