DEPARTMENT OF HEALTH & HUMAN SERVICES
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Center for Clinical Standards and Quality/Survey & Certification Group

Admin Info: 13-34-CLIA

DATE: **September 13, 2013**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Issuance of Clinical Laboratory Improvement Amendments of 1988 (CLIA) State Agency Performance Review (SAPR)—Fiscal Year 2013 (FY2013)

Memorandum Summary

- **CLIA SAPR Review Protocol:** The FY 2013 review is limited to six of the original Criteria, to provide time for the extensive activities related to a new quality control (QC) option under CLIA. The Criterion #8 review procedures are modified, based on Regional Office (RO) reviewer feedback. (See Attachment #1).
- **Goal:** CLIA State Agency (SA) optimal performance, with CMS RO support, as necessary.
- **Summary Report for Each CLIA SA:** The aim of each report is a balanced picture of the CLIA SA's operations, including activities the SA performs well, area(s) where improvement may be needed, noteworthy accomplishments, and any special circumstances affecting performance.
- **Review of Other Subject Areas:** CMS ROs have the overarching responsibility and authority for SA oversight, which is not superseded nor limited by the CLIA SAPR. Subject areas not specifically addressed by the FY 2013 Review Criteria may also be reviewed, at the RO's option.
- **Review of CLIA SAPR Criteria 10 and 11:** The RO Review Tool instituted last year is utilized again this year, with slight modification, based on RO reviewer feedback. (See Attachment #8).
- **Due Date**: Draft CLIA SAPR Summary Reports, Worksheets, Cover Letters and RO Review Tools are due in Central Office (CO) by **March 3, 2014.**

Background

The CLIA SAPR is a mandated annual evaluation of each SA's performance of its survey and certification responsibilities under the CLIA program. The evaluation is performed by the CMS RO CLIA program personnel.

Objectives and Goal

The objectives are: to document CLIA program oversight of SA performance and to support and facilitate SA performance improvement, as needed. The goal is optimal SA performance to further quality in patient testing.

FY2013 Protocol

The FY 2013 standard review is limited to six of the original CLIA SAPR Criteria, to provide time for the continued extensive activities related to CMS' implementation of modifications to CLIA QC policy. CMS ROs have the option to expand the review to include additional areas of CLIA SA responsibilities which, in their judgment, merit evaluation or monitoring. (Also see "Relationship to Other RO Oversight Responsibilities"). The six Criteria are:

Criterion #6—Survey Time Frames
Criterion #8—Proficiency Testing (PT) Desk Review
Criterion #9—Outcome-Oriented Survey Process
Criterion #10—Principles of Documentation (POD)
Criterion #11—Acceptable Plan of Correction (POC)
Criterion #13—Complaints

RO Collaborative Support

RO collaborative support is an integral part of the CLIA SAPR. This includes assistance with CLIA SA internal reviews of Statements of Deficiencies and POCs, where circumstances warrant, such as States with less than 1.0 CLIA surveyor full-time equivalent, or non-laboratorian supervisors. This activity can double as an onsite training opportunity. Collaboration also provides further opportunities for mutual understanding of obstacles to optimal CLIA SA performance, brainstorming for solutions, learning about best practices of other similarly-situated States, additional face-to-face conversations about application of POD and acceptability of laboratory POCs and Allegations of Compliance (AOC), as well as further enhancing RO/SA communication—all aimed at the goal of optimal CLIA SA performance and quality patient testing.

Relationship to Other RO Oversight Responsibilities

ROs, as always, have the overarching responsibility and authority for CLIA SA oversight, which is neither superseded nor limited by the CLIA SAPR. Thus, the RO may review a State's performance related to any aspect of CLIA SA responsibility not specifically evaluated by the standard protocol for FY 2013. Any review conducted in addition to the standard protocol should be documented in a separate section of the CLIA SAPR Summary Report, and presented separately from the review outcomes of the standard Criteria designated for the FY 2013 review.

Attachments—Listing and Descriptions

Attachment #	Name
1	**FY 2013 CLIA SAPR Document: Performance Review Criteria, Performance Indicators, and Worksheets**
2	**FY 2013 CLIA SAPR Data Reports for Standard Review Protocol—Instructions and Description**
3	**CLIA Data Reports—Optional Review of Additional Subject Areas**
4	**FY 2013 CLIA SAPR Summary Report Template—Completion Instructions**
5	**FY 2013 CLIA SAPR—The Summary Report Template**

Attachment #	Name
6	**FY 2013 CLIA SAPR Cover Letter Template—for Transmitting the Summary Report to the SA**
7	**FY 2013 CLIA SAPR Model Letter—for Response to SA Corrective Action Plans**
8	**FY2013 CLIA SAPR Criteria 10 and 11 RO Review Tool—Principles of Documentation (POD) and Acceptable Plan of Correction /Credible Allegation of Compliance (PoC/AoC)**

Attachment #1: FY 2013 CLIA SAPR Document: Performance Review Criteria, Performance Indicators, and Worksheets

The Review Criteria, Performance Indicators, and instructions for completing the Worksheets are consolidated into one Excel document, for ease of reference. Instructions for completion are contained in the section entitled "Criterion Review Procedures". The Worksheets must be completed electronically. Calculations are automated in Excel. Ann Snyder, of the CO SAPR Team, is available to provide assistance with any aspect of Excel. She can be reached at 410-786-6812 or Ann.Snyder@cms.hhs.gov. **Please note: Review procedures for Criterion #8 have been modified, based on RO Reviewer feedback. The SA's timeliness of PT desk review is now addressed overall in Performance Indicator (PI) 1, rather than individually in PI 2 and PI 3. The SA's role, for sanctioning a non-initial unsuccessful, was corrected to indicate referral to RO, rather than direct sanction (PI 3d).**

Attachment #2: FY 2013 CLIA SAPR Data Reports for Standard Review Protocol—Instructions and Description

These data reports are referenced in Criteria #6, 8, 9, 10, 11 or 13. For consistency purposes, they must be used as indicated in the Criterion Review Procedures for the respective Criterion.

Attachment #3: CLIA Data Reports—Optional Review of Additional Subject Areas

These data reports are available for monitoring work, or RO optional review of subject areas not specifically addressed by the six standard Criteria of the FY 2012 CLIA SAPR. These reports were developed for the CLIA SAPR in previous years, and have been updated with FY 2013 data. Please note they are accessible for CLIA SA as well as RO use.

Attachment #4 : FY 2013 CLIA SAPR Summary Report Template—Completion Instructions

This template has been updated for FY 2013 and is compatible with Word 97-2003.

Attachment #5: FY 2013 CLIA SAPR Summary Report Template

It is very important to provide in the narrative a balanced picture of activities that the CLIA SA performs well, any areas where improvement is needed, noteworthy accomplishments, and any special circumstances positively or negatively affecting the SA's performance.

Attachment #6: FY 2013 CLIA SAPR Cover Letter Template—for Transmitting the Summary Report to the SA

Model language is included, for instances where the RO has exercised the option to review additional subject areas. Instructions for the associated narrative are now more specific.

Attachment #7: FY 2013 CLIA SAPR Model Letter for Response to SA Corrective Action Plan
This model letter has been updated for FY 2013.

Attachment #8: FY2013 CLIA SAPR Criteria 10 and 11 RO Review Tool—Principles of Documentation (POD) and Acceptable Plan of Correction /Credible Allegation of Compliance (PoC/AoC)
This tool is used by the RO Reviewer to review CMS-2567 Statements of Deficiency and Plan of Correction for adherence to POD and proper acceptance of PoC/AoC. This version is slightly modified from the version used last year, based on RO reviewer feedback. Outcomes from this review will be used for year-to-year comparisons, monitoring for improvement, and needs assessment for national training, as needed.

Due-Date for Draft Summary Reports, Worksheets and Cover Letters and RO Review Tools
Draft FY 2013 CLIA SAPR packages are due in CO by **March 3, 2014**. Please forward the **Summary Report,** along with the **Worksheets, undated Cover Letter, RO Review Tool and associated CMS-2567s with PoC or AoC.** When e-mailing messages regarding CLIA SAPR matters, including the draft CLIA SAPR packages, please address as follows:

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Additionally, please name each file as follows**:**

SAPR CLIA FY2012_2-digit abbreviation of State name.doc
For example, the file for Ohio would be named <**SAPR CLIA FY2013_OH.doc**>

Effective Date: October 1, 2013. This information should be shared with all CLIA Program survey and certification staff, their managers, State/RO training coordinators, State/RO CLIA budget personnel, State/RO CLIA data entry/data management personnel, and State human resources personnel (hiring of CLIA SA surveyors) within 30 days of this memorandum.

/s/
Thomas E. Hamilton

Attachments

cc: Survey and Certification Regional Office Management