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Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Admin Info: 23-16-CLIA

DATE: September 29, 2023

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Issuance of Clinical Laboratory Improvement Amendments of 1988 (CLIA) State Agency Performance Review (SAPR)—Fiscal Year 2023 (FY 2023)

Memorandum Summary

- **CLIA SAPR Review Protocol:** The FY 2023 review has been updated from FY 2022. We are introducing a new performance indicator in criterion #5 (educational only), a new Criterion #8, Budget (educational only), and requirements for running and monitoring mandatory and quarterly reports beginning in October 2023.
- **Goal:** To ensure optimal CLIA State Agency (SA) performance with support from the Centers for Medicare & Medicaid Services (CMS) Branch Locations, as necessary.
- **Summary Report for Each CLIA SA:** The aim of each report is a balanced picture of the CLIA SA's operations. **The SA "Performance Thresholds for Written Corrective Action Plan," "Quantified Performance Results" and "Written Corrective Action Plan" results will be reported on the Summary Report. The review year in FY 2023 is October 1, 2022, through September 30, 2023.**
- **Review of Other Subject Areas:** CMS Branch Locations have the overarching responsibility and authority for SA oversight, which is not superseded nor limited by the CLIA SAPR.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 2023 Review Criteria may also be reviewed at the CMS Branch Location's discretion.
- **Due Date**: Draft CLIA SAPR Summary Reports, Worksheets and Cover Letters are due to the applicable Operations Branch Manager by Friday, **March 1, 2024.**

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 Branch Locations CLIA program personnel.

Discussion:

The objectives of the SAPR 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.

Beginning in FY 2024, SAs must utilize the mandatory and quarterly SAPR reports enclosed in Attachment 2 throughout the fiscal year to identify any areas that may need to be addressed before each annual SAPR review. SAs should contact their CMS Branch Location if they wish to request and receive a specific report throughout the year that does not appear on this list.

CMS Branch Location Collaborative Support

CMS Branch Location collaborative support is an integral part of the CLIA SAPR. The collaboration includes assistance with CLIA SA internal review of Statements of Deficiencies (SoDs), Allegations of Compliance (AoCs), and Plans of Corrections (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 a training opportunity. Collaboration also provides further opportunities for mutual understanding of obstacles to optimal CLIA SA performance, brainstorming for solutions, and learning best practices of similar states. The SAPR process supports and enhances communication between the SA, CMS Branch Locations, and CMS Policy.

In addition, the SAPR enables the SA to identify and correct issues related to their survey and certification activities in a timelier manner. The goal of the SAPR process, whether onsite or remote, is to ensure optimal CLIA SA performance and quality patient testing.

Please Note: The SAPR Summary report should not identify individual surveyors, laboratories, or CLIA numbers. Discussions regarding issues related to specific surveyors, laboratories, or CLIA numbers should occur at the onsite or virtual visit, as applicable.

FY 2023 Protocol

The CLIA SAPR review for FY 2023 includes SA "Performance Thresholds for Written Corrective Action Plan," "Quantified Performance Results," and "Written Corrective Action Plan" results on the Summary Report. CMS Branch Locations have the option to expand the review to include additional areas of CLIA SA responsibilities which, in their judgment, merit evaluation or monitoring. The eight criteria for FY 2023 are:

Criterion #1 - Personnel Qualifications, Training, and Competency
Criterion #2 - Data Management
Criterion #3 - Proficiency Testing (PT) Desk Review
Criterion #4 - Principles of Documentation (PoD), Plan of Correction (PoC)/Allegation of Compliance (AoC)
Criterion #5 - Survey Workload and Outcome-Oriented Survey Process (OOSP)
Criterion #6 - Complaints
Criterion #7 - Quality Assessment
Criterion #8 - Budget – Educational Only for FY 2023

The CMS Branch Locations are required to enter comments in the "Findings," and "Special Circumstances and Noteworthy Accomplishments" sections of the Summary report to address any accomplishments (e.g., up-to-date on workload) or extenuating circumstances related to the public health emergency (PHE) and prioritization of surveys during the PHE.

It is strongly recommended that the States upload all documents into ASPEN (e.g., applications, change requests). This makes for a more efficient review process and allows for a more streamlined sharing of documents between the SA and the CMS Branch Location.

FY 2023 SAPR Review

The CMS Branch Locations are required to enter comments in the "Findings," and "Special Circumstances and Noteworthy Accomplishments" sections of the FY 2023 Summary report to address any accomplishments (e.g., up-to-date on workload) or extenuating circumstances related to the public health emergency (PHE) and prioritization of surveys during the PHE.

Criterion #1: Personnel Qualifications, Training, and Competency Goal:

The SA has an:

- Effective system is in place to ensure that all CLIA surveys are conducted by qualified and competent individuals.
- Ongoing training program to improve survey skills.
- Ongoing program to ensure that SA CLIA clerical staff and surveyors are properly trained in a timely manner.
- Ongoing mechanism to maintain and improve competency.

This criterion remains unchanged from the FY 2022 SAPR Criterion #1.

This criterion includes performance indicators (PIs) related to personnel qualifications and training. It also includes a PI related to competency to ensure all SAs have an ongoing program to utilize feedback and focus on interpreting regulations consistently, adhering to the State Operations Manual, and improving/maintaining surveyor skills.

Criterion #2: Data Management

Goal: The SA has implemented a mechanism to ensure that data entry is done both accurately and within the appropriate timeframe and that all personnel responsible for data management have been trained.

New for FY 2023 under this criterion: two additional reviews have been added for Initial CLIA Applications (Form CMS-116), PI #2 + PI #3 on the "Criterion #2 Review Tool. The SA can miss 1 of the 20 total CMS-116 entries on the "Criterion #2 Review Tool" for accuracy and timeliness and still meet PI #2 and PI #3.

The five fields included in the FY 2023 review are: Facility Name, Federal Tax Identification Number (TIN), Facility Address, Name of Director, and telephone number. The expectation is that if other demographic information is provided, this information should be accurately reflected in the database. No other CMS-116 fields are required to be reviewed unless the CMS Branch Location determines an expanded review is warranted.

Criterion #3: Proficiency Testing (PT) Desk Review

Goal: The SA conducts PT Desk Review in a timely manner and initiates appropriate action regarding unsuccessful participation.

This criterion remains unchanged from the FY 2022 SAPR Criterion #3.

Criterion #4: Principles of Documentation (PoD), Plan of Correction (PoC), Allegation of Compliance (AoC)

Goal: The SA has a review system/process to ensure that all CLIA surveyors:

- Write clear, concise, and legally defensible SODs (CMS-2567) that are consistent with the CLIA PoD.
- Accept only PoC/AoCs that meet the criteria for acceptability.

This criterion remains unchanged from the FY 2022 SAPR Criterion #4.

This criterion combines a review of the PoDs and PoC/AoCs as well as including a PI related to the utilization and understanding of mandatory citations.

Criterion #5: Survey Workload and Outcome-Oriented Survey Process (OOSP)

Goal: The SA has a system to ensure that all surveyors conduct surveys using the outcome-oriented survey process, and the SA has implemented a tracking system that ensures the survey time frames are met.

New for FY 2023, the SA runs the CASPER 0080D report every 30-45 days. This new PI #4 will be educational for the FY 2023 review. Ask the SA to demonstrate that they have generated, evaluated, and acted on the CASPER 0080D reports every 30-45 days. This criterion includes PIs related to the OOSP and the timeliness of survey upload.

For FY 2023, the performance threshold for this criterion has been changed from 90% to 85%.

Criterion #6: Complaints

Goal: The SA accepts and processes all complaints from receipt to closeout, following CMS policies and procedures.

This criterion remains unchanged from the FY 2022 SAPR Criterion #6.

Criterion #7: Quality Assessment (QA)

Goal: The SA has developed specific written procedures related to SAPR, and the SA has an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in their survey and certification activities (i.e., quality assessment).

New for FY 2023 under this criterion, PI #2 has been updated to state that the SA must establish and follow a written standard operating procedure (SOP) for Budget. This update is mandatory for FY 2024.

This criterion requires the SA to have an overall QA program to identify and correct issues related to their certification and survey responsibilities throughout the year rather than annually. This criterion results in a more systemic look at the processes and procedures of the SA as related to their responsibilities, thus affecting a more proactive approach rather than a reactive approach.

Quarterly Reports

To help the State Agencies (SA) monitor and track activities related to survey and certification responsibilities, a requirement to generate quarterly reports will be implemented starting **October 1, 2023**. The purpose of these quarterly reports is to ensure that the SA and CMS identify any issues that arise so that they can be addressed in a timely manner.

Performance indicators PI #4 and PI #5 have been added to Criterion #7, Quality Assessment, for the FY 2023 review. These performance indicators will be educational for the FY 2023 review.

The applicable quarterly reports should be generated by both CMS and the SAs the **first week of each quarter**, i.e., the first week of January 2024 (for Q1), April 2024 (for Q1 - Q2), July 2024 (for Q1 - Q3), and October 2024 (for Q1 - Q4).

The reports include:

- Mandatory SAS Viya Reports
- CASPER 0850D, CLIA SAPR Current Certificates Expiring Before Survey Upload
- CASPER 0080D, CLIA Laboratory Paid Compliance Fees
- CASPER 0074D, CLIA Labs with AO Remarks
- CASPER 1400D, Recertification Kits Not Uploaded
- ASPEN Tracking Report for Failed and Overdue Certification Kit Uploads
- Survey Backlog Report (SAS Viya)
- Budget Report

The SAs will be responsible for generating, reviewing, and addressing any issues related to the following reports:

- CASPER 0850D, CLIA SAPR Current Certificates Expiring Before Survey Upload
- CASPER 0080D, CLIA Laboratory Paid Compliance Fees
- CASPER 0074D, CLIA Labs with AO Remarks
- CASPER 1400D, Recertification Kits Not Uploaded
- ASPEN Tracking Report for Failed and Overdue Certification Kit Uploads

Note: CMS will also run these reports as an internal tool to work with the SA on any issues arising from the reports.

CMS will be responsible for generating and forwarding the following reports to the SA so that the SA can review and address any issues:

- Mandatory SAS Viya Reports
- Survey Backlog Report (SAS Viya)

Budget reports will be for CMS internal use only.

<u>Criterion #8: Budget:</u>

Goal: The SA submits all required documents into the Survey and Certification and Clinical Laboratory Improvement Amendments System (SCCLIA) within the specified time limits.

This is a new criterion and will be educational for the FY 2023 review.

This criterion includes PIs that require SAs to submit the following reports:

- An “activity plan” to the CMS Branch Location per the SOM within the specified time limit
- Budget forms for formulating the State budget for the current fiscal year
- CMS 102 (CLIA budget expenditure report) no later than 45 days after the end of the quarter into SCCLIA for review by the CMS Branch Location
- CMS 105 reports no later than 45 days after the end of the quarter into SCCLIA for review by the CMS Branch Location

- Workload reports by the 10th of the month to the CMS Branch Location

Relationship to Other CMS Branch Location Oversight Responsibilities

CMS Branch Locations have the overarching responsibility and authority for CLIA SA oversight, which is neither superseded nor limited by the CLIA SAPR. Thus, the CMS Branch Location may review a State Agency's performance related to any aspect of CLIA SA responsibility not specifically evaluated by the standard protocol for FY 2023. 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 2023 review.

Attachments—Listing and Descriptions

Attachment #	Name
1	• FY 2023 CLIA SAPR Document: Performance Review Criteria, Performance Indicators, and Worksheets, Review Tools, Examples • FY 2023 CLIA SAPR Criterion 2 Review Tool – Data Management *(required)* • FY 2023 CLIA SAPR Criterion 4, POD Principle 3, Composition of a Deficiency Citation, Review Tool (with reference sheet) *(required)* • FY 2023 CLIA SAPR Criterion 4 CMS Branch Location Review Tool—Principles of Documentation (PoD) and Acceptable Plan of Correction /Credible Allegation of Compliance (PoC/AoC) (*optional*)
2	• FY 2023 CLIA SAPR Data Reports –Description of Mandatory, Quarterly, and Optional Reports – CMS Baltimore will provide electronic copies of these reports. Only CASPER 104 Instructions will be utilized for FY 2023 review.
3	• FY 2023 CLIA SAPR—The Summary Report Template
4	• FY 2023 CLIA SAPR Cover Letter_CAP Resp Template—for Transmitting the Summary Report to the SA • FY 2023 CLIA SAPR Model Letter - for Response to SA Corrective Action Plans

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. For FY 2023, the instructions for completing data fields in the worksheets associated with Performance Indicators are contained in each of the criteria. The Worksheets must be completed electronically.

- **<u>Criterion #2 CMS Branch Location Review Tool—Data Management</u>**
  (<u>Required</u>) This tool is used by the CMS Branch Location Reviewer to review the accuracy and timeliness of input into the database for initial Form CMS-116, certificate type changes, and updated demographic information. For FY 2023, the Review Tool for Criterion #2, Data Management, remains the same five (5) fields on the Form CMS-116 reviewed in FY 2022. The 5 fields include: Facility Name, Federal Tax Identification Number (TIN), Facility Address, Name of Director, and telephone number.

  Criterion Review Tool #2 remains next to Criterion #2 for ease of use.

- **<u>Criterion #4, POD Principle 3, Composition of a Deficiency Citation, Review Tool</u>**
  (<u>Required</u>) This tool is used by the CMS Branch Location Reviewer to review CMS-2567 Statements of Deficiency for adherence to PoD Principle 3, Composition of a Deficiency Citation. Outcomes from this review will be used for year-to-year comparisons, monitoring for improvement, and assessment for national training, as needed. This review tool remains next to Criterion #4 for ease of use. References remain at the end.

- **<u>Criteria #4 CMS Branch Location Review Tool—Principles of Documentation (PoD) and Acceptable Plan of Correction/Credible Allegation of Compliance (PoC/AoC)</u>**

  (<u>Optional</u>) This tool is used by the CMS Branch Location Reviewer to review CMS-2567 Statements of Deficiency and Plan of Correction for adherence to PoD and proper acceptance of PoC/AoC. This review tool remains next to Criterion #4 for ease of use. References remain at the end.

<u>Attachment #2:</u>

- **<u>FY 2023 CLIA SAPR Data Reports – Instructions and Description for both Mandatory and Optional Reports</u>**

  CMS Baltimore will provide electronic copies of all SAS Viya mandatory and optional reports for each CMS Branch Location for FY 2023.

  Each CMS Branch Location Reviewer will need to utilize CASPER 104 to evaluate demographic changes for Criterion #2, Data Management, PIs #6 and #7. See pages 3-4, Attachment 2.

  It is recommended that the report "ACTS Complaint/Incident Investigation Log" be used to identify complaints for Criterion #6, Complaints for the FY 2023; however, details regarding the timeline should be verified either onsite or remotely with the SA as the documentation is a true indication of whether timelines have been met. In addition, tracking sheets developed and implemented at the CMS Branch Locations may be used.

  CMS Branch Locations have the overarching responsibility and authority for SA oversight; therefore, subject areas not specifically addressed by the FY 2023 Review Criteria may also be reviewed at the CMS Branch Location's discretion. The addendum report should indicate why the additional measure(s) are being reviewed.

<u>Attachment #3:</u>

- **<u>FY 2023 CLIA SAPR Summary Report Template</u>**
  All narrative sections, "Findings" and "Special Circumstances and Noteworthy

Accomplishments" appear on the CLIA FY 2023 Summary Report **and must be completed**. It is very important to provide a narrative in these sections so that CMS has a complete picture of the SA's performance.

The CMS Branch Locations are required to enter feedback in the "Findings" and "Special Circumstances and Noteworthy Accomplishments" sections to address any accomplishments (e.g., up-to-date on workload) or extenuating circumstances related to the public health emergency (PHE) and prioritization of surveys during the PHE.

Please note: The CLIA SAPR review for FY 2023 will include reporting of SA "Performance Thresholds for Written Corrective Action Plan," "Quantified Performance Results," or "Written Corrective Action Plan" results on the Summary Report. Criterion #8 is Educational for FY 2023.

Attachment #4:

- **FY 2023 CLIA SAPR Cover Letter CAP Response Template for Transmitting the Summary Report to the SA**

  The language in this model letter has been updated to address the FY 2023 review. Model language is included for instances where the CMS Branch Location has exercised the option to review additional subject areas. Instructions for the associated narrative are more specific.

- **CLIA SAPR Model Letter for Response to SA Corrective Action Plan**

  The language in this model letter has been updated to address the FY 2023 review.

Due Date for Draft Summary Reports, Worksheets, and Cover Letters and CMS Branch Location Review Tools

Draft FY 2023 CLIA SAPR packages are due to the applicable Operations Branch Manager by **Friday, March 1, 2024**. Please upload the following into the FY 2023 Draft Review folder in the SAPR Document library located in SharePoint:

- Summary Report
- Excel Worksheets
- Cover Letter
- CMS Branch Locations Review Tool for Criterion #4 and POD Principle 3, Composition of a Deficiency Citation, and associated CMS-2567s

Contact: For questions or concerns relating to this memorandum, please contact Karen Sutterer (karen.sutterer@cms.hhs.gov), Jennifer Street (Jennifer.street@cms.hhs.gov), and Ann Snyder (ann.snyder@cms.hhs.gov).

Effective Date: October 1, 2023. 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 5 for Listing and Descriptions

cc: CMS Branch Locations

Resources to Improve Quality of Care:

Check out CMS's new Quality in Focus interactive video series. The series of 10–15 minute videos are tailored to provider types and aim to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid.

Learn to:

- *Understand surveyor evaluation criteria*
- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus

CLIA SAPR Documents FY2023
Performance Review Criteria 1-8 with Performance Indicators

General Instructions, References, Worksheets and Review Tools

Criterion #1 Personnel Qualifications, Training & Competency
SOM §§4003.2, 4009A-E, 4018. 6234.2, 6410, 6434
Budget Call Letter
1864 Agreement – Article IV-A, B; Article V–C
****

Criterion #2: Data Management
SOM §6135
Budget Call Letter
1864 Agreement – Article V-C
****

Criterion #3: Proficiency Testing Desk Review
SOM §§6052-6058
Budget Call Letter
1864 Agreement – Article II-E
****

Criterion #4: POD/POC, AOC
SOM §6130
Appendix C
Laboratory Principles of Documentation
1864 Agreement – Article II-A, E; Article V-C
****

Criterion #5: Survey Process & Workload
SOM §6102
1864 Agreement, Article II-A-C, E; Article V-C
Validation Survey Protocol
Appendix C, I.-A.
****

Criterion #6: Complaints
SOM: Chapter 5, sections for CLIA;
ACTS Procedure Guide
1864 Agreement, Article II-E; Article V-C
****

Criterion #7: Quality Assessment
1864 Agreement – Article II-A, E, I-J; Article IV-A, B; Article
****

Criterion #8: Budget

1864 Agreement, Article V.C.9., Article IX.M.

Special Instructions for Criterion #1: Personnel Qualifications, Training & Competency

Overall Goal:

The SA has an:

- Effective system in place to ensure that all CLIA surveys are conducted by qualified and competent individuals.
- Ongoing training program to improve survey skills.
- Ongoing program to ensure that SA CLIA clerical staff and surveyors are properly trained in a timely manner.
- Ongoing mechanism to maintain and improve competency

Instructions for Completing Data Fields associated with Performance Indicators

1. Complete data fields that require information (i.e. Evaluator, Date, CLIA #, Analyte, Specialty/Subspecialty/Event, etc.) by typing the information into the space below the column header.
2. On Criterion #1 tab, please enter the State name and it will self-populate on all tabs.
3. For all Performance Indicators--**Enter a "1" into the YES, NO, or NA column**

Ongoing Training & Annual Competency Programs Performance Indicators (PIs): Personnel Qualifications

Ask the SA how each surveyor meets the PIs.

1. The staff positions (professional and clerical) listed on CMS-1465A are occupied as reported.
2. Health Professional Qualifications as set forth in the SOM at 4009B.
3. For new surveyors, completion of a CMS-developed Basic Surveyor Training Course within the first three (3) months of employment (4009-C) AND the individual has completed sufficient orientation for the CMS Location to evaluate their survey skills (Federal Monitoring Survey Assessment) within one year.

Note for PI #3*: If a newly hired surveyor (less than 3 months) has not completed the training, please enter a "1" in NA.*

Note for PI#2, #3*: If no new surveyors have been hired in the FY under review, then PIs #2 and #3 are considered met and enter a "1" into the yes column. Please indicate under the "New Surveyor Name/ID" column "None".*

4. For all surveyors, the SA's ongoing training and annual competency program utilizes feedback or information from and focuses on:
   a. SA orientation, FMS, CMS Location review of any CMS-2567s and PoC/AoCs to improve surveyor skills;
   b. Consistency in the interpretation of the regulations;
   c. Ensuring surveyor adherence to the SOM;
   d. Improving individual surveyor skills, as needed;

Ask the SA to demonstrate how each surveyor meets PI #4. If any one of the PIs #4 a. → d. is not met, indicate which was not met in the "Comment" column.

5. All SA surveyors attend CMS-funded mandatory training, including those budgeted for in the annual SA budget apportionment (e.g., Consortium/Division meetings).

Note for PI #5*: In some instances, a SA surveyor is unable to attend mandatory training for a variety of reasons (e.g., personal commitment or medical issue); however, the intent is that if CMS funds mandatory training, all SA surveyors must attend unless a staff member is given an approved exception. Denial by the SA to approve CMS-funded training is not an acceptable exception.*

6. All SA surveyors participate in mandatory online training, as applicable.

A Written Corrective Action Plan is required if the Quantified Performance Result is less than 100% or if Performance Indicator 1 is not met.

In the box labeled "Written Corrective Action Plan Required?," if the answer is "Yes" enter an "X" in the "Yes" box, if "No" enter an "X" in the "No" box.

***EXCEPTION*:** Performance Indicators #3 and 4 may not be applicable to an individual who was hired shortly before the time of review.

CLIA State Agency Performance Review FY2023
Criterion #1: Personnel Qualifications Training and Competency

Performance Indicator 1:	Yes	No
The staff positions (professional and clerical) listed on CMS-1465A are occupied as reported.		

Personnel Qualifications: New Surveyors Hired During FY2023

New Surveyor		Performance Indicators					
Name or ID #	Date of Hire	PI 2		PI 3			
		Y	N	Y	N	NA	Comments

Ongoing Training and Annual Competency Programs: All Surveyors

	Performance Indicators							
	PI 4			PI 5		PI 6		
	Y	N	NA	Y	N	Y	N	Comments
PI 4: For all surveyors, the SA's ongoing training and annual competency program utilizes feedback and focuses on improving/maintaining surveyor skills.								
PI 5: Attend CMS-funded mandatory training								
PI 6: Participate in mandatory online training, as applicable								

State Agency:	Enter State Name
Date:	
Evaluator:	

Performance Threshold:	100%	
Quantified Performance Result:	#DIV/0!	
	YES	NO

Performance Measurement:
Performance Threshold: 100%
A Written Corrective Action Plan is required if the Quantified Performance Result is less than 100% or if Performance Indicator 1 is not met.

Written Corrective Action Plan Required?		

Special Instructions for Criterion #2: Data Management

Overall Goal:

The SA has implemented a mechanism to ensure that data entry is done both accurately and within the appropriate timeframe and that all personnel responsible for data management have been trained.

Instructions for Completing Data Fields associated with Performance Indicators:

1. Complete data fields that require information (i.e. Evaluator, Date, CLIA #, Analyte, Specialty/Subspecialty/Event, etc.) by typing the information into the space below the column header.
2. On Criterion #1 tab, please enter the State name and it will self-populate on all tabs.
3. For all Performance Indicators--**Enter a "1" into the YES or NO column.**

Performance Indicators

Use the Criterion #2 Review Tool.

****New for FY23** The SA can miss 1 of the 20 total 116 entries on the"Criterion #2 Review Tool" for accuracy and timeliness and still meet PI #2 and PI #3. 2 additional reviews have been added for Initial CLIA Applications (Form CMS-116), PI #2 + PI #3 on the "Criterion #2 Review Tool."** The following 5 selected fields will be reviewed for this criterion: Facility Name, Federal Tax Identification (TIN), Facility Address, Name of Director, telephone number. No other CMS-116 fields are required to be reviewed unless the CMS Location determines an expanded review is warranted. All information for PI #2- PI #7 should be collected from the Criterion #2 Review Tool.

1. The SA has a mechanism to track receipt and entry of initial applications (Form CMS-116s), certificate type changes, and demographic updates.

2. The SA has entered all reviewed initial applications (Form CMS-116) information accurately into the CMS-116 database.
Note for PI #2: When evaluating PI #2, the CMS Location reviewer should compare the initial Form CMS-116 to the information entered into the CLIA CMS-116 database. As long as the SA has requested additional information (e.g., laboratory director qualifications) prior to the 30 days, this PI is considered met as it is beyond the SA's control if a laboratory does not provide the requested information in a timely manner. The name of the laboratory only allows for 50 characters to be entered, so the SA may use abbreviations in order to meet this requirement. The abbreviations must be reflective of information on the CMS-116.

3. The SA has entered all reviewed initial application (Form CMS-116) information into the CMS-116 database within 30 calendar days of receipt by the SA.
Note for PI #3: This performance indicator is met if the SA has requested from the laboratory any additional information which is needed to approve the initial Form CMS-116 within 30 days of receipt by the SA.

4. The SA has entered all reviewed certificate changes accurately into the CMS-116 database.
Note for PI #4: If, when reviewing for certificate changes, it is noted that the demographic information does not match, further investigation should be done to ensure that the demographic information is correct, e.g., check for later CMS-116 submissions with demographic changes.

5. The SA has entered all reviewed certificate changes into the CMS-116 database within 45 calendar days of receipt by the SA.
6. The SA has entered all reviewed demographic updates into the CMS-116 database accurately.
7. The SA has entered all reviewed demographic updates into the CMS-116 database within 45 calendar days of receipt by the SA.
8. All personnel responsible for data entry have been trained to enter the information into the CMS data systems in accordance with their responsibilities.

A Written Corrective Action Plan is required if the Quantified Performance Result is less than 100% or if Performance Indicator 1 is not met.

In the box labeled "Written Corrective Action Plan Required?," if the answer is "Yes" enter an "X" in the "Yes" box, if "No" enter an "X" in the "No" box.

CLIA State Agency Performance Review FY2023
Criterion #2: Data Management

Performance Indicator 1:	Yes	No
The SA has a mechanism to track receipt and entry of initial applications (Form CMS-116s), certificate type changes, and demographic updates.		

	PI 2		PI 3		PI 4		PI 5		PI 6		PI 7		PI 8		
	CMS-116		CMS-116		Cert Changes		Cert Changes		Updates		Updates		Data Entry		
	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Comments
PI 2: CMS-116 Accuracy															
PI 3: CMS-116 Timeliness															
PI 4: Certificate Changes: Accuracy															
PI 5: Certificate Changes: Timeliness															
PI 6: Demographic Updates: Accuracy															
PI 7: Demographic Updates: Timeliness															
PI 8: Data Entry Personnel: Training and Data Entry															

State Agency:	Enter State Name
Date:	
Evaluator:	

Performance Threshold:	100%	
Quantified Performance Result:	#DIV/0!	
	YES	NO
Written Corrective Action Plan Required?		

Performance Measurement:
Performance Threshold: 100%
A Written Corrective Action Plan is required if the Quantified Performance Result is less than 100% or if Performance Indicator 1 is not met.

FY 2023 CLIA SAPR CRITERIA 2, Data Management

CMS Location Review Date:			State:
CMS Location Reviewer:			

Initial CLIA Applications (Form CMS-116), PI2 + PI3

CLIA Number	Selected* Fields Accurately Entered Into CMS-116 Database	All CMS-116s Entered Within 30 Days	Comments List All Fields Not Accurately Entered AND/OR Entered > 30 Days
			Put a "Y" or "N" in column B and C. *For FY2023 only the following 5 selected fields will be reviewed for this criterion: Facility Name, Federal Tax Identification (TIN), Facility Address, Name of Director, and telephone number. No other CMS-116 fields are required to be reviewed unless the CMS Location determines an expanded review is warranted.**NEW for FY2023** THE SA CAN MISS 1 OUT OF THE TOTAL OF 20 ENTRIES from PI2 and PI3 (BOTH FIELDS) AND STILL MEET PI2 AND PI3.
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

Certificate Changes, PI4 + PI5

CLIA Number	All Certificate Changes Entered Accurately	All Certificate Changes Entered Within 45 Days	Comments List Certificate Changes Not Accurately Entered AND/OR Entered > 45 Days
1			
2			
3			
4			

Demographic Updates, PI 6 + PI7

CLIA Number	All Demographic Updates Entered Accurately	All Demographic Updates Entered Within 45 Days	Comments List All Demographic Updates Not Accurately Entered AND/OR Entered > 45 Days
1			
2			
3			
4			

Special Instructions for Criterion #3: Proficiency Testing Desk Review

Overall Goal:

The SA conducts PT Desk Review timely and initiates appropriate action in regard to unsuccessful participation.

Instructions for Completing Data Fields associated with Performance Indicators:

1. Complete data fields that require information (i.e. Evaluator, Date, CLIA #, Analyte, Specialty/Subspecialty/Event, etc.) by typing the information into the space below the column header.
2. On Criterion #1 tab, please enter the State name and it will self-populate on all tabs.
3. For all Performance Indicators--**Enter a "1" into the YES, NO, OR NA column.**

Performance Indicators (PIs)

1. The SA has implemented a mechanism to track PT scores every 30 - 45 days. Review the SA's PT tracking process to determine whether Performance Indicator #1 is met.

- Select **10 laboratories** (or the SA total if less than 10) and include a cross-section of initial and non-initial (subsequent) unsuccessful events.
- Indicate whether unsuccessful PT is either the initial unsuccessful or the non-initial unsuccessful.
- If no non-initial unsuccessful events occurred during the FY under review, select 10 initial unsuccessful events or all, whichever is fewer.

***NOTE**: If no unsuccessful events appear on CASPER 0153D, **interview SA personnel** to ascertain their understanding of the proper procedure in the case of initial or non-initial unsuccessful events. Treat the criterion as met (enter a "1" in the Yes column) and note the interview and any related comments in line #1, PI #2 chart on this worksheet.*

2. **Unsuccessful Participation:**
   a. Verifies the scores using information from the PT provider and/or the laboratory prior to recommending an action, and takes any necessary follow-up actions based on their collaboration with their CMS Location.
   b. Prepares CMS-2567, including appropriate D-Tags.
   c. Notifies the laboratory to seek training/technical assistance for initial unsuccessful participation, as appropriate.
   d. Notifies the CMS Location for all non-initial unsuccessful participation.
   e. Tracks each case to completion/resolution (SA can verify corrective actions and effectiveness evaluated).

A Written Corrective Action Plan is required if the Quantified Performance Result is less than 85 percent or Performance Indicator 1 is not met.

In the box labeled "Written Corrective Action Plan Required?," if the answer is "Yes" enter an "X" in the "Yes" box, if "No" enter an "X" in the "No" box.

CLIA State Agency Performance Review FY2023
Criterion #3: Proficiency Testing Desk Review

Performance Indicator 1:	Yes	No
The SA has implemented a mechanism to track PT scores every 30 - 45 days.		

			Performance Indicators														
			Unsuccessful Participation														
PT Desk Reviews	Initial Unsuccessful	Non-Initial (Subsequent) Unsuccessful	PI 2a			PI 2b			PI 2c			PI 2d			PI 2e		
CLIA #			Y	N	NA	Y	N	NA	Y	N	NA	Y	N	NA	Y	N	NA
1																	
2																	
3																	
4																	
5																	
6																	
7																	
8																	
9																	
10																	

State Agency:	Enter State Name	
Date:		
Evaluator:		
Performance Threshold:	85%	
Quantified Performance Result:	#DIV/0!	
	YES	NO
Written Corrective Action Plan Required?		

Performance Measurement:
Performance Threshold: 85 percent
A Written Corrective Action Plan is required if the Quantified Performance Result is less than 85 percent or Performance Indicator 1 is not met.

Special Instructions for Criterion #4: Principles of Documentation (POD) & Plan of Correction (PoC), Allegation of Compliance (AoC)

Overall Goal:

The SA has a review system/process to ensure that all CLIA surveyors:

- Write clear, concise, and legally defensible Statements of Deficiencies (SoD) (CMS-2567) that are consistent with the Principles of Documentation (POD).
- Accept only POC/AOCs that meet the criteria for acceptability.

Instructions for Completing Data Fields associated with Performance Indicators:

1. Complete data fields that require information (i.e. Evaluator, Date, CLIA #, Analyte, Specialty/Subspecialty/Event, etc.) by typing the information into the space below the column header.
2. On Criterion #1 tab, please enter the State name and it will self-populate on all tabs.
3. For all Performance Indicators--**Enter a "1" into the YES or NO column.**

Performance Indicators (PIs):

***NOTE**: In States with few surveyors, particularly those with fewer than 2 FTEs, the CMS Location staff may need to be more directly involved in the review activities and should apply the performance indicators in a manner that is reasonable for the particular SA administrative and operational set-up. This may include CMS Location participation in the SA POD and PoC/AoC review process. Ask the SA for an overview of their review system and/or other review activities they may use, and documentation of their review findings during the FY under review. Seek sufficient information about the review system to determine whether the performance indicators are met.*

1. The SA utilizes and understands mandatory citations.
2. The SA reviews the Statements of Deficiencies for clarity, conciseness and consistency with the POD on an ongoing basis.
3. The SA reviews the POC/AOCs for consistency with SOM 6130.
4. The SA reviews at least 10 of each surveyor's CMS-2567s prepared during the federal fiscal year (FFY) under review for both POD and acceptability of POC/AOCs.
5. The SA review process includes participation by all surveyors as an opportunity for skill improvement.
6. The review process must include at least quarterly review and must track the progress of surveyor improvement or document sustained proficiency.
7. Specific area(s) of improvement identified in CMS Location feedback (FMS Assessment and other CMS Location reviews), if any, are incorporated by the SA into their review process.
8. The SA review process quantifies* and documents the state-wide results annually so that the State can compare results across federal fiscal years (FFY) (October 1 to September 30).

*To quantify results, the following formula **must** be used by the SA in its internal review process.

POD: Divide the total number of D-tags that meet the Principles of Documentation by the total number of D-tags cited on the CMS-2567s reviewed during the FY under review.

POC/AOC: Divide the total number of D-tags on the POC that meet the Criteria for Acceptability by the total number of D-tags cited on the CMS-2567s reviewed during the FY under review.

NOTE: The result of this calculation is used for SA's internal review only; it is not related to the performance threshold listed below.

A Written Corrective Action Plan is required if the Qquantified Performance Result is less than 100 percentt or Performance Indicator 1 is not met.

In the box labeled "Written Corrective Action Plan Required?," if the answer is "Yes" enter an "X" in the "Yes" box, if "No" enter an "X" in the "No" box.

<u>REQUIRED-- ADDITIONAL REVIEW BY THE CMS LOCATION REVIEWER</u>:

• Completion of the **"Criterion #4, POC Principle 3, Composition of a Deficiency Citation Review Tool"** is **REQUIRED** (see Attachment #1 of the CLIA SAPR Admin Memo).

• Select one CMS-2567 for each CLIA surveyor in the SA. Use a separate CMS Location Review Tool for each CMS-2567 reviewed, and record the findings for Criterion #4, Principle 3, on the review tool. If all D-Tags in the CMS-2567 being reviewed meet POD, enter an **"X"** in column C, "All D-Tags Meet POD." **OR**, if one or more D-Tags do not meet POD, enter the applicable D-Tag that does not meet POD and the reason in column E, "D-Tag Not Meeting POD + Reason."

• Leave the "All D-Tags Meet POD" column blank if 1 or more D-Tags do not meet POD.

• If there are more than 5 CLIA surveyors in the SA, review other surveyors' CMS-2567s in a subsequent year. If only 1 CLIA surveyor, select a minimum of 2 CMS-2567s.

Refer, as needed, to the CLIA Principles of Documentation, when you discuss the outcome of Principle 3 with the SA.

The outcomes of the CMS Location Review Tool are for year-to-year comparison and monitoring for improvement, and assessment for national training, as needed.

<u>OPTIONAL:</u>

Completion of the **"CLIA SAPR Criterion #4 D-tag CMS Location review tool"** is **<u>OPTIONAL</u>** for FY2023.

Performance Indicator #1	Yes	No

To calculate the Results of the SA Internal Review:

The SA utilizes and understands mandatory citations.		

Type the number in the data field labelled "# D-tags meeting POD". Do the same with "Total # D-tags reviewed" data filed..
The result will auto-calculate.

P.I. 9 Results of SA Internal Review:

Performance Indicators	Yes	No
2		
3		
4		
5		
6		
7		
8		

show calculation **# D-tags meeting PoD** / **Total # D-tags reviewed** = #VALUE!

P.I. 9 Results of SA Internal Review:

show calculation **# D-tags PoC/AoC was acceptable** / **Total # D-tags reviewed** = #VALUE!

Comments

State Agency:	Enter State Name	
Date:		
Evaluator:		
Performance Threshold:	100%	
Quantified Performance Result:		
	Yes	No
Written Corrective Action Plan Required?		

Performance Measurement:
Performance Threshold: 100% (100 percent = the SA has a review process in place that includes all activities described in Performance Indicators #1-8. It does NOT refer to the % outcome of the SA's internal review specified in Performance Indicator 6.)

A Written Corrective Action Plan is required if the Qquantified Performance Result is less than 100 percentt or Performance Indicator 1 is not met.

Criterion #4, POD Principle 3, Composition of a Deficiency Citation
CMS Branch Location Review Tool FY2023

CLIA Number:	Facility Name:	
Enter State Name	CMS Loc. Reviewer:	Review Date:
Total Number of D-Tags on CMS-2567:		

Principle Requirement	All D-Tags Meet POD	D-Tag Not Meeting POD + Reason
Statement of Deficient Practice aka Deficient Practice Statement (DPS)		
The specific violation of regulations stated clearly, e.g., Specific action(s), error(s), lack of action (i.e., deficient practice)		
The DPS does not simply restate regulation.		
Extent		
Extent of deficient practice is stated in DPS		
Extent is expressed in a numerical value		
Sources of Evidence		
DPS contains the source(s) of evidence		
At least 2 sources, if possible?		
Identifiers		
Identifiers are included		
Individual's names/titles are referred to by a coding system so they remain confidential		
Findings/Facts		
Findings support the DPS		
Findings/facts are organized in a concise, chronological and logical order		
The questions who, what, when, where, and how are answered		
Sources of Evidence		
All sources of evidence in the DPS are also reflected in the findings		
Observations: date, time, location		
Interviews: date, time, identifier		
Record/Document review: record name/type		
Identifiers		
Individual's names are referred to by a coding system so they remain confidential		
Unique patient identifiers are used so patients cannot be identified		
General		
The D-Tag applicable to the requirement cited		
The deficiency citation is free of extraneous remarks and advice		

FY 2023 CLIA SAPR CRITERIA #4 D-TAG CMS BRANCH LOCATION REVIEW TOOL

OPTIONAL

CLIA Number:		Facility Name:		Enter State Name
Survey Date:		CMS Location Reviewer:		CMS Location Review Date:

CRITERION #4, PI #4, POD			CRITERION #4, PI #4, POC/AOC				
A	B	C	D	E	F	G	H
Identify D-tag(s) which do not meet POD	Identify principle(s) of POD not met	Total # of D-tags which meet POD	POC: Is the POC acceptable? (Y, N, N/A)	AOC: Is the AOC credible? (Y, N, N/A)	Total # of acceptable and/or credible D-tag(s)	Total # D-tags cited in CMS-2567	Additional Comments, Reason why D-tag does not meet POD OR Why POC/AOC was not acceptable/credible
CRITERION #4: % D-tags which meet POD		#DIV/0!	CRITERION #4: % D-tags which meet requirements for POC or AOC		#DIV/0!		

6. All surveys are uploaded in a timely manner (within 45 days).

***NOTE for PI #6**: • Ask the SA to demonstrate their system for uploading surveys. The format need not be elaborate or automated.*

***EXCEPTION:** If the SA can demonstrate that survey kit uploads were due to circumstances beyond the SA's control (e.g., laboratory did not respond to a request for an AoC/PoC), do not hold the SA accountable. Enter a "1" in "Yes." Document the exception(s) in the Comments section of this worksheet.*

***Please note:** If the laboratory does not provide an acceptable POD/credible AOC within 45 days, the SA will not be able to upload the kit within 45 days. If the*

SA has documentation to show this is the case (i.e., extenuating circumstances), the SA will not be held to the 45 day upload timeframe. SA can upload Condition-level noncompliant survey kits and the system will register the upload by the SA even though L32 and L33 error messages are received.

Outcome-Oriented Survey Process:

- Any CMS-2567s reviewed throughout the FY by the CMS Location (e.g., for the purpose of FMS Assessments, Condition-level non-compliance) can be incorporated into the CMS Location review to meet this criterion. For example, a sample of FMS Assessment surveys may be reviewed to ensure follow-up actions and monitoring were completed as required.
- Interview the surveyor and/or supervisor to ascertain how the SA utilizes FMS feedback in the FMS Cover Letter and Summary Report, if any, for improving surveyor proficiency in OOSP.
- Review the SA's mechanism for communicating SOM directives and changes to surveyors.
- Select a couple of major program directives or SOM issuances on the OSP and interview surveyors to determine whether they are familiar with them.

If, during the FY under review, no new directives or changes were issued, interview surveyors, including newly hired, to ascertain their familiarity with SOM directives in the OOSP.

Performance Indicators: OOSP

7. All surveyors conduct surveys using the OOSP and focus on the:
   a. overall performance of the laboratory;
   b. laboratory's ongoing mechanisms to monitor and evaluate its practices and solve its problems
8. Each surveyor demonstrates proficiency in assessing outcome by citing those problems or potential problems which:
   a. relate to laboratory testing;
   b. cause or have a potential to cause a negative impact on patient test results; and
   c. are regulatory under CLIA.
9. All surveyors have access to the SOM and the SA ensures SOM directives and/or changes related to OOSP are implemented by all surveyors.
10. SA follows the SOM for enforcement and SA identifies the appropriate cases that go to the CMS Location.

A Written Corrective Action Plan is required if the Quantified Performance Result is less than 85 percent.

In the box labeled "Written Corrective Action Plan Required?," if the answer is "Yes" enter an "X" in the "Yes" box, if "No" enter an "X" in the "No" box.

CLIA State Agency Performance Review FY2023
Criterion #5: Survey Workload and Outcome-Oriented Survey Process (OOSP)

Performance Indicators	Yes	No	Comments
PI 1: All initial surveys (CoR) completed within 3-12 months.			
PI 2: All recertification of CoC laboratories are completed timely.			
PI 3: All budgeted validation surveys are completed within 90 days of the AO survey date.			
EDUCATIONAL-PI 4: The SA generated and utilized the CASPER 0080D every 30-45 days.			
PI 5: The SA generated and utilized the CASPER 0850D quarterly reports.			
PI 6: All surveys are uploaded in a timely manner (w/i 45 days).			
PI 7: All surveyors conduct surveys using the OOSP.			
PI 8. Each surveyor demonstrates proficiency in assessing outcome by citing those problems or potential problems.			
PI 9: All surveyors have access to the SOM and the SA ensures SOM directives and/or changes related to OOSP are implemented by all surveyors.			
PI 10: SA follows the SOM for enforcement and SA identifies the appropriate cases that go to the CMS Location.			

State Agency:	Enter State Name
Date:	
Evaluator:	

Special Instructions for Criterion #6: Complaints

Overall Goal:

The SA accepts and processes all complaints from receipt to closeout in accordance with CMS policies and procedures.

Instructions for Completing Data Fields associated with Performance Indicators:

1. Complete data fields that require information (i.e. Evaluator, Date, CLIA #, Analyte, Specialty/Subspecialty/Event, etc.) by typing the information into the space below the column header.
2. On Criterion #1 tab, please enter the State name and it will self-populate on all tabs.
3. For all Performance Indicators--**Enter a "1" into the yes or no column.**

Performance Indicators:

NOTE: *All (i.e., CLIA and non-CLIA) complaints should be tracked by the SA in some way, not just CLIA-related complaints. Ask the SA to demonstrate how they track all complaints. The method of tracking non-CLIA complaints may be manual or electronic.*
NOTE: *If the SA received no complaints, interview the SA surveyor to ascertain their understanding of the complaints process and complete PI #2 - #9 based upon the interview*

1. The SA utilizes the Automated Complaints Tracking Systems (ACTS) in Aspen, in accordance with the current ACTS Procedure Guide.

NOTE: The guide is kept current at the following website: https://qtso.cms.gov/software/aspen/reference-manuals
NOTE PI #1*: Review the SA mechanism for logging in and tracking complaints and verify that all CLIA-related complaints are entered into ACTS.*

2. The SA has a mechanism to track all complaints received by the SA.

NOTE PI #2*: Interview SA surveyor(s) to determine how complaints are handled.*
- *Verify their understanding that ALL CoA complaints must be forwarded via ACTS to the CMS Location for disposition.*
- *Also verify that all SA surveyor(s) would closely coordinate with the CMS Location when the SA is delegated the complaint for action, especially when issues have attracted media attention.*

3. The SA adheres to the SOM instructions for complaints as well as the current ACTS Procedure Guide for entry of data into ACTS.

Performance Indicators #4 - #9:
Proceed to assess Performance Indicators #2 through #9.
- Randomly select some complaints. If the total number of complaints is 1 -10, review all.
- If the total number is more than 10, review 10.
- Follow the path of the complaint through ACTS and determine if the applicable performance indicators are met. Verify that each complaint was entered into the ACTS system, all associated actions fulfilled, and ACTS data screens completed, as appropriate. If the complaint was forwarded to the AO, note that action in the Comments section

4. The SA acknowledges and notifies the complainant.

NOTE for PI #4*: Many of the complaints that are received are anonymous and cannot be acknowledged, mark "N/A" as applicable.*

5. The SA triages/evaluates complaints for proper disposition.
   a. SA conducts investigations for the following only when authorized by the CMS Location: CoW, PPMP, CoA, Facilities testing w/out a certificate (NOCN).
   b. Forwards via ACTS all CoA complaints received in the SA to the CMS Location for disposition.
   c. Forwards to another agency (OIG, FDA, OSHA, another SA as required by law, etc), as necessary.

6. Complaints are scheduled in accordance with established procedures/priorities.

7. Complaint investigations are:
   a. Conducted in accordance with established time-frames.
   b. Unannounced.

8. The SA adheres to the SOM instructions for post-investigation actions.

NOTE for PI #8: *If the SA has followed the SOM and has forwarded the complaint to the CMS Location for investigation and the SA is not required to perform the post-investigation, enter "1" in the "Yes" box.*

9. There is resolution and closeout of each complaint (completion of all actions required by SOM, including follow-up to the complaint, if not anonymous).

NOTE for PI #9: *If the SA has followed the SOM and has forwarded the complaint to the CMS Location for disposition or if the complaint is anonymous, the SA is not responsible for the resolution or close out of the complaint. Enter a "1" in "Yes."*

A Written Corrective Action Plan is required if the Quantified Performance Result is less than 90 percent or if Performance Indicator 1 is not met.
A Written Corrective Action Plan is required if the Quantified Performance Result is less than 90 percent or if Performance Indicator 1 is not met.

A Written Corrective Action Plan is required if the Quantified Performance Result is less than 90 percent or if Performance Indicator 1 is not met.

In the box labeled "Written Corrective Action Plan Required?," if the answer is "Yes" enter an "X" in the "Yes" box, if "No" enter an "X" in the "No" box.

CLIA State Agency Performance Review FY2023
Criterion #6: Complaints

Performance Indicator	Y	N
PI1: The SA utilize ACTS for all complaints in accordance with the current ACTS Procedure Guide.		

Performance Indicator	Y	N	Comments
PI 2:The SA has a mechanism to track all complaints received by the SA.			
PI 3: The SA adheres to the SOM instructions for complaints as well as the current ACTS Procedure Guide for entry of data into ACTS.			

CLIA # or SA Complaint ID # (if no complaints, indicate here results based on interview)	Performance Indicators																											
	PI 4			PI 5a			PI 5b			PI 5c			PI 6			PI 7a			PI 7b			PI 8			PI 9			
	Y	N	NA	Y	N	NA	Y	N	NA	Y	N	NA	Y	N	NA	Y	N	NA	Y	N	NA	Y	N	NA	Y	N	NA	Comments
1																												
2																												
3																												
4																												
5																												
6																												
7																												
8																												
9																												
10																												

State Agency:	Enter State Name	
Date:		
Evaluator:		
Performance Threshold:	90%	
Quantified Performance Result:	#DIV/0!	
	YES	NO
Written Corrective Action Plan Required?		

Performance Measurement:
Performance Threshold: 90 percent
A Written Corrective Action Plan is required if the Quantified Performance Result is less than 90 percent or if Performance Indicator 1 is not met.

Special Instructions for Criterion #7: Quality Assessment

Overall Goal:

The SA has developed written specific procedures related to SAPR.
The SA has an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in their survey and certification activity (i.e., quality assessment).
Ensure that the SA has, and is following, the five required SAPR procedures. The procedures may be written (either hardcopy or electronic).

Instructions for Completing Data Fields associated with Performance Indicators:

1. Complete data fields that require information (i.e. Evaluator, Date, CLIA #, Analyte, Specialty/Subspecialty/Event, etc.) by typing the information into the space below the column header.
2. On Criterion #1 tab, please enter the State name and it will self-populate on all tabs.
3. For all Performance Indicators--**Enter a "1" into the yes or no column.**

Performance Indicators:

1. The SA has documented evidence of the implementation of CAP (Corrective Action Plan) and/or QIP (Quality Improvement Process).
2. The SA must establish and follow a written standard operating procedure (SOP) for:
    a. Surveyor and clerical orientation, training, and annual competency;
    b. Entry of initial application, certificate changes, and demographic information updates;
    c. Performing PT desk review every 30-45 days;
    d. Handling and triaging all complaints;
    e. Quality Assessment, including quality indicators; and
    f. Budget- ****Educational for FY 23****-will be mandatory for FY 2024.

NOTE for PI #2: *If any one of the SOPs as required for PI #2 (see assessment section below of this worksheet) is missing, indicate which is missing in the "Comment" column*

3. The SA QA Program must include an on-going mechanism to monitor, assess, and when indicated, correct problems identified in their survey and certification activity, and must include:
    a. Identification of areas needing improvement for surveyors;
    b. Utilization of FMS Assessments and other CMS Location feedback when identifying areas for surveyor improvement;
    c. Measuring progress in improving surveyor skills when needed (data from SoD review, PoC/AOC review or other SA internal measurement);
    d. Tracking of errors in data management
    e. Interval between running CASPER 0153D and CASPER 0155D and review of information for PT desk review;
    f. Timeliness of sending letters and CMS 2567s for unsuccessful participation in PT;
    g. Identification of issues in the overall process;
    h. All activities related to QA must be documented

NOTE for PI #3: *If any one of PIs, PI 3 a. → h. is not met, indicate which was not met in the "Comment" column.*

A Written Corrective Action Plan is required if the Quantified Performance Result is less than 100 percent.
In the box labeled "Written Corrective Action Plan Required?," if the answer is "Yes" enter an "X" in the "Yes" box, if "No" enter an "X" in the "No" box.

4.**** Educational for FY 23**** The SA runs quarterly monitoring reports and when indicated, corrects problems identified in the reports. The quarterly reports include: ASPEN Tracking Report for Failed and Overdue Certification Kit Uploads, CASPER 0074D, and CASPER 1400D. Please note evaluation of the PI #4 is educational for FY 2023, but will be mandatory for FY 2024. The SA must run quarterly reports starting the first quarter of FY 2024 (10/1/2023).
5. ****Educational for FY 23**** The SA must address, and when indicated, correct problems identified in the quarterly reports provided by CMS. Quarterly reports include: Mandatory SAS Viya SAPR Reports and Survey Backlog Report. Please note evaluation of the PI #5 is educational for FY 2023, but will be mandatory for FY 2024. The SA must run quarterly

CLIA State Agency Performance Review FY2023
Criterion #7: Quality Assessment

CAP/QIP Performance Indicator	Yes	No	NA	Comments
PI 1: The SA has documented evidence of the implementation of a CAP and/or QIP.				

SA Standard Operating Procedures

Performance Indicator	Yes	No	NA	Comments
PI 2: The SA must establish and follow a standard operating procedure (SOP).				

SA Quality Assessment Program

Performance Indicator	Yes	No	NA	Comments
PI 3: The SA QA must include an on-going mechanism to monitor, assess, and when indicated, correct problems identified in their survey and certification activity.				

SA Quarterly Monitoring Reports

Performance Indicator	Yes	No	NA	Comments
PI 4: The SA runs quarterly monitoring reports and when indicated, correct problems identified in the reports. Mandatory quarterly reports include: ASPEN Tracking Report for Failed and Overdue Certification Kit Uploads, CASPER 0074D, CASPER 1400D.				
PI 5: The SA must address, and when indicated, correct problems identified in the quarterly reports provided by CMS. Quarterly reports include: Mandatory SAS Viya SAPR Reports and Survey Backlog Report.				

State Agency:	Enter State Name
Date:	
Evaluator:	
Performance Threshold:	100%
Quantified Performance Result:	#DIV/0!

	YES	NO
Written Corrective Action Plan Required?		

Performance Measurement:
Performance Threshold: 100 percent
A Written Corrective Action Plan is required if the Quantified Performance Result is less than 100 percent.

CLIA State Agency Performance Review FY2023
Criterion #8: Budget

****EDUCATIONAL FOR FY2023**** Criterion will be mandatory for FY2024

Special Instructions for Criterion #8: Budget

Overall Goal:
The SA submits all required documents into the Survey and Certification and Clinical Laboratory Improvement Amendments System (SCCLIA) within the specified time limits.

Instructions for Completing Data Fields associated with Performance Indicators:
1. Complete data fields that require information (i.e. Evaluator, Date, CLIA #, Analyte, Specialty/Subspecialty/Event, etc.) by typing the information into the space below the column header.
2. On Criterion #1 tab, please enter the State name and it will self-populate on all tabs.
3. For all Performance Indicators--**Enter a "1" into the yes or no column.**

Performance Indicators:
1. The SA submits an "activity plan" to the Branch Location in accordance with the SOM within the specified time limit.
2 The budget forms below are submitted for formulating the State budget for the current fiscal year.
3. The SA submits the CMS 102 (CLIA budget expenditure report) no later than 45 days after the end of the quarter into SCCLIA for review by the Branch Location.
4. The SA submits the CMS 105 (CLIA accomplished/planned workload report) no later than 45 days after the end of the quarter into SCCLIA for review by the Branch Location.
5. The workload reports are submitted by the 10th of the month to the Branch Location.

****Educational for FY 2023 and NO CAP required if the Quantified Performance Result is less than 80 percent.****

CLIA State Agency Performance Review FY2023
Criterion #8: Budget

Performance Indicator	Yes	No	Comments
PI 1: Budget reports activity plan in accordance with SOM.			

Performance Indicator	Yes	No	Comments
PI 2: Budget reports in accordance with CLIA Budget Call letter FY23 Fiscal year: i.e., CMS-102,105,1465,1466 initial report for the year			

PI 3: CMS-102 Quarterly report submitted timely-no later than 45 days after the end of QTR	Yes	No	Comments
FY Quarter 1			
FY Quarter 2			
FY Quarter 3			
FY Quarter 4			

PI 4: CMS-105 Quarterly report submitted timely-no later than 45 days after the end of QTR	Yes	No	Comments
FY Quarter 1			
FY Quarter 2			
FY Quarter 3			
FY Quarter 4			

Performance Indicator	Yes	No	Comments
PI 5: Workload reports are submitted to the BL by the 10th of each month			

CLIA State Agency Performance Review FY2023
Criterion #8: Budget

State Agency:	Enter State Name	
Date:		
Evaluator:		
Performance Threshold:	**80%**	
Quantified Performance Result:	**#DIV/0!**	
	YES	**NO**
Written Corrective Action Plan Required? **Educational for FY23**	NA	NA

Performance Measurement:
Performance Threshold: 80 percent
Eductional for FY 2023-NO CAP is required if the Quantified Performance Result is less than 80 percent.

Total of all "Yes" PI1 - 5	0
Total of all "Yes" & "No"PI 1 -5	0

FY 2023 CLIA SAPR CRITERIA 2, Data Management

CMS Location Review Date:			State:
CMS Location Reviewer:			

Initial CLIA Applications (Form CMS-116), PI2 + PI3

	CLIA Number	All Fields Accurately Entered Into CMS-116 Database	All CMS-116s Entered Within 30 Days	Comments List All Fields Not Accurately Entered AND/OR Entered > 30 Days
1	21D0000000	Y	Y	
2	21D1111111	N	Y	Facility Address, LD name misspelled
3	21D2222222	Y	N	43 days - backlog for entry
4	21D3333333	N	N	48 days - no reason given
5				
6				
7				
8				
9				SAMPLE
10				

Certificate Changes, PI4 + PI5

	CLIA Number	All Certificate Changes Entered Accurately	All Certificate Changes Entered Within 45 Days	Comments List Certificate Changes Not Accurately Entered AND/OR Entered > 45 Days
1	21D4444444	N	Y	PPM entered instead of CoW
2	21D5555555	Y	N	57 days - data entry person out on medical leave, no back up
3				SAMPLE
4				

Demographic Updates, PI 6 + PI7

	CLIA Number	All Demographic Updates Entered Accurately	All Demographic Updates Entered Within 45 Days	Comments List All Demographic Updates Not Accurately Entered AND/OR Entered > 45 Days
1	21D6666666	N	Y	Facility address - street address #
2	21D7777777	Y	N	61 days - data entry position vacant
3				SAMPLE
4				

Reference Sheet, Principle #3, Composition of a Deficiency Citation

A deficiency citation consists of (A) a regulatory reference, (B) a deficient practice statement and (C) relevant findings.

A. Regulatory Reference:

A Regulatory Reference includes the following components:
1. A survey data tag (D-Tag) number,
2. The CFR (Code of Federal Regulations),
3. The language from that regulatory reference which specifies the aspect(s) of the requirement with which the laboratory was non-compliant, and
4. An explicit statement that the requirement was "NOT MET".

B. Deficient Practice Statement (DPS)

The statement of deficient practice is one component of the evidence. It includes:
1. The specific action(s), error(s), or lack of action (deficient practice),
2. Outcome(s) relative to the deficient practice, when possible,
3. A description of the extent of the deficient practice or the number of deficient cases relative to the total number of such cases,
4. The identifier of the individuals or situations referenced in the extent of the deficient practice; and
5. The source(s) of the information through which the evidence was obtained.

C. Relevant Facts and Findings
The facts and findings relevant to the deficient practice answer the questions: who, what, where, when, and how. They illustrate the laboratory's noncompliance with the requirement or regulation.

How the deficiency was determined and how the evidence relates to the requirement.
What laboratory practice was non-compliant?
Who were the patients of the failed practice or the laboratory staff involved?
Where the deficient practice occurred, e.g., specific locations in the laboratory documents; and
When the problem occurred and for how long. Include the number of records or observations and the duration of the records or observations. Include the specific dates or time period for the noncompliance.

Reference Sheet for CMS Location REVIEW TOOL, Criterion #4
Required Elements for acceptable POC and credible AOC

Acceptable Plan of Correction

Evaluation

Does it address:

1. What corrective action(s) have been taken for patients found to have been affected by the deficient practice?
2. How the laboratory has identified other patients having the potential to be affected by the same deficient practice and applicable corrective action (s)?
3. What measure has been put into place or what systemic changes will be made to ensure that the deficient practice does not recur?
4. How the corrective action(s) will be monitored to ensure the deficient practice does not recur?

Credible Allegation of Compliance

Evaluation

Lab's Statement or documentation:

a. Is it made by a representative of a laboratory with a history of commitment to compliance and taking action when required?
b. Is it realistic; is it possible to accomplish corrective action(s) by date of AoC?
c. Does it indicate that the problem has been resolved?

Lab's AoC must include acceptable evidence of correction with documentation. Does the evidence show:

1. What corrective action(s) have been taken for patients found to have been affected by the deficient practice?
2. How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) have been taken?
3. What measure has been put into place or what systemic changes have been made to ensure that the deficient practice does not recur?
4. How the corrective action(s) are being monitored to ensure the deficient practice does not recur?

Reference Sheet for CMS Location REVIEW TOOL, Criterion #4 Principles of Documentation (POD) - Key Points	
POD Principle	**Key Points**
1, Lab Compliance and Noncompliance	◊ Compliance → D0000 (only used for compliance when all requirements met) ◊ Noncompliance → List of condition level deficiencies ◊ Type of survey
2, Using Plain Language	◊ Written clearly, objectively in active voice and in layman's terms ◊ Avoid words such as: *seems, appears, inadequate, unnecessary* ◊ No extraneous advice, comments, directions, slang ◊ Should contain only evidence to support noncompliance ◊ Define acronyms, abbreviations 1st time used ◊ Ensure accuracy of cited/quoted material
3, Composition of Deficiency Statement	◊ Deficient Practice Statement: ◦ Clearly states what lab did/did not do to cause noncompliance ◦ Do not merely repeat the regulation ◦ Includes: specific action(s) or lack of action(s), outcome(s) when possible, extent, sources (2) ◦ Name of individuals/patients should never be used ◊ Findings Statement: ◦ Supports/illustrates lab's noncompliance ◦ Who, what, where, when, how ◦ Citations specific to lab, in concise and chronological or logical order ◦ Date and time for observations
4, Relevance of Onsite Correction Findings	◊ Must be documented on CMS-2567 as "NOT MET"
5, Interpretive Guidelines (IG)	◊ May not be used as a basis for citation(s) ◊ IGs do not replace/supersede statute or regs
6, Citation of State/Local Code Violation	◊ Only used for 2 reasons, see POD
7, Cross References	◊ Applicable and provides additional strength to linked citation(s) ◊ Must support noncompliance with requirement
8, Condition Deficiencies	◊ Includes only requirements to be corrected to achieve condition-level compliance ◊ May stand alone as single cite or include accompanying standards ◊ Condition statement is written as a practice statement. Findings are listed or cress-referenced

FY 2023 CLIA SAPR CRITERIA 4 D-TAG CLIA LOCATION REVIEW TOOL

CLIA Number:		Facility Name:		State:
Survey Date:		CMS Location Reviewer:		CMS Location Review Date:

CRITERION 4, PI #4, POD			CRITERION 4, PI #4, PoC/AoC				
A	B	C	D	E	F	G	H
Identify D-tag(s) which do not meet POD	Identify principle(s) of POD not met	Total # of D-tags which meet POD	POC: Is the POC acceptable? (Y, N, N/A)	AOC: Is the AOC credible? (Y, N, N/A)	Total # of acceptable and/or credible D-tag(s)	Total # D-tags cited in CMS-2567	Additional Comments, Reason why D-tag does not meet POD OR Why PoC/AoC was not acceptable/credible
			Y				
D5411							missing impact on patients
		7			8	8	
CRITERION 4: % D-tags which meet POD		88%	**CRITERION 4:** % D-tags which meet requirements for POC or AOC		100%		

Mandatory SAPR Reports

Report Name	Description	Criterion	Performance Indicator
DM-A: 116 Entry	A **DETAIL** report, sorted by application type, identifies the laboratories that applied and entered into the CLIA program in the FY under review.	2	2,3
DM-B: Cert Changes	A **DETAIL** report listing all Certificate changes made during the fiscal year under review with a run time parameter for Geography.	2	4,5
CASPER 0104D CLIA 116 Activity	A **DETAIL** report identifying the names of laboratories that had specific demographic fields updated during the FY under review. The report also displays the date the change was made, the user ID of the person who made the change, and fields changed.	2	6,7
PT-A: PT Desk Rvw	A **DETAIL** report listing all PT Desk Reviews performed during the fiscal year under review with a run time parameter for Geography	3	All
SOD-A Mandatory Citation List	A **DETAIL** report listing surveys in which mandatory citations were cited during the fiscal year under review with a run time parameter for Geography. Does not include PT Desk Review.	4	1
SVY-A: Initial Surveys	A **DETAIL** report identifying the laboratories that had early/late initial surveys in the fiscal year under review.	5	1
SVY-B: Expired CoC	A **DETAIL** report identifying the laboratories that had Recertification Surveys after the certificate expired.	5	2
SVY-C: Validation	A **DETAIL** report identifying the accredited labs (ap type 3) that had Validation surveys during the fiscal year under review and showing the number of days between the AO survey date and the Validation date. Note: The report displays the laboratories by AO, so a laboratory accredited by both ASHI and AABB would display (and be counted) on 2 lines.	5	3
SVY-D: Survey Upload	A **DETAIL** report showing laboratories surveyed during the FY under review, and first uploaded into the ACO system more than 45 days after the survey date. **Note:** "Survey Transaction Date" is a date generated at the time the State first attempts to upload a certification kit in ACO.	5	8

Quarterly SA Monitoring Reports*

Report**	Purpose	Run By			CMS Share with SAs**
		CMS Baltimore	CMS Branch Location	State Agency	
Mandatory SAPR Reports (SAS Viya)	Monitor SAPR criteria quarterly	√			√
CASPER 0850D	Monitor expired/expiring certificates		√	√	
CASPER 0080D	Monitor laboratory for paid compliance fee/used for survey scheduling		√	√	
Survey Process/ASPEN Tracking Report for Failed and Overdue Certification Kit Uploads	Monitor ASPEN uploads and survey workload		√	√	
Survey Backlog Report (SAS Viya)	Monitor SA survey backlog	√			√
Budget Report	Monitor the SA's submission of budget reports into SCCLIA		√		
CASPER 0074D	CLIA Labs with AO Remarks		√	√	
CASPER 1400D	Recertification Kits Not Uploaded		√	√	

*All monitoring reports will be run by CMS and the SA the first week of each quarter, beginning in January 2024 with Q1 (October 2023 - December 2023).

Optional SAPR Reports

Report Name	Description	Performance Indicator
OPT-A: 116 · Entry, Total	A **SUMMARY** report providing totals on the number of CMS-116s entered in FY. **Note:** Used 'ap received date', a system-generated date based on date user enters CMS-116 into CLIA data base.	n/a
OPT-B: 116 Entry, Outliers	A **DETAIL** report showing the outlier records, i.e., States entering the CMS-116 more than 30 days after receipt of the CMS-116 form in the State agency, designated by the date stamp on the form. **Note:** Report compares “state agency receipt date” to “app received date”	n/a
OPT-C: Total Surveys	A **SUMMARY** report provides totals on the number of laboratories surveyed during the FY.	n/a
OPT-D: Surveyed Labs	A **DETAIL** report identifies the laboratories that were surveyed during the FY.	n/a
OPT-E: Recert	A **SUMMARY** report providing totals on the number of laboratories that had recertification surveys accepted into the data system during the FY.	n/a
OPT-F: Uploaded Recerts	A **DETAIL** report identifying the labs that had recertification surveys accepted into the data system during FY.	n/a
OPT-G: Initials	A **SUMMARY** report providing totals on the number of laboratories that had initial surveys accepted into the data system during FY.	n/a
OPT-H: Uploaded Initials	A **DETAIL** report identifies the laboratories that had initial surveys accepted into the data system during FY.	n/a
OPT-I: Follow-ups, Total	A **DETAIL** report identifying the compliance laboratories, surveyed during FY, that had follow-up surveys (including onsite and offsite revisits). **Note:** The report is sorted by a counter that totals the number of onsite hours spent in the laboratory. Offsite revisits are identified with “00” in the “Total Onsite Team hrs” column. The report also displays 4 deficiency counters: 1) “Curr Tot Defs” counts the total number of Dtags cited on the CMS-2567, 2) “Cur Def Nocor” counts the number of Dtags that have not been corrected, 3) “Curr std all” counts the number of Dtag deficiencies at the standard level, and, 4) “Curr cop all' counts the number of Dtag deficiencies at the condition level.	n/a
CASPER 157D: PT Excused Nonparticipation	This **DETAIL** report identifies the laboratories that have been given a pass for failure to participate in proficiency testing for one or more analvtes/events.	n/a

Instructions for Printing CASPER 0104D CLIA 116 Activity (Criterion 2 Data Management PI 6,7)

[Use “DM-B: Cert Changes” for Status changes] [104 is just for Demographic changes]

1. Log into CASPER Reporting and locate CASPER report 0104D CLIA 116 Activity.
2. Select the following criteria:

Geographic Breakdown: the state on which you are performing the SAPR.
Exempt Status: Non-Exempt
Provider Status: Both
User ID: CLIAUSER [Note: CLIAUSER sets the filter to Humans, not the system]
Application Type: Select All

3. Note: The CMS Location may choose to run one Report or multiple Reports based on varying time frames. Then, use the listing to ask the State agency to pull a representative sample of lab records and, as part of the review process, compare and assess the accuracy of the ASPEN data with the associated written notifications (email, letter, CMS-116).
4. Using a time period that falls within the fiscal year SAPR under review, complete the DATE CRITERIA as illustrated below using the dates for this review period:

Press NEXT

5. Leave default either as NO SELECTION, or select change types that represent application*, termination, or demographic updates, as shown below:

Press SAVE AND SUBMIT

Important Notes

- **This year the CMS Locations should not use CASPER 104D to find laboratories with certificate type changes. Instead use the new SAPR report: DM-B: Cert Changes.**
- When searching for demographic updates, we would recommend highlighting all fields, but only selecting 4-5 separate weeks, not 4-5 continuous weeks, throughout the FY rather than the entire FY. If you choose the entire FY, the report may be very long.

6. Once submitted, you can go into the “Folders” then to “My Inbox” to see the report. Double click on the 104D report in the inbox.
7. Below is an excerpt of CASPER Report 104D that identifies the labs that had specific fields updated during the time period selected. On the bottom left side of the report you will see some total numbers. You can use these to determine how many changes were made in the state, region and nation for the changes requested in the report.

CASPER Report 0104D
CLIA 116 Activity
Change Dates from 05/01/2018 thru 05/31/2018
Connecticut - Exclude FJ Labs
USER ID - CLIAUSER

Run Date: 06/26/2018
Job # 70539853
Last Update: 06/25/2018
Page 1 of 7

CCN	Provider Name	App Type Code	Term Code	Change Date	User ID	Data Changed	Cert Exp Date
07D0094149	QUEST DIAGNOSTICS	1	00	05/03/2018	1004651	Application Signature Date, Director Name, Mailing Address	02/02/2019
07D0094355	QUEST DIAGNOSTICS		00	05/03/2018	1004651	Application Signature Date, Director Name, Mailing Address	08/11/2018
07D0095024	HARTFORD HEALTHCARE MEDICAL	2	00	05/02/2018	1004731	Director Name, Provider Name, Mailing Address	07/22/2018
07D0098549	QUEST DIAGNOSTICS		00	05/03/2018	1004651	Application Signature Date, Director Name, Generate Replacement Certificate, Mailing Address	10/13/2019
07D2003939	LABORATORY - HARTFORD LIFE	2	00	05/02/2018	1004731	Generate Replacement Certificate, Mailing Address	02/21/2020
07D2092236	HARTFORD HEALTHCARE CANCER I	3	00	05/16/2018	1004651	Application Information, Application Signature Date, Mailing Address	08/11/2019

Total Selected Criteria Changes for Connecticut = 6
Total Selected Criteria Changes for Boston Regional Office = 31
Total Selected Criteria Changes for Nation = 1,289

This 104D report was for Region 1 and mailing address changes. One page of the report displays the mailing address changes in Connecticut for the time period chosen (Change Dates from 05/01/2018 thru 05/31/2018 – see the third line in the report header).

The report lists the labs with mailing address changes – and if that lab had other changes made at the same time those are listed also.

The statistics do not count the other changes, just the number of labs with mailing address changes. In this case for the month of May 2018 Connecticut had 6 labs with mailing address changes – and those 6 labs are listed. The entire Region for May had 31 mailing address changes entered and the nation had 1,289 mailing address changes for the same timeframe.

You can also see that two different people were making these changes in Connecticut – User IDs 1004651 and 1004731.

Clinical Laboratory Improvement Amendments (CLIA) Program

State: [NAME]

CLIA State Agency Performance Review

SUMMARY REPORT

Review Period: Fiscal Year 2023

(October 1, 2022 to September 30, 2023)

CLIA STATE AGENCY PERFORMANCE REVIEW
FISCAL YEAR 2023

REVIEW CRITERIA

Criterion # 1: Personnel Qualifications, Training, and Competency

Criterion # 2: Data Management

Criterion # 3: Proficiency Testing Desk Review

Criterion # 4: Principles of Documentation (POD), Plans of Correction (POC), Allegations of Compliance (AOC)

Criterion # 5: Survey Workload and Outcome-Oriented Survey Process (OOSP)

Criterion # 6: Complaints

Criterion # 7: Quality Assessment

Criterion # 8: Budget – Educational Only for FY 2023

CLIA STATE AGENCY PERFORMANCE REVIEW FY 2023 SA:

Performance Review Criterion #1: Personnel Qualifications, Training, and Competency

The SA has an:
- Effective system in place to ensure that all CLIA surveys are conducted by qualified and competent individuals.
- Ongoing training program to improve survey skills.
- Ongoing program to ensure that SA CLIA clerical staff and surveyors are properly trained in a timely manner.
- Ongoing mechanism to maintain and improve competency.

DID THE SA HIRE ANY NEW SURVEYORS IN FY 2023? YES/NO

PERFORMANCE MEASUREMENT:

Performance Thresholds for Written Corrective Action Plan

A written corrective action plan is required if:
- Quantified performance results are less than 100%; **OR**
- The staff positions (professional and clerical) listed on CMS-1465A are not occupied as reported.

SA Performance Results

FY 2023 Quantified Performance Results: %

PREVIOUS 2-YEAR QUANTIFIED PERFORMANCE RESULTS

FY 2021 Quantified Performance Results: %
FY 2022 Quantified Performance Results: %

WRITTEN CORRECTIVE ACTION PLAN: YES/NO

FINDINGS:

SPECIAL CIRCUMSTANCES AND NOTEWORTHY ACCOMPLISHMENTS:

Performance Review Criterion #2: Data Management

The SA has implemented a mechanism to ensure that data entry is done both accurately and within the appropriate timeframe and that all personnel responsible for data management have been trained.

PERFORMANCE MEASUREMENT:

Performance Thresholds for Written Corrective Action Plan

A written corrective action plan is required if:

- Quantified performance results are less than 100%; **OR**
- The SA does not have a mechanism to track the receipt and entry of initial applications (Form CMS-116s), certificate type changes, and demographic updates.

SA Performance Results

FY 2023 Quantified Performance Results: %

PREVIOUS 2-YEAR QUANTIFIED PERFORMANCE RESULTS

FY 2021 Quantified Performance Results: %
FY 2022 Quantified Performance Results: %

WRITTEN CORRECTIVE ACTION PLAN: YES/NO

FINDINGS:

SPECIAL CIRCUMSTANCES AND NOTEWORTHY ACCOMPLISHMENTS

Performance Review Criterion #3: Proficiency Testing (PT) Desk Review

The SA conducts PT Desk Review timely and initiates appropriate action regarding unsuccessful participation.

PERFORMANCE MEASUREMENT:

Performance Thresholds for Written Corrective Action Plan

A written corrective action plan is required if:

- Quantified performance Results are less than 85%; **OR**
- SA has not implemented a mechanism to track PT scores every 30 – 45 days.

SA Performance Results

SA has implemented a mechanism to track PT scores every 30 – 45 days? YES/NO

FY 2023 Quantified Performance Results: %

PREVIOUS 2-YEAR QUANTIFIED PERFORMANCE RESULTS

FY 2021 Quantified Performance Results: %
FY 2022 Quantified Performance Results: %

WRITTEN CORRECTIVE ACTION PLAN: YES/NO

FINDINGS:

SPECIAL CIRCUMSTANCES AND NOTEWORTHY ACCOMPLISHMENTS:

CLIA STATE AGENCY PERFORMANCE REVIEW FY 2023 SA:

Performance Review Criterion # 4: Principles of Documentation (POD), Plan of Correction (POC)/Allegation of Compliance (AOC)

The SA has a review system/process to ensure that all CLIA surveyors:
- Write clear, concise, and legally defensible Statements of Deficiencies (SOD) (CMS-2567) that are consistent with the CLIA Principles of Documentation (POD).
- Accept only POC/AOCs that meet the criteria for acceptability.

PERFORMANCE MEASUREMENT:

Performance Thresholds for Written Corrective Action Plan

A written corrective action plan is required if:
- Quantified performance results are less than 100%; **OR**
- The SA does not utilize and understand mandatory citations.

SA Performance Results

FY 2023 Quantified Performance Results: %

PREVIOUS 2-YEAR QUANTIFIED PERFORMANCE RESULTS

FY 2021 Quantified Performance Results: %
FY 2022 Quantified Performance Results: %

WRITTEN CORRECTIVE ACTION PLAN: YES/NO

FINDINGS:

SPECIAL CIRCUMSTANCES AND NOTEWORTHY ACCOMPLISHMENTS

Performance Review Criterion # 5: Survey Workload and Outcome-oriented Survey Process

- The SA has a system to ensure that all surveyors conduct surveys using the outcome-oriented survey process.
- The SA has implemented a tracking system and ensures that the survey time frames are met.

PERFORMANCE MEASUREMENT:

Performance Thresholds for Written Corrective Action Plan

A written corrective action plan is required if quantified performance results are less than 85%.

SA Performance Results

FY 2023 Quantified Performance Results: %

PREVIOUS 2-YEAR QUANTIFIED PERFORMANCE RESULTS

FY 2021 Quantified Performance Results: %
FY 2022 Quantified Performance Results: %

WRITTEN CORRECTIVE ACTION PLAN: YES/NO

FINDINGS:

SPECIAL CIRCUMSTANCES AND NOTEWORTHY ACCOMPLISHMENTS

Performance Review Criterion #6: Complaints

The SA accepts and processes all complaints from receipt to closeout in accordance with CMS policies and procedures.

PERFORMANCE MEASUREMENT:

Performance Thresholds for Written Corrective Action Plan

A written corrective action plan is required if:

- Quantified Performance Results are less than 90%; **OR**
- SA does not utilize ACTS for all complaints.

SA Performance Results

- SA utilizes ACTS for all complaints? YES/NO

FY 2023 Quantified Performance Results: %

PREVIOUS 2-YEAR QUANTIFIED PERFORMANCE RESULTS

FY 2021 Quantified Performance Results: %
FY 2022 Quantified Performance Results: %

WRITTEN CORRECTIVE ACTION PLAN: YES/NO

FINDINGS:

SPECIAL CIRCUMSTANCES AND NOTEWORTHY ACCOMPLISHMENTS

CLIA STATE AGENCY PERFORMANCE REVIEW FY 2023 SA:

Performance Review Criterion #7: Quality Assessment

- The SA has developed specific procedures related to SAPR.
- The SA has an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in their survey and certification activity (i.e., quality assessment).

PERFORMANCE MEASUREMENT:

Performance Threshold for Written Corrective Action Plan

A written corrective action plan is required if the Quantified Performance Results are less than 100%.

SA Performance Result

FY 2023 Quantified Performance Results: %

PREVIOUS 2-YEAR QUANTIFIED PERFORMANCE RESULTS

FY 2021 Quantified Performance Results: %
FY 2022 Quantified Performance Results: %

WRITTEN CORRECTIVE ACTION PLAN: YES/NO

FINDINGS:

SPECIAL CIRCUMSTANCES AND NOTEWORTHY ACCOMPLISHMENTS:

CLIA STATE AGENCY PERFORMANCE REVIEW FY 2023 SA:

****Educational for FY 2023****

Performance Review Criterion #8: Budget

- The SA submits all required documents into the Survey and Certification and Clinical Laboratory Improvement Amendments System (SCCLIA) within the specified time limits.

PERFORMANCE MEASUREMENT:

Performance Threshold for Written Corrective Action Plan

A written corrective action plan is required if the Quantified Performance Results are less than 80%.

SA Performance Result

FY 2023 Quantified Performance Results: %

WRITTEN CORRECTIVE ACTION PLAN: **Educational for FY 2023**

FINDINGS:

SPECIAL CIRCUMSTANCES AND NOTEWORTHY ACCOMPLISHMENTS:

Attachment #4

COVER LETTER TEMPLATE FOR FY 2023 CLIA SAPR SUMMARY REPORTS

(**Date**)

(**Name & Address of SA Official**)

Dear (**SA Official**):

Re: Clinical Laboratory Improvement Amendments State Agency Performance Review (CLIA SAPR) Summary Report—Fiscal Year 2023 (FY 2023)

Thank you for your cooperation and the courtesies extended to ***[Name of CMS Branch Location SAPR Reviewer]*** during the CLIA SAPR review of ***[name of SA]*** conducted on ***[Dates]***. Enclosed is the Summary Report for the FY 2023 review.

The Section 1864 Agreement requires that the CMS Branch Location conduct a performance evaluation of each State Agency performing CLIA survey and certification activities. The CLIA SAPR is structured to accomplish an annual evaluation of the State Agency. The goal of the CLIA SAPR is optimal performance by the State Agency as our partner in ensuring quality in laboratory practices and testing. The CMS Branch Location can provide educational assistance, information, and support, whenever needed.

The following are the eight criteria included in the FY 2023 SAPR review:

Criterion #1 - Personnel Qualifications, Training, and Competency
Criterion #2 - Data Management
Criterion #3 - Proficiency Testing (PT) Desk Review
Criterion #4 - Principles of Documentation (POD), Plan of Correction (POC)/Allegation of Compliance (AOC)
Criterion #5 - Survey Workload and Outcome-Oriented Survey Process (OOSP)
Criterion #6 - Complaints
Criterion #7 - Quality Assessment
Criterion #8 - Budget – Educational for FY 2023

We encourage you to communicate any feedback regarding the SAPR process to your CMS Branch Location.

However, the subject areas of the other Criteria from the previous version of the SAPR could be examined separately at each CMS Branch Location's discretion, under our overarching authority for SA oversight, and reported in addition to the outcomes of the standardized review.

The CLIA SAPR process is not an exhaustive evaluation, nor an exact measurement of state agency performance. Therefore, we do not issue an overall score or grade. Performance measurements consist of gathering and quantifying a snapshot of data in a standardized fashion:

- To ascertain objectively whether your agency has fulfilled the expectations of each CLIA SAPR Performance Criterion, as delineated in the Performance Indicators; and
- To determine whether your agency must submit any written corrective action plans.

The CLIA SAPR Summary Report recognizes your agency's strengths and accomplishments in meeting your CLIA program responsibilities, as well as any areas that may need improvement. If your agency has experienced special circumstances that affected your performance, they are also indicated in the interest of providing a balanced view of your state's operations.

As you examine the summary report, please keep in mind that the Performance Threshold is neither a score nor a pass/fail rating. It serves as a demarcation point for the CMS Branch Location to request a written corrective action plan. The Performance Threshold also serves to ensure nationwide consistency among the CMS Branch Locations.

(***Add the following paragraph if NO written CAP is needed***)
We are pleased to report that your agency's performance met or exceeded the Performance Threshold for all Criteria, thus no written corrective action plan is requested. Your agency is to be commended for its performance. **(*Add the following sentence to this paragraph or at another suitable placement if optimal performance outcome has been sustained over multiple years*).** We note that your agency has sustained optimal performance outcomes for **(Criterion # /Criteria ##)** for several years. With your permission, we would like to share the "best practices" employed by your SA with other states.

(***Add the following paragraphs if one or more CAPs are needed***)

A written corrective action plan is required for the following:

(***Only list the Number and Name for each Criterion needing a CAP)***
Criterion #1—Personnel Qualifications, Training, and Competency
Criterion #2—Data Management
Criterion #3—Proficiency Testing (PT) Desk Review
Criterion #4—Principles of Documentation (POD), Plan of Correction (POC)/Allegation of Compliance (AOC)
Criterion #5—Survey Workload and Outcome-Oriented Survey Process (OOSP)
Criterion #6—Complaints
Criterion #7—Quality Assessment
Criterion #8—Budget—Educational for FY 2023

The corrective action plan should be received in this office no later than 30 days from your receipt of this letter, and should contain the following information:

1) Name of your State;
2) Name and number of the Criterion needing corrective action and the action that will be taken;
3) How it will be monitored and evaluated to verify that it was successful and complete;
4) Name of the individual responsible for completion of the corrective action;
5) Expected dates of institution and completion of the corrective action; and
6) Any other information that may be necessary to show that correction can be achieved or has already been achieved.

The CLIA SAPR Summary Report recognizes your agency's strengths and accomplishments in meeting your CLIA program responsibilities, as well as any areas that may need improvement. If your agency has experienced special circumstances that affected your performance, they are also indicated.

(***If other subject areas were reviewed, add the following language in this cover letter)***

Other Subject Areas Reviewed

The CMS Branch Location exercised the option to review the following subject ***(area) (areas)*** *under* our overarching authority for SA oversight:

List each subject area by Name (without Criterion # to maintain separation from the standard protocol, e.g. "Financial Management" rather than "Criterion #3"), and add the following information in a narrative:

- ***For each subject area, indicate what was reviewed, including a description of the data gathered, the specific findings, and the overall outcome.***

Again, we commend you and your staff for all your efforts related to the CLIA Program, and we appreciate your commitment to quality improvement. If you have any questions, comments, or concerns about this letter or the Summary Report, please contact **[*Name of CMS Branch Location Reviewer*]** at **[*phone #*].**

Sincerely,

Add appropriate signature.

Also, see next page: use or delete optional language.

CLIA STATE AGENCY PERFORMANCE REVIEW

FISCAL YEAR 2023

STANDARD REVIEW

The following are the eight criteria included in the FY 2023 SAPR review:

Criterion #1—Personnel Qualifications, Training, and Competency
Criterion #2—Data Management
Criterion #3—Proficiency Testing (PT) Desk Review
Criterion #4—Principles of Documentation (POD), Plan of Correction (POC)/Allegation of Compliance (AOC)
Criterion #5—Survey Workload and Outcome-Oriented Survey Process (OOSP)
Criterion #6—Complaints
Criterion #7—Quality Assessment
Criterion #8—Budget – Educational only for FY 2023

Use or delete the following, as appropriate:

OTHER SUBJECT AREAS REVIEWED

If other subject areas were reviewed, list each by name rather than Criterion#, as shown by the following example:

- Financial Management

CLIA SAPR LETTER TEMPLATE
For
RESPONSE TO SA CORRECTIVE ACTION PLAN

(Date)

Name of CLIA State Agency official
CLIA State Agency name
Address
City, State, ZIP code

Re: CLIA State Agency Performance Review (SAPR), Fiscal Year 2023 (FY 2023)—***(State)***
Corrective Action Plan

Dear ***(CLIA SA official)*****:**

Thank you for the corrective action plan submitted in response to the FY 2023 CLIA SAPR. We have reviewed the plan and find that it ***(includes) (does not include)*** all the items, as specified in our cover letter to the CLIA SAPR summary report, dated ***(date)*****.**

If the corrective action plan does NOT include all the specified items, add the following paragraph, individualized for each Criterion:
Following is the information that should be ***(added to) (clarified in)*** your corrective action plan.

CRITERION ***(number and name)***

Informational Item(s): ***(refer to bullets listed on the model cover letter of the SAPR Summary Report, for example… "How corrective action will be monitored and evaluated to verify that it was successful and complete".)***

Comments: ***(for example… "Your plan indicates how the action will be monitored. Please also indicate how the action will be evaluated to verify that it was successful")***
Please re-submit your corrective action plan with the requested modifications no later than 30 days from your receipt of this letter.

Finish each letter with the following paragraph:
As always, we appreciate your efforts in the CLIA program and your commitment to laboratory quality improvement. If you have any questions or comments about this letter, please call ***(name)*** at ***(telephone number)*****.**

Sincerely,

Add appropriate signature.