



Center for Clinical Standards and Quality/Survey & Certification Group

**Admin Info: 17-34-CLIA**

**DATE:** September 29, 2017

**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 2017 (FY2017)

**Memorandum Summary**

- **CLIA SAPR Review Protocol:** The FY 2017 review is limited to **eight** of the original Criteria, to provide time for the extensive activities related to 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of Other Subject Areas:** CMS ROs have the overarching responsibility and authority for SA oversight, which is not superseded nor limited by the CLIA SAPR.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 2017 Review Criteria may also be reviewed at the RO's discretion.
- **Review of CLIA SAPR Criterion 4:** A new RO Review Tool has been updated based on RO reviewer feedback (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, 2018**.

**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.

## **FY2017 Protocol**

The FY 2017 standard review is limited to eight of the original CLIA SAPR Criteria. 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 2017. 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 2017 review.

**Attachments—Listing and Descriptions**

<b><u>Attachment #</u></b>	<b><u>Name</u></b>
<b>1</b>	<ul style="list-style-type: none"> <li>• FY 2017 CLIA SAPR Document: Performance Review Criteria, Performance Indicators, and Worksheets</li> <li>• FY2017 CLIA SAPR Criterion 10, POD Principle 3, Composition of a Deficiency Citation, Review Tool</li> <li>• FY2017 CLIA SAPR Criteria 10 and 11 RO Review Tool—Principles of Documentation (POD) and Acceptable Plan of Correction /Credible Allegation of Compliance (PoC/AoC) (optional)</li> <li>• FY2017 CLIA SAPR Criterion 4 Review Tool – Data Management</li> </ul>
<b>2</b>	<ul style="list-style-type: none"> <li>• FY 2017 CLIA SAPR Data Reports for Standard Review Protocol—Instructions and Description</li> <li>• CLIA Data Reports—Optional Review of Additional Subject Areas</li> <li>• FY 2017 CLIA SAPR Summary Report Template—Completion Instructions</li> </ul>
<b>3</b>	<ul style="list-style-type: none"> <li>• FY 2017 CLIA SAPR—The Summary Report Template</li> </ul>
<b>4</b>	<ul style="list-style-type: none"> <li>• FY 2017 CLIA SAPR Cover Letter Template—for Transmitting the Summary Report to the SA</li> <li>• FY 2017 CLIA SAPR Model Letter—for Response to SA Corrective Action Plans</li> </ul>
<b>5</b>	<ul style="list-style-type: none"> <li>• Instructions for Printing CASPER 850D– CLIA SAPR Current Certificates Expiring Before Survey Upload</li> <li>• Special Instructions for Accessing CASPER Report 104 during FY17</li> <li>• Step-by-Step Instructions: Accessing SAPR data reports in QW</li> </ul>

**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.

- **Criterion 10, POD Principle 3, Composition of a Deficiency Citation, Review Tool**  
*This tool is used by the RO Reviewer to review CMS-2567 Statements of Deficiency for adherence to POD Principle 3, Composition of a Deficiency Citation. Based on review of data from FY2012 through FY2016, 60-70% of the reviews from “Criteria 10 and 11 RO Review Tool” had identified issues with POD Principle 3. Outcomes from this review will be used for year-to-year comparisons and monitoring for improvement, and assessment for national training needs, as needed.*

- **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. *This tool will become optional for the FY2017 review as a new review tool specific to Principles of Documentation (POD), Criterion 3, Composition of a Deficiency Citation, review tool will be introduced.*
- **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 eight standard Criteria of the FY 2017 CLIA

SAPR. These reports were developed for the CLIA SAPR in previous years, and have been updated with FY 2017 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 2017 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 2017 CLIA SAPR Summary Report Template—Completion Instructions**  
This template has been updated for FY 2017.

**Attachment #3:**

- **FY 2017 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 2017 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 2017 CLIA SAPR Model Letter for Response to SA Corrective Action Plan**  
No changes were made to this model letter for FY 2017.

**Attachment #5:**

- **Instructions for Printing CASPER 850D – CLIA SAPR Current Certificates Expiring Before Survey Upload**

This report replaces OSCAR reports 30 through 33.

- **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 2017 CLIA SAPR packages are due in CO by **March 2, 2018**. Please forward the **Summary Report**, along with the **Excel Worksheets**, **undated Cover Letter**, **RO Review Tool for Criterion 4**, **RO Review Tool for POD Principle 3**, **Composition of a Deficiency Citation and associated CMS-2567s**.

**Contact:** 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, 2017. This information should be shared with all CLIA Program survey and certification staff and their managers 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