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

Admin Info: 16-35-CLIA

DATE: **September 30, 2016**

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 2016 (FY2016)

Memorandum Summary

- **CLIA SAPR Review Protocol:** The FY 2016 review is limited to **eight** of the original Criteria, to provide time for the extensive activities related the implementation of IQCP (Individualized Quality Control Plan). Criterion 1, Personnel Qualification/Training, and Criterion 4, Data Management, have been added as mandatory.
- **Goal:** CLIA State Agency (SA) optimal performance, with support from the Centers for Medicare & Medicaid Services (CMS) Regional Offices (ROs) 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of Other Subject Areas:** CMS ROs have the overarching responsibility and authority for SA oversight, which is not superseded nor limited by the CLIA SAPR.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 2016 Review Criteria may also be reviewed at the RO's discretion.
- **Review of CLIA SAPR Criterion 4:** A new RO Review Tool has been developed to aid in the evaluation of Criterion 4 (See Attachment #1)
- **Review of CLIA SAPR Criteria 10 and 11:** The RO Review Tool is utilized again this year, with slight modification, based on RO reviewer feedback. (See Attachment #1).
- **Due Date**: Draft CLIA SAPR Summary Reports, Worksheets, Cover Letters and RO Review Tools are due in Central Office (CO) by **March 2, 2017.**

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.

State Agencies are encouraged to utilize the SAPR reports enclosed in Attachment 2 throughout the entire fiscal year in order to identify any areas which may need to be addressed prior to each annual SAPR review.

FY2016 Protocol

The FY 2016 standard review is limited to eight of the original CLIA SAPR Criteria, to provide time for the continued extensive activities related to CMS' implementation of IQCP (Individualized Quality Control Plan). 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 eight Criteria are:

Criterion #1—Personnel Qualifications/Training
Criterion #4 – Data Management
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-laboratorial 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. The SAPR Summary report should not identify individual surveyors, labs, or CLIA numbers. Discussions regarding issues related to specific surveyors, labs, or CLIA numbers should occur at the on-site visit.

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 2016. 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 2016 review.

Attachments—Listing and Descriptions

Attachment #	Name
1	• **FY 2016 CLIA SAPR Document: Performance Review Criteria, Performance Indicators, and Worksheets** • **FY2016 CLIA SAPR Criteria 10 and 11 RO Review Tool—Principles of Documentation (POD) and Acceptable Plan of Correction /Credible Allegation of Compliance (PoC/AoC)** • **FY2016 CLIA SAPR Criterion 4 Review Tool – Data Management**
2	• **FY 2016 CLIA SAPR Data Reports for Standard Review Protocol—Instructions and Description** • **CLIA Data Reports—Optional Review of Additional Subject Areas** • **FY 2016 CLIA SAPR Summary Report Template—Completion Instructions**
3	• **FY 2016 CLIA SAPR—The Summary Report Template**
4	• **FY 2016 CLIA SAPR Cover Letter Template—for Transmitting the Summary Report to the SA** • **FY 2016 CLIA SAPR Model Letter—for Response to SA Corrective Action Plans**
5	• **Instructions for Printing CASPER 850D– CLIA SAPR Current Certificates Expiring Before Survey Upload** • **Special Instructions for Accessing CASPER Report 104 during FY16** • **Step-by-Step Instructions: Accessing SAPR data reports in QW**

Attachment #1:

- **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. All formatting was reviewed and updated for consistency. In addition, all calculations were checked to ensure they are computing correctly.

- **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. Outcomes from this review will be used for year-to-year comparisons, monitoring for improvement, and assessment for national training, as needed.

- **Criterion 4 RO Review Tool**—Data Management This tool is used by the RO Reviewer to review accuracy and timeliness of input into the database for initial Form CMS-116, certificate type changes, and updated demographic information.

Attachment #2:

- **SAPR Data Reports for Standard Review Protocol—Instructions and Description**
These data reports are referenced in Criteria #4, 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. It is recommended that the report "ACTS Complaint/Incident Investigation Log" be used to identify complaints for Criterion #13, Complaints for the FY; however, details regarding timeline should be verified onsite at the SA as the documentation is a true indication of whether timelines have been met. In addition, tracking sheets developed and implemented at the RO may be used.

- **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 2016 CLIA SAPR. These reports were developed for the CLIA SAPR in previous years, and have been updated with FY 2016 data. Please note they are accessible for CLIA SA as well as RO use. CMS ROs have the overarching responsibility and authority for SA oversight, therefore, subject areas not specifically addressed by the FY 2016 Review Criteria may also be reviewed at the RO's discretion. The addendum report should indicate why the additional measure(s) are being reviewed.

- **FY 2016 CLIA SAPR Summary Report Template—Completion Instructions**
This template has been updated for FY 2016.

Attachment #3:

- **FY 2016 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 #4:

- **FY 2016 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.

- **FY 2016 CLIA SAPR Model Letter for Response to SA Corrective Action Plan**
  No changes were made to this model letter for FY 2016.

Attachment #5:

- **Instructions for Printing CASPER 850D – CLIA SAPR Current Certificates Expiring Before Survey Upload**
  This report replaces OSCAR reports 30 through 33.

- **Instructions for Accessing CASPER Report 104 during FY16Prior to Revision (to be completed by 12/1/15)**
  This attachment includes step-by-step instructions for accessing CASPER report 104.

- **Step-by-Step Instructions: Accessing SAPR data reports in QW**
  This attachment includes the step-by-step instructions for accessing the SAPR reports in QW.

Due-Date for Draft Summary Reports, Worksheets and Cover Letters and RO Review Tools

Draft FY 2016 CLIA SAPR packages are due in CO by **March 2, 2017**. Please forward the **Summary Report,** along with the **Excel Worksheets, undated Cover Letter, RO Review Tool for Criterion 4, RO Review Tool for Criteria 10 and 11 and associated CMS-2567s which include PoC or AoC. It is not necessary to include the supporting documentation (evidence) with the PoC or AoC.**

When e-mailing messages regarding CLIA SAPR matters, including the draft CLIA SAPR packages, please include the entire SAPR team:

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Effective Date: October 1, 2016. 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/
David R. Wright

Attachments: See Table on Page 3 for Listing and Descriptions

cc: Survey and Certification Regional Office Management