DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality/ Quality, Safety & Oversight Group

Admin Info: 24-23-CLIA

DATE: September 26, 2024

TO: State Survey Agency Directors

FROM: Director, Quality, Safety & Oversight Group (QSOG)

SUBJECT: Issuance of Clinical Laboratory Improvement Amendments of 1988 (CLIA) State Agency Performance Review (SAPR)—Fiscal Year 2024 (FY 2024)

Memorandum Summary

- The Centers for Medicare & Medicaid Services (CMS) is releasing the FY 2024 guidance for the State Agency Performance Review (SAPR).
- **CLIA SAPR Review Protocol:** The FY 2024 review has been updated from FY 2023. We are updating three documents to improve readability and ease by which SAs may complete the templates: the FY 2024 SAPR Excel Workbook, the FY 2024 Summary Report, and the FY 2024 CLIA SAPR Cover Letter CAP Resp Template.
- **Goal:** The purpose of the SAPR is to ensure optimal State Agency (SA) performance to improve quality in patient laboratory testing and promote health and safety.
- **Review of Other Subject Areas:** CMS's Division of Clinical Laboratory Improvement and Quality (DCLIQ) has the overarching responsibility and authority for SA oversight, which is neither superseded nor limited by the CLIA SAPR. Subject areas not specifically addressed by the FY 2024 Review Criteria may also be reviewed at CMS DCLIQ's discretion.

Background:

The CLIA SAPR is an annual evaluation of each SA's performance of its survey and certification responsibilities under the CLIA program. The evaluation is performed by CMS DCLIQ 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 of the SAPR is optimal SA performance to further quality in patient laboratory testing and promote health and safety. The 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. SAs should contact the CMS DCLIQ State Agency Oversight Branch (SAO Branch) if they wish to request and receive a specific report throughout the year that does not appear on this list.

FY 2024 Protocol

The CLIA SAPR review for FY 2024 includes SA "Performance Thresholds for Written Corrective Action Plan," "Quantified Performance Results," and "Written Corrective Action Plan" results on the Summary Report. CMS DCLIQ SAO Branch has the option to expand the review to include additional areas of CLIA SA responsibilities which, in their judgment, merits evaluation or monitoring. The eight criteria for FY 2024 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

The CMS DCLIQ SAO Branch will enter comments in the "Findings & Special Circumstances (if applicable)" section of the Summary Report to address any accomplishments (e.g., up to date on workload) or extenuating circumstances.

It is strongly recommended that the States upload all documents into the Automated Survey Process Environment (ASPEN) Web application (e.g., Form CMS-116, laboratory change requests). This will facilitate a more efficient review process and allow for a more streamlined sharing of documents between the SA and SAO Branch.

FY 2024 SAPR Review

Criterion #1: Personnel Qualifications, Training, and Competency

Goal: The SA has:

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

This criterion remains unchanged from the FY 2023 SAPR Criterion #1.

This criterion includes performance indicators (PIs) related to personnel qualifications and training. It also includes a PI related to SA CLIA staff competency to ensure all SAs have an ongoing program to utilize feedback and focus on consistently interpreting regulations, 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.

Two additional reviews were added in the FY 2023 SAPR review 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 Form 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 2024 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 Form CMS-116 fields are required to be reviewed unless the CMS DCLIQ SAO Branch determines an expanded review is warranted.

This criterion remains unchanged from the FY 2023 SAPR Criterion #2.

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 2023 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 Statement of Deficiencies (SoDs) (Form CMS-2567) that are consistent with the CLIA PoD.
- Accept only PoC/AoCs that meet the criteria for acceptability.

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

This criterion remains unchanged from the FY 2023 SAPR Criterion #4.

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.

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.

PI #5 is no longer educational as it was in FY 2023.

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 2023 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).

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.

PI #2 was updated in FY 2023 to state that the SA must establish and follow a written standard operating procedure (SOP) for Budget. PI #2 is mandatory for FY 2024. PI #4 and #5 are no longer educational as they were in FY 2023.

The applicable quarterly reports are generated by both CMS DCLIQ and the SAs the **first week of each quarter**. SAS Viya reports are generated by CMS DCLIQ. See Attachment #2.

Criterion #8: Budget:

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

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

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

Workload reports by the 10th of the month to the CMS DCLIQ SAO Branch. This criterion is no longer educational as it was in FY 2023.

Relationship to Other CMS Oversight Responsibilities

CMS DCLIQ has the overarching responsibility and authority for CLIA SA oversight, which is neither superseded nor limited by the CLIA SAPR. Thus, the CMS DCLIQ may review an SA's performance related to any aspect of CLIA SA responsibility not specifically evaluated by the standard protocol for FY 2024. 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 2024 review.

Attachments—Listing and Descriptions

Attachment #	Name
1	• FY 2024 CLIA SAPR Document - Performance Review Criteria, Performance Indicators, and Worksheets, Review Tools, Examples • FY 2024 CLIA SAPR Criterion 2 Review Tool - Data Management *(required)* • FY 2024 CLIA SAPR Criterion 4, POD Principle 3, Composition of a Deficiency Citation, Review Tool (with reference sheet) *(required)* • FY 2024 CLIA SAPR Criterion 4 CMS Review Tool - Principles of Documentation (PoD) and Acceptable Plan of Correction /Credible Allegation of Compliance (PoC/AoC) (*optional*)
2	• FY 2024 CLIA SAPR Data Reports - Description of Mandatory and Quarterly Reports – CMS DCLIQ SAO Branch will provide electronic copies of all SAS Viya mandatory reports to each SA quarterly. Only CASPER 104 Instructions will be utilized for FY 2024 review.
3	• FY 2024 CLIA SAPR - Summary Report Template
4	• 1 - FY 2024 CLIA SAPR Cover Letter CAP Resp Template - for Transmitting the Summary Report to the SA • 2 - FY 2024 CLIA SAPR Model Letter - for Response to SA Corrective Action Plans

Attachment #1:
Performance Review Criteria, Performance Indicators, and Worksheets
For FY 2024, the Excel workbook has been updated to improve readability. Each worksheet and its associated Review tool(s) must be completed electronically by CMS DCLIQ.

Attachment #2:
FY 2024 CLIA SAPR Data Reports – Instructions and Description for both Mandatory and Optional Reports
The CMS DCLIQ SAO Branch will provide electronic copies of all SAS Viya mandatory reports to each SA quarterly.

Each CMS DCLIQ 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 2024; however, details regarding the timeline should be verified with the SA as the documentation is a true indication of whether timelines have been met.

Attachment #3:
FY 2024 CLIA SAPR Summary Report Template
The narrative section "Findings and Special Circumstances" appears on the FY 2024 Summary Report on the last page and must be completed. It is very important to provide a narrative in this section so that CMS DCLIQ has a complete picture of the SA's performance.

Please note: The CLIA SAPR review for FY 2024 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.

Attachment #4:
FY 2024 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 2024 review and improve readability. Model language is included for instances where the CMS DCLIQ will exercise 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 2024 review.

Contact:
For questions or concerns relating to this memorandum, please contact *DCLIQStateAOOversight@cms.hhs.gov*.

Effective Date:
Immediately. Please communicate to all appropriate staff within 30 days.

/s/
David R. Wright
Director, Quality, Safety & Oversight Group

Attachments: See Table on page 5 for Listing and Descriptions

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

Get guidance memos issued by the Quality, Safety and Oversight Group by going to CMS.gov page and entering your email to sign up. Check the box next to "CCSQ Policy, Administrative, and Safety Special Alert Memorandums" to be notified when we release a memo.

SAPR FY24 Criterion #1: Personnel Qualifications Training and Competency

Performance Threshold:	**100%**	**Evaluator:**	
State Agency:		**Date:**	
Quantified Performance:			
Written Corrective Action Required:	**No**	(A Written Corrective Action Plan is required if the Quantified Performance Result is less than Performance Threshold above)	
Instructions and Note	The overall goal of criterion 1 is to ensure 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 *Note: Performance Indicators **#3 and 4** may not be applicable to an individual who was hired shortly before the time of review.* *Complete the 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.*		

Performance Indicator	Requirements	Requirements Met (Yes or No)	Comments
PI 1	The staff positions—professional and clerical listed on CMS-1465A are occupied as reported.		
PI 2	Each Surveyor meets the Health Professional and clerical qualifications according to SOM @ 4009b		
PI 3	New surveyors complete a CMS-developed Basic Surveyor Training Course within the first three (3) months of employment (SOM 4009-C) AND the individual has completed sufficient orientation for DCLIQ 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 "NA". Note for PI #2 and PI #3: If no new surveyors have been hired in the FY under review, then PIs #2 and #3 are considered met. Please use the table below to list the new surveyors and evaluation of PI 1 and 2.		
PI 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, DCLIQ review of any CMS-2567s and PoC/AoCs to improve surveyor skills; b. Consistency in the interpretation of the regulations; and c. Ensuring surveyor adherence to the SOM;* *d. Improving individual surveyor skills, as needed.*		

PI 5	All SA surveyors attend CMS-funded mandatory training, including those budgeted for in the annual SA budget apportionment (e.g., National Training. Note: 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.**		
PI 6	Participate in mandatory online training, as applicable		

Worksheet for New Surveyor

Date of Hire	Surveyor Name or ID	PI 2	PI 3
	None	na	

Number of No	0
Number of Yes	0
Number of Yes and No	0

SAPR FY24 Criterion #2: Data Management

Performance Threshold:	**85%**	**Evaluator:**	
State Agency:		**Date:**	
Quantified Performance:			
Written Corrective Action Required:	**No**	(A Written Corrective Action Plan is required if the Quantified Performance Result is less than Performance Threshold above)	
Instructions and Note	**The overall goal of criterion 2 is to ensure the SA 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.** Complete the 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.		

Performance Indicator	Requirements	Requirements Met (Yes or No)	Comments
PI 1	The SA has a mechanism to track receipt and entry of initial applications (Form CMS-116s), certificate type changes, and demographic updates.		
PI 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 DCLIQ 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 *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 DCLIQ determines an expanded review is warranted. All information for PI #2- PI #7 should be collected from the Criterion #2 Review Tool .*		
PI 3	The SA has entered all complete initial applications (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.		
PI 4	The SA has entered all complete 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. See the review tool.		
PI 5	The SA has entered all complete certificate changes into the CMS-116 database within 45 calendar days of receipt by the SA.		
PI 6	The SA has entered all complete demographic updates into the CMS-116 database accurately.		
PI 7	The SA has entered all complete demographic updates into the CMS-116 database within 45 calendar days of receipt by the SA.		
PI 8	All personnel responsible for data entry have been trained to enter the information into the CMS data systems in accordance with their responsibilities.		

Number of No	0
Number of Yes	0
Number of Yes and No	0

SAPR FY24 Criterion #2: Data Management

	CMS Reviewer:				**State:**					
	CMS Review Date:									
	Instructions and Note	Put a "Yes" or "No" in column B and C. *For FY2024 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 DCLIQ determines an expanded review is warranted. The SA can miss 1 out of the total of 20 entries from PI #2 and PI #3 (both fields) and still mee PI #2 and PI #3.								
		Initial CLIA Applications PI 2 & 3		**Certificate Changes PI 4 & 5**			**Demographic Changes PI 6 & 7**			
	CLIA Number - Initial	**Selected fields Accurately Entered into CMS 116 Database (PI 2 & 3)**	**Information Entered Within 30 Days (PI 2 & 3)**	**CLIA Number-changes**	**All Certificate Changes Entered Accurately**	**Certificate Changes Entered Within 30 Days**	**CLIA Number Demographic**	**All Demographic changes Entered Accurately**	**All Demographic Updates Entered within 45 Days**	**Comments: List inaccurate data or entry that passed the time frame indicated.**
1				1			1			
2				2			2			
3				3			3			
4				4			4			
5										
6										
7										
8										
9										
10										

Number of No	0			
Number of Yes	0	PI 2 & 3	Overall:	
Number of Yes and No	0			
Number of No	0			
Number of Yes	0	PI 4 & 5		
Number of Yes and No	0			
Number of No	0			
Number of Yes	0	PI 6 & 7		
Number of Yes and No	0			

SAPR FY24 Criterion #3: Proficiency Testing Desk Review

Performance Threshold:	**85%**	**Evaluator:**	
State Agency:		**Date:**	
Quantified Performance:			
Written Corrective Action Required:	**No**	(A Written Corrective Action Plan is required if the Quantified Performance Result is less than Performance Threshold above)	
Instructions and Note	The SA conducts PT Desk Review timely and initiates appropriate action in regard to unsuccessful participation. 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.		

Performance Indicator	Requirements	Requirements Met (Yes or No)	Comments
PI 1	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. See the worksheet below.		

PI 2

CLIA Number	Unsuccessful PT Type Classification	Unsuccessful Participation (Yes or No)	Unsuccessful Participation: 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 collaboration with DCLIQ.	Prepares CMS-2567, including appropriate D-Tags.	Notifies the laboratory to seek training/technical assistance for initial unsuccessful participation, as appropriate.	Notifies DCLIQ for all non-initial unsuccessful participation.	e. Tracks each case to completion/resolution (SA can verify corrective actions and effectiveness evaluated).
1		Yes					
2		Yes					
3		Yes					
4		Yes					
5		Yes					
6		Yes					
7		Yes					
8		Yes					
9		Yes					
10		Yes					

Number of No	0	0	0
Number of Yes	0	0	0
Number of Yes and No	0	0	0

SAPR FY24 Criterion #4: Principles of Documentation (PoD) and Plan of Correction (PoC)/Allegation of Compliance (AoC)

Performance Threshold:	**100%**	**Evaluator:**	
State Agency:		**Date:**	
Quantified Performance:			
Written Corrective Action Required:	**No**	(A Written Corrective Action Plan is required if the Quantified Performance Result is less than Performance Threshold above)	
Instructions and Note	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. Note: Performance Indicators #3 and 4 may not be applicable to an individual who was hired shortly before the time of review. Complete data fields that require information (i.e. Evaluator, Date, CLIA #, Analyte, Specialty/Subspecialty/Event, etc.) by typing the information into the space provided Requirements: NOTE: In States with few surveyors, particularly those with fewer than 2 FTEs, DCLIQ staff may need to be more directly involved in the review activities and should apply the performance indicators in a manner that is reasonable.		

Performance Indicator	Requirement	Requirements Met (Yes or No)	Comments
PI 1	The SA utilizes and understands mandatory citations.		
PI 2	The SA reviews the Statements of Deficiencies for clarity, conciseness and consistency with the POD on an ongoing basis.		
PI 3	The SA reviews the POC/AOCs for consistency with SOM 6130.		
PI 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.		
PI 5	The SA review process includes participation by all surveyors as an opportunity for skill improvement.		
PI 6	The review process must include at least quarterly review and must track the progress of surveyor improvement or document sustained proficiency.		
PI 7	Specific area(s) of improvement identified in DCLIQ feedback (FMS Assessment and other DCLIQ reviews), if any, are incorporated by the SA into their review process.		
PI 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). 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.		

REQUIRED-- ADDITIONAL REVIEW BY THE DCLIQ REVIEWER:

• 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 DCLIQ 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 DCLIQ Review Tool are for year-to-year comparison and monitoring for improvement, and assessment for national training, as needed.

	Additional Review by CMS	Number	Result must be 100%
PI 9	# Dtags meeting PoD		
	Total # D-Tags Reviewed		
	# D-tags PoC/AoC was acceptable		
	Total # D-Tags Reviewed		

Number of No	0
Number of Yes	0

Number of Yes and No	0

P4 for each surveyor

SURVEYOR ID OR NAME:

CLIA Number (2567)	POC requirements met?	AOC requirement met?	Total Number of D tag cited on 2567	If No, Reason why D-tag does not meet POD OR Why PoC/AoC was not acceptable/credible
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

SURVEYOR ID OR NAME:

CLIA Number (2567)	POC requirements met?	AOC requirement met?	Total Number of D tag cited on 2567	If No, Reason why D-tag does not meet POD OR Why PoC/AoC was not acceptable/credible
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

SURVEYOR ID OR NAME:

CLIA Number (2567)	POC requirements met?	AOC requirement met?	Total Number of D tag cited on 2567	If No, Reason why D-tag does not meet POD OR Why PoC/AoC was not acceptable/credible
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

Criterion #4, POD Principle 3, Composition of a Deficiency Citation
CMS Review Tool FY2024

CLIA Number:	Facility Name:	
The name of the State	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		

SAPR FY24 Criterion #5: Survey Workload and Outcome-Oriented Survey Process (OOSP)

Performance Threshold:	**85%**	**Evaluator:**	
State Agency:		**Date:**	
Quantified Performance:			
Written Corrective Action Required:	**No**	(A Written Corrective Action Plan is required if the Quantified Performance Result is less than Performance Threshold above)	
Instructions and Note	Special Instructions for Criterion #5: Survey Workload and Outcome-Oriented Survey Process (OOSP) **Overall Goal:** 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. **Instructions for Completing Data Fields associated with Performance Indicators:** 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.		

Performance Indicator	Requirements	Requirements Met (Yes or No)	Comments
PI 1	The SA completes all initial surveys within 3-12 months. NOTE for PI #1: If the SA can demonstrate that all expired Certificates of Registration (CoR) listed on these reports were due to circumstances beyond the SA's control, do not hold the SA accountable. Enter "Yes". Document the exceptions in the Comments section of this worksheet.		
PI 2	The SA completes all recertification surveys timely so that no Certificates of Compliance expire. NOTE for PI #2: If all expired Certificates of Compliance (CoC) listed on these reports were due to circumstances beyond the CLIA SA's control, do not hold the SA accountable. Enter a "Yes". Document the exceptions in the Comments section of this worksheet.		
PI 3	The SA completes budgeted validation surveys within 90 days of the AO survey date. NOTE for PI #3: If zero or one of the time intervals between AO and CLIA surveys exceeded 90 days, enter "Yes." If two or more of the time intervals exceeded 90 days enter "No". EXCEPTION: If the SA can demonstrate that all of the intervals which exceeded 90 days were due to scheduling changes by the laboratory or accreditation organization, do not hold the SA accountable. Enter "Yes". Document the exception(s) in the Comments section of this worksheet. Postponing a validation survey more than once, at the request of the laboratory, is contrary to SOM instructions, and is not considered an exception for SAPR purposes.		
PI 4	The SA must demonstrate that they have generated, evaluated, and acted on the CASPER 0080D reports every 30-45 days. NOTE for PI #4: Please enter "Yes" if the SA generated, evaluated and acted on the CASPER 0080D every 30-45 days, and enter "No" if the SA did not. The result for PI #4 is not included in the calculation.		
PI 5	The SA has generated and utilized the CASPER 0850D quarterly reports to address expired certificates (CoR, CoC). NOTE for PI #5: Ask the SA to demonstrate that they have generated, evaluated and acted on the CASPER 0850D reports each quarter of the FY. If the SA has no expired certificates (CoR, CoC) on the CASPER 0850D report, enter "Yes." If there are mitigating circumstances beyond the SA's control as to why certificates expired, enter a "Yes." The SA should be able to show that they have generated the CASPER 0850D reports each quarter even if the reports show that the State has no expired certificates. If the SA has generated the CASPER 0850D report and has no expired certificates, enter a "Yes"; however, if the State has no expired certificates and has NOT generated the CASPER 0850D report, enter a "No".		

PI 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 "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.		

Number of No	0
Number of Yes	0
Number of Yes and No	0

SAPR FY24 Criterion #6: Complaints

Performance Threshold:	**90%**	**Evaluator:**	
State Agency:		**Date:**	
Quantified Performance:			
Written Corrective Action Required:	**No**	(A Written Corrective Action Plan is required if the Quantified Performance Result is less than Performance Threshold above)	
Instructions and Note	The overall goal of criterion 6: The SA accepts and processes all complaints from receipt to closeout in accordance with CMS policies and procedures. 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. **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 **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. Document your review of complaints in the table at the bottom.		

Performance Indicator	Requirements	Requirements Met (Yes or No)	Comments
PI 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.		
PI 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. should we change mechanism to "process" to triage track all complaints and determine CLIA applicability??? Is the triage appropriate???* *• Verify their understanding that ALL CoA complaints must be forwarded via ACTS to DCLIQ for disposition.* *• Also verify that all SA surveyor(s) would closely coordinate with DCLIQ when the SA is delegated the complaint for action, especially when issues have attracted media attention .*		
PI 3	The SA adheres to the SOM instructions for complaints.		
PI 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.		
PI 5	The SA triages/evaluates complaints for proper disposition. a. SA conducts investigations for the following only when authorized by DCLIQ: CoW, PPMP, CoA, Facilities testing w/out a certificate (NOCN). b. Forwards via ACTS all CoA complaints received in the SA to DCLIQ for disposition. c. Forwards to another agency (OIG, FDA, OSHA, another SA as required by law, etc), as necessary.		
PI 6	Complaints are scheduled in accordance with established procedures/priorities.		
PI 7	Complaint investigations are: a. Conducted in accordance with established time-frames. b. Unannounced.		

PI 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 DCLIQ for investigation and the SA is not required to perform the post-investigation, enter a "Yes" .		
PI 9	There is resolution and closeout of each complainant (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 DCLIQ 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.		

Number of No	0
Number of Yes	0
Number of Yes and No	0

S/N	CLIA ID or SA Complaint ID (if no complaints, indicate here, results based on interview)	PI 1	PI 2	PI 3	PI 4	PI 5	PI 6	PI 7	PI 8	PI 9
1	None	na	na							
2										
3										
4										
5										
6										
7										
8										
9										
10										

SAPR FY24 Criterion #7: Quality Assessment

Performance Threshold:	**100%**	**Evaluator:**	
State Agency:		**Date:**	
Quantified Performance:			
Written Corrective Action Required:	**No**	(A Written Corrective Action Plan is required if the Quantified Performance Result is less than Performance Threshold above)	
Instructions and Note	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: 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.		
Performance Indicator	**Requirements**	**Requirements Met (Yes or No)**	**Comments**
PI 1	The SA has documented evidence of the implementation of CAP (Corrective Action Plan) and/or QIP (Quality Improvement Process).		
PI 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		

PI 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 DCLIQ 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.		
PI 4	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).		
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.		

Number of No	0
Number of Yes	0
Number of Yes and No	0

SAPR FY24 Criterion #8: Budget

Performance Threshold:	**80%**	**Evaluator:**	
State Agency:		**Date:**	
Quantified Performance:			
Written Corrective Action Required:	**No**	(A Written Corrective Action Plan is required if the Quantified Performance Result is less than Performance Threshold above)	
Instructions and Note	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. Complete data fields that require information (i.e. Evaluator, Date, CLIA #, Analyte, Specialty/Subspecialty/Event, etc.) by typing the information into the space where required.		

Performance Indicator	Requirements	Requirements Met (Yes or No)	Comments
PI 1	The SA submits an "activity plan" to the Branch Location in accordance with the SOM within the specified time limit.		
PI 2	The budget forms are submitted for formulating the State budget for the current fiscal year. CMS-102,105,1465,1466 initial report for the year.		
PI 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. **Evaluate for the four quarters**.		
PI 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. **Evaluate for the four quarters.**		
PI 5	The workload reports are submitted by the 10th of the month to the Branch Location.		

Number of No	0
Number of Yes	0
Number of Yes and No	0

Performance Indicator	Requirement	Quarter 1	Quarter 2	Quarter 3	Quarter 4
PI 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.				
PI 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.				

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 DCLIQ 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 DCLIQ REVIEW TOOL, Criterion #4
Principles of Documentation (POD) - Key Points

POD Principle

1, Lab Compliance and Noncompliance **Key Points:**

- ◊ Compliance → D0000 (only used for compliance when all requirements met)
- ◊ Noncompliance → List of condition level deficiencies
- ◊ Type of survey

2, Using Plain Language **Key Points:**

- ◊ 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 **Key Points:**

- ◊ 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 **Key Point:**

- ◊ Must be documented on CMS-2567 as "NOT MET"

5, Interpretive Guidelines (IG) **Key Points:**

- ◊ 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 **Key Points:**

- ◊ Applicable and provides additional strength to linked citation(s)
- ◊ Must support noncompliance with requirement

8, Condition Deficiencies **Key Points:**

◊ Includes only requirememements 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 2024 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							
A	B	C				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				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
D5411							missing impact on patients
		7				8	
CRITERION 4: % D-tags which meet POD		88%					

Criterion	References
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
2. Data Management	SOM §6135 Budget Call Letter 1864 Agreement – Article V-C
3. Proficiency Testing Desk Review	SOM §§6052-6058 Budget Call Letter 1864 Agreement – Article II-E
4. POD/POC, AOC	Appendix C Laboratory Principles of Documentation 1864 Agreement – Article II-A, E; Article V-C
5. Survey Process & Workload	SOM §6102 1864 Agreement, Article II-A-C, E; Article V-C Validation Survey Protocol Appendix C, I.-A.
6. Complaints	SOM: Chapter 5, sections for CLIA; ACTS Procedure Guide 1864 Agreement, Article II-E; Article V-C
7. Quality Assessment	1864 Agreement – Article II-A, E, I-J; Article IV-A, B; Article
8. Budget	1864 Agreement, Article V.C.9., Article IX.M. SOM § 6408

Mandatory SAPR Reports

Report Name	Description	Criterion	Performance Indicator
SAS-Viya Report 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
SAS-Viya Report 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 the fields changed.	2	6,7
SAS-Viya Report 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
SAS-Viya Report 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. Note: Does not include PT Desk Review.	4	1
SAS-Viya Report SVY-A: Initial Surveys	A **DETAIL** report identifying the laboratories that had early/late initial surveys in the fiscal year under review.	5	1
SAS-Viya Report SVY-B: Expired CoC	A **DETAIL** report identifying the laboratories that had Recertification Surveys after the certificate expired.	5	2
SAS-Viya Report SVY-C: Validation	A **DETAIL** report identifying the accredited labs (application 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
SAS-Viya Report 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 Shares with SAs**
		CMS DCLIQ	State Agency	
Mandatory SAPR Reports (SAS Viya)	Monitor SAPR criteria quarterly	X		X
CASPER 0850D	Monitor expired/expiring certificates	X	X	
CASPER 0080D	Monitor laboratory for paid compliance fee/used for survey scheduling	X	X	
ASPEN Tracking Report for Failed and Overdue Certification Kit Uploads	Monitor ASPEN uploads and survey workload	X	X	
Survey Backlog Report (SAS Viya)	Monitor SA survey backlog	X		X
Budget Report	Monitor the SA's submission of budget reports into SCCLIA	X		
CASPER 0074D	CLIA Labs with AO Remarks	X	X	
CASPER 1400D	Recertification Kits Not Uploaded			

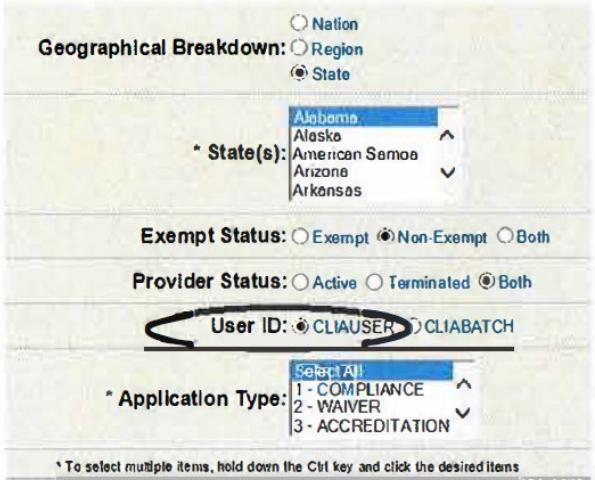
*All monitoring reports will be run by CMS and the SA the first week of each quarter, beginning in January 2025 with Q1 (October 2024 - December 2025).

Optional SAPR Reports

Report Name	Description
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 the date the user enters the CMS-116 into the CLIA database.
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".
OPT-C: Total Surveys	A **SUMMARY** report provides totals on the number of laboratories surveyed during the FY.
OPT-D: Surveyed Labs	A **DETAIL** report identifies the laboratories that were surveyed during the FY.
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.
OPT-F: Uploaded Recerts	A **DETAIL** report identifying the labs that had recertification surveys accepted into the data system during FY.
OPT-G: Initials	A **SUMMARY** report providing totals on the number of laboratories that had initial surveys accepted into the data system during FY.
OPT-H: Uploaded Initials	A **DETAIL** report identifies the laboratories that had initial surveys accepted into the data system during FY.
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.
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 analytes/events.

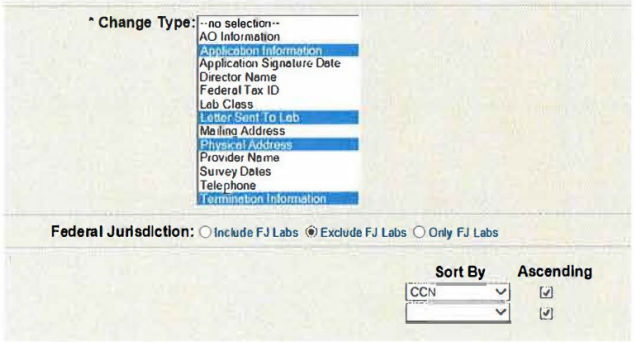
Instructions for Printing the CASPER 01040 CLIA 116 Activity
(Criteria 2 Data Management, PI 6 and 7)
[Use DM-B: Cert Changes" for Status Changes] [104 is just for Demographic Changes]

1) Log into CASPER Reporting and locate CASPER Report 0104D CLIA 116 Activity.
2) Select the following criteria:
   Geographic Breakdown
   Exempt Status: Non-Exempt
   Provider Status: Both
   User ID: CLIAUSER
   Application Type: Select All



3) Note: The CMS DCLIQ 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:

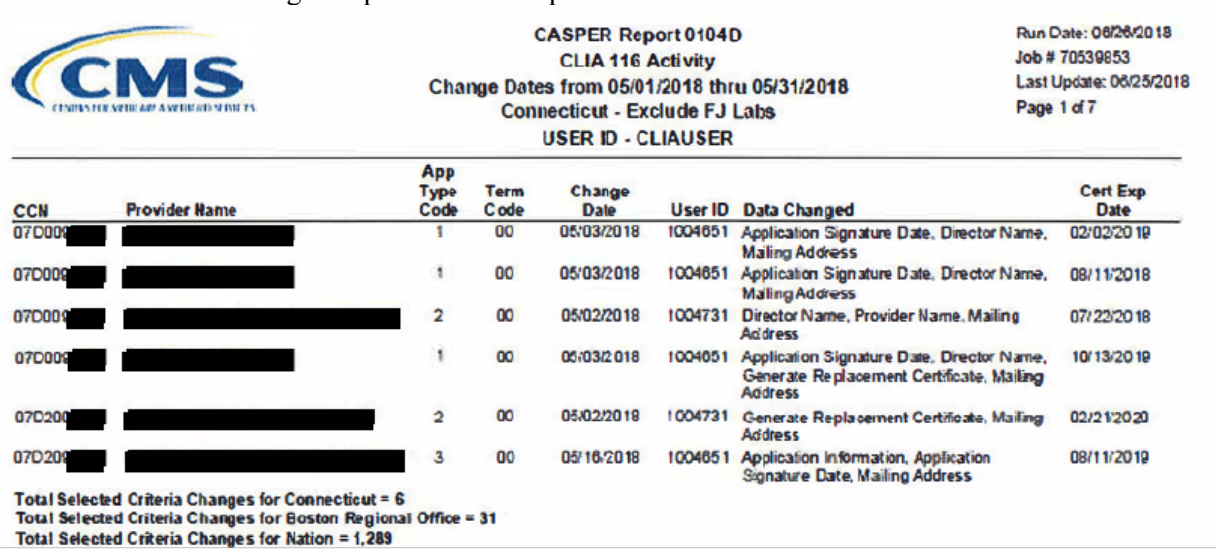


   Press SAVE AND SUBMIT

Important Notes

- CMS DCLIQ personnel should not use CASPER 104D to find laboratories with certificate type changes. Instead, they should use the SAPR report DM-B: Cert Changes.
- When searching for demographic updates, we 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" and 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
07D009[redacted]	[redacted]	1	00	05/03/2018	1004651	Application Signature Date, Director Name, Mailing Address	02/02/2019
07D009[redacted]	[redacted]	1	00	05/03/2018	1004651	Application Signature Date, Director Name, Mailing Address	08/11/2018
07D009[redacted]	[redacted]	2	00	05/02/2018	1004731	Director Name, Provider Name, Mailing Address	07/23/2018
07D009[redacted]	[redacted]	1	00	05/03/2018	1004651	Application Signature Date, Director Name, Generate Replacement Certificate, Mailing Address	10/13/2019
07D209[redacted]	[redacted]	2	00	05/02/2018	1004731	Generate Replacement Certificate, Mailing Address	02/21/2020
07D209[redacted]	[redacted]	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 2024

(October 1, 2023, to September 30, 2024)

<STATE NAME> - CLIA STATE AGENCY PERFORMANCE REVIEW FISCAL YEAR 2024 (FY 2024)

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 staff competency.

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 2024 Quantified Performance Results: %

WRITTEN CORRECTIVE ACTION PLAN: (Yes or No):

(PREVIOUS QUANTIFIED PERFORMANCE RESULTS: FY 2023: % || FY 2022: %)

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 2024 Quantified Performance Results: %

WRITTEN CORRECTIVE ACTION PLAN: (Yes or No):

(PREVIOUS QUANTIFIED PERFORMANCE RESULTS: FY 2023: % || FY 2022: %)

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

FY 2024 Quantified Performance Results: %

WRITTEN CORRECTIVE ACTION PLAN: (Yes or No):

(PREVIOUS QUANTIFIED PERFORMANCE RESULTS: FY 2023: % || FY 2022: %)

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 2024 Quantified Performance Results: %

WRITTEN CORRECTIVE ACTION PLAN: (Yes or No)

(PREVIOUS QUANTIFIED PERFORMANCE RESULTS: FY 2023: % || FY 2022: %)

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 2024 Quantified Performance Results: %

WRITTEN CORRECTIVE ACTION PLAN: (Yes or No)

(PREVIOUS QUANTIFIED PERFORMANCE RESULTS: FY 2023: % || FY 2022: %)

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

FY 2024 Quantified Performance Results: %

WRITTEN CORRECTIVE ACTION PLAN: (Yes or No)

(PREVIOUS QUANTIFIED PERFORMANCE RESULTS: FY 2023: % || FY 2022: %)

<State Name> CLIA STATE AGENCY PERFORMANCE REVIEW FY 2024

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 2024 Quantified Performance Results: %

WRITTEN CORRECTIVE ACTION PLAN: (Yes or No)

(PREVIOUS QUANTIFIED PERFORMANCE RESULTS: FY 2023: % || FY 2022: %)

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 2024 Quantified Performance Results: %

WRITTEN CORRECTIVE ACTION PLAN: (Yes or No)

(PREVIOUS QUANTIFIED PERFORMANCE RESULTS: FY 2023: % || FY 2022: %)

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FINDINGS AND SPECIAL CIRCUMSTANCES (IF APPLICABLE FOR ALL OR ANY OF THE CRITERIA):

COVER LETTER TEMPLATE FOR FY 2024 CLIA SAPR SUMMARY REPORTS

(**Date**)

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

Re: Clinical Laboratory Improvement Amendments (CLIA) State Agency Performance Review(SAPR) Summary Report—Fiscal Year 2024 (FY 2024)

Dear (**SA Official**):

The Section 1864 Agreement requires that the Centers for Medicare and Medicaid Services (CMS) conduct a performance evaluation of each State Agency performing CLIA survey and certification activities. The CLIA SAPR is structured to accomplish this end in a manner consistent with the performance improvement model employed throughout the CLIA Program. Thus, the CLIA SAPR aims to promote optimal performance by the State Agency as our partner in ensuring quality in laboratory practices and testing, using an efficient and effective mechanism that recognizes State-specific circumstances and fosters a positive performance incentive.

Thank you for your cooperation and the courtesies extended to the CMS Division of Clinical Laboratory Improvement and Quality (DCLIQ) staff during the gathering of information for the 2024 fiscal year CLIA SAPR report. Please find the Summary Report for the FY 2024 review with this letter.

As you examine the summary report, please note that the Performance Threshold is neither a score nor a pass/fail rating. It serves as a demarcation point for this office to request a written corrective action plan. The Performance Threshold also serves to ensure nationwide consistency when requesting plans.

While the CLIA SAPR addresses major CLIA survey and certification responsibilities, it 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.

The following are the eight criteria included in the FY 2024 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

(***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, we are not requesting any corrective action.

We commend your agency for its exemplary performance **(*Add the following sentence to this paragraph or at another suitable placement if optimal performance outcome has been sustained over multiple years*).** and for sustaining optimal performance outcomes for **(Criterion # /Criteria ##)** for several years.

(***Add the following paragraphs if one or more CAPs are needed-***)
We are pleased to report that your agency's performance met or exceeded the Performance Threshold for some of the criteria listed above. However, a written corrective action plan is required for each of 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

The corrective action plan should be received in this office no later than 30 days from your receipt of this letter and must 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 the 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.

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 CMS at DCLIQStateAOOversight@cms.hhs.gov.

Sincerely,
Add appropriate signature.

CLIA SAPR LETTER TEMPLATE
For
RESPONSE TO SA CORRECTIVE ACTION PLAN

(**Date**)

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

Re: CLIA State Agency Performance Review (SAPR), Fiscal Year 2024 (FY 2024)—***(State)*** Corrective Action Plan

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

Thank you for the corrective action plan submitted in response to the FY 2024 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 the date you receive this letter.

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 contact CMS at DCLIQStateAOOversight@cms.hhs.gov.

Sincerely,

Add appropriate signature.