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

Admin Info: 25-09-CLIA

DATE: July 11, 2025

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)— Calendar Year (CY) 2025

Memorandum Summary

The Centers for Medicare & Medicaid Services (CMS) is releasing the CY 2025 guidance for the State Agency Performance Review (SAPR). The SAPR has been changed from a Fiscal Year (FY) to a CY schedule. Historically, this review was performed after the end of the prior FY. For CY 2025, the SAPR will consist of five quarters – 4th quarter of CY 2024, and quarters 1 through 4 of CY 2025. This shift will allow us to:

- **Improve transparency**: By reviewing SA performance and providing feedback on a quarterly basis, CMS can ensure timely review and response, and consistent alignment with the CLIA program's goals and mission.
- **Enhance collaboration**: Quarterly reviews will provide an opportunity to address challenges and celebrate successes in real time.
- **Increase efficiency**: Quarterly reviews will allow SAs and CMS to quickly adapt to any CMS program changes and facilitate SA performance.

CLIA SAPR Review Protocol:

The 2025 SAPR has been modified as follows:

- **Criterion (CR) #1**: The State Agency (SA) must notify CMS within 30 days of the end of the quarter of all CLIA staff changes.
- **CR #2:** An additional field on Form CMS-116 (email address) will be reviewed.
- **CR #4:** CMS will review at least one Form CMS-2567 for adherence to Principles of Documentation (POD), and at least one Plan of Correction (POC) or Allegation of Compliance (AOC) for acceptability, written or accepted by each surveyor.
- **CR #5:** The SA must provide CMS all required data reports, including evidence of review and all follow-up actions taken. Additionally, all states that have a backlog of overdue surveys must submit, quarterly, their plan to complete all overdue surveys.
- **CR #7**: SA written procedures must follow all written guidance from CMS.
- **CR #8**: Submission of Form CMS-105, and submission of Workload reports are no longer required.

Review of Other Subject Areas:

- CMS has the overarching responsibility and authority for SA oversight, which is neither superseded nor limited by the CLIA SAPR.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 CY 2025 Review Criteria may also be reviewed at CMS's discretion.

Background:
Under §1864 Agreements established through the Social Security Act, SAs are authorized to perform CLIA survey and certification functions as CMS' designated agents, ensuring compliance with federal laboratory standards within their jurisdictions. CMS maintains program oversight responsibility while providing education and support for SA improvement.

As part of this program oversight, CMS reviews each SA's fulfillment of its survey and certification responsibilities under the CLIA program.

When an SA does not achieve the performance threshold, CMS requests a Corrective Action Plan that includes the actions the SA will take, an explanation of how they will monitor and evaluate outcomes, and expected implementation and completion dates.

This memo serves as a notification of the upcoming CY 25 criteria and protocol as discussed below. Under §1864 Agreements established through the Social Security Act, SAs are authorized to perform CLIA survey and certification functions as CMS' designated agents, ensuring compliance with federal laboratory standards within their jurisdictions. CMS maintains program oversight responsibility while providing education and support for SA improvement.

Discussion:

CY 25 Criteria:
The objectives of the SAPR are to document CLIA program oversight of SA performance and to support and facilitate SA performance improvement, as needed. To ensure an effective and comprehensive evaluation, the 2025 SAPR criteria (CR) includes:

- **CR #1:** Personnel Qualifications, Training, and Competency - SAs will be required to notify CMS of all CLIA staff changes, including separated staff, within 30 days of the end of the applicable quarter.
- **CR #2:** Data Management - An additional field (email address) will be reviewed for data entry accuracy in the Form CMS-116.
- **CR #3:** Proficiency Testing (PT) Desk Review - No changes from FY 2024.
- **CR #4:** Principles of Documentation (PoD), Plan of Correction (PoC), Allegation of Compliance (AoC) - CMS will review, from each surveyor, at least one CMS-2567 for adherence to PoD and at least one PoC or AoC accepted by the surveyor.
- **CR #5:** Survey Workload and Outcome-Oriented Survey Process (OOSP) - The SA must provide CMS with all required data reports, including evidence of review and follow-up actions taken, and submit a quarterly plan to complete any overdue surveys.
- **CR #6:** Complaints - No changes from FY 2024.
- **CR #7:** Quality Assessment (QA) - SA written procedures must follow all written guidance from CMS.
- **CR #8:** Budget - Submission of Form CMS-105 and Workload reports are no longer required.

See Attachment #1 for details on each criterion and the associated performance indicators.

2025 Protocol

CMS is transitioning from an annual to a quarterly review cycle. This shift will allow us to:

- **Improve transparency**: CMS can ensure timely review and response, and consistent alignment with the CLIA program's goals and mission by reviewing SA performance and providing feedback on a quarterly basis,.
- **Enhance collaboration**: Quarterly reviews will provide an opportunity to address challenges and celebrate successes in real time.
- **Increase efficiency**: Quarterly reviews will allow SAs and CMS to quickly adapt to any CMS program changes that may impact SA performance.

All quarterly SAPR reviews and follow-up actions taken by the SA are due to CMS within 30 days of the end of the applicable quarter. The quarters are:

- October 1, 2024 through December 31, 2024
- January 1, 2025 through March 31, 2025
- April 1, 2025 through June 30, 2025
- July 1, 2025 through September 30, 2025
- October 1, 2025 through December 31, 2025

During the transition, there will be a "catch-up" period at the end of CY quarter 2 (April 1 through June 30). All quarterly evidence of SA review and all follow-up actions taken by the SA from October 1, 2024 through June 30, 2025 will be due to CMS within 30 days of the effective date of this memo.

See Attachment #2 for a list of reports the SA is required to submit to CMS as quarterly evidence of SA review.

SA quarterly performance assessments will be completed by CMS and posted on the SAPR Dashboard approximately 45 days after the end of each applicable quarter. CMS has the option to expand the review to include additional areas of CLIA SA responsibilities, which may warrant additional evaluation or monitoring. CMS will provide an annual summary report and, if required, request a corrective action plan (CAP) from the SA. The SA must respond to CMS with a CAP within 30 days of receipt of the summary report. Annual summary reports will be released by March 2026.

See Attachment #3 for an example of the cover letter and annual summary report.

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:
Attachment #1: CY 2025 Performance Review Criteria, Performance Indicators, and Worksheets

Attachment #2: CY 2025 CLIA SAPR Data Reports – Instructions and Description for both Mandatory and Optional Reports

Attachment #3: CY 2025 CLIA SAPR Final Summary Report Template

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 FY25 Criterion #1: Personnel Qualifications Training and Competency

Performance Threshold:	**100%**	**Evaluator:**	
State Agency:		**Date:**	
Quantified Performance:	FALSE		
Written Corrective Action Required:	**No**	(A Written Corrective Action Plan is required if the Quantified Performance Result is less than Performance Threshold above)	
2025 changes	PI 1: State Agencies (SAs) must now notify CMS within 30 days of quarter end about all CLIA staff changes.		
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 **Instructions for Completing Data Fields associated with Performance Indicators:** This Worksheet is intended for use by CMS DCLIQ for its review. However, the SAs are welcome to use the template if it will help them track their compliance with the CLIA requirements. CMS staff will complete the necessary fields with the appropriate information.		

Performance Indicator	Requirements	SA Response, if applicable	CMS use only: Requirements Met (Yes or No)	Responsible Branch for the Review	Comments
PI 1	The staff positions—professional and clerical listed on CMS-1465A are occupied as reported. All staff changes are reported to CMS within 30 days of the end of each quarter via email to the DCLIQ State Oversight Branch			Oversight	*The SA will provide the list of their current CLIA staff and their designation—Surveyor versus Administrative roles. Provide the list of their current CLIA staff utilizing the State-specific personnel audit spreadsheet.*
PI 2	Each Surveyor meets the Health Professional and clerical qualifications according to the SOM @ 4009b			Oversight	*This requirement is applicable to new staff as it is presumed the previous staff have been vetted earlier.*
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.			Oversight	*The SA will provide documentation to support that the new staff completed the Basic training within the first 3 months of employment.*
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.*			Oversight	*The SA will provide documentation if applicable.*
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.**			Oversight	*The SA will provide documentation.*
PI 6	Participate in mandatory online training, as applicable.			Oversight	*The SA provides supporting documents if applicable.*

Worksheet for New Surveyor

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

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

SAPR FY25 Criterion #2: Data Management

Performance Threshold:	**85%**	**Evaluator:**	
State Agency:		**Date:**	
Quantified Performance:	FALSE		
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.** **Instructions for Completing Data Fields associated with Performance Indicators:** This Worksheet is intended for use by CMS DCLIQ for its review. However, the SAs are welcome to use the template if it will help them track their compliance with the CLIA requirements. CMS staff will complete the necessary fields with the appropriate information.		
2025 Changes	PI 2 Review now include email address as a required field, bringing the total required fields to six: Facility Name, TIN, Facility Address, Director Name, Email Address, and Telephone Number.		

Performance Indicator	Requirements	SA Response	CMS use only: Requirements Met (Yes or No)	Responsible Branch	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.			Oversight	*The SA will provide CMS with information on how this is done, including the supporting evidence.*
PI 2	The SA has entered all reviewed initial applications (Form CMS-116) information accurately into the ASPEN Web 116. Note for PI #2: When evaluating PI #2, the DCLIQ reviewer should compare the initial Form CMS-116 to the information entered into the ASPEN Web-116. If 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 to meet this requirement. The abbreviations must be reflective of information on the Form 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 or miss a total of 2 fields for PIs #2, 3, 4, 5, 6, and 7 entries and still meet the requirements. The SA can miss an overall of 3 fields and still meet the requirements for the Criterion. 2 additional reviews have been added for Initial CLIA Applications (Form CMS-116), PI #2 and PI #3 on the "Criterion #2 Review Tool". The following six selected fields will be reviewed for this criterion: Facility Name, Email Addresses, Federal Tax Identification (TIN), Facility Address, Name of Director, telephone number. No other Form CMS-116 fields are required to be reviewed unless CMS DCLIQ determines an expanded review is warranted. All information for PI #2- PI #7 should be collected from the Criterion #2 Review Tool.			Oversight	*The SA is required to enter all Form CMS-116 information accurately as received. Where the SA encountered data system limitation, the SA must indicate what was done on the submitted form, which is uploaded to the system.* *CMS may review the Form CMS-116 information for all the facilities listed on DM – A or review a sample thereof for the accuracy of the highlighted fields. Note, CMS may request that the SA correct any other errors found during the review.*
PI 3	The SA has entered all complete initial applications (Form CMS-116) information into the ASPEN Web-116 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.			Oversight	*The SA is required to enter initial applications into ASPEN web no more than 30 days after the application is received.*
PI 4	The SA has entered all complete certificate changes accurately into the ASPEN Web-116. Note for PI #4: If, when reviewing 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.			Oversight	*Sample of facilities listed on DM – B SAS Viya Report may be used to complete this review and additional source of changes may include the CASPER 0140.*
PI 5	The SA has entered all complete certificate changes into the ASPEN Web-116 within 45 calendar days of receipt by the SA.			Oversight	*The SA adheres to entry of certificate changes into the ASPEN Web-116 no more than 45 days after the application is received.*
PI 6	The SA has entered all complete demographic updates into the ASPEN Web-116 accurately.			Oversight	*CMS may review the Form CMS-116 information for all the facilities listed on DM – B or review a sample thereof to review the accuracy of the information in the database. Note, CMS may request that the SA correct any other errors found during the review.*
PI 7	The SA has entered all complete demographic updates into the ASPEN Web-116 within 45 calendar days of receipt by the SA.			Oversight	*CMS reviews the timeliness of the data entry of demographic changes into the ASPEN Web-116.*
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.			Oversight	*The SA **must** provide training documentation, if applicable, especially for new staff members.*
Number of No	0				
Number of Yes	0				
Number of Yes and No	0				

SAPR FY25 Criterion #2: Data Management Tool

CMS Reviewer:	
CMS Review Date:	
State:	
Instructions and Note	Put a "Yes" or "No" in column B and C. *For FY2025 the following 6 selected fields will be reviewed for this criterion: Facility Name, Federal Tax Identification (TIN), Facility Address, Name of Director, email address, 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 of the 20 total 116 entries on the"Criterion #2 Review Tool" for accuracy and timeliness and still meet PI #2 and PI #3 and miss a total of 2 fields for PIs 2,3,4,5,6 and 7 entries and still meet the requirements. The SA can miss an overall of 3 fields and still meet the requirements for the Criterion.

		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				Note: Manually enter 'Yes' or 'No' in the column below based on the instruction						

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

SAPR FY25 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. **Instructions for Completing Data Fields associated with Performance Indicators:** This Worksheet is intended for use by CMS DCLIQ for its review. However, the SAs are welcome to use the template if it will help them track their compliance with the CLIA requirements. CMS staff will complete the necessary fields with the appropriate information.		

Performance Indicator	Requirements	SA Response	CMS use only: Requirements Met (Yes or No)	Responsible Branch	Comments
PI 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.			Enforcement	*The SA provides information on the mechanism implemented by the SA to track PT score.*
PI 2	Using the table below, CMS will 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. Note: There can be a maximum of eight (8) (15%) disparities (No) in the reviewed fields for a SA to get an overall response of "Yes."			Enforcement	*The SA submits information on all the PT scores reviewed, to include all CASPER 153D and CAPSER 155D reports generated in the quarter. The PT-A Desk Review SAS Viya report captures only the reviews that resulted in a survey.* *CMS may select any of the surveys for the review of the SOD.*

	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								
2								
3								
4								
5								
6								
7								
8								
9								
10								

Number of No	0	Overall No	0
Number of Yes	0	Overall Yes	0
Number of Yes and No	0	Total	0

SAPR FY25 Criterion #4: Principles of Documentation (PoD) and Plan of Correction (PoC)/Allegation of Compliance (AoC)

Performance Threshold:	**100%**	**Evaluator:**	
State Agency:		**Date:**	
Quantified Performance:	FALSE		
Written Corrective Action Required:	**No**	A Written Corrective Action Plan is required if the Quantified Performance Result is less than 100 percent or Performance Indicator 1 is not met.	
Instructions and Note	The SA has a review system/process to ensure that all CLIA surveyors: • Write clear, concise, and legally defensible SAments 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. In SAs 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. Instructions for Completing Data Fields associated with Performance Indicators: This Worksheet is intended for use by CMS DCLIQ for its review. However, the SAs are welcome to use the template if it will help them track their compliance with the CLIA requirements. CMS staff will complete the necessary fields with the appropriate information. Requirements: 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 8.) - The SA surveyor POD review result does not have to be 100%.		
2025 Changes	PI 9 has been added to include CMS DCLIQ review of at least one CMS-2567 per surveyor and one POC/AOC for acceptability.		

Performance Indicator	Requirement	State Response	CMS use only: Requirements Met (Yes or No)	Responsible Branch(es)	Comments
PI 1	The SA utilizes and understands mandatory citations.			Oversight lead with input from Survey & Enforcement	*The SA will review a 2567 where any of the mandatory Dtags were used to ensure its appropriate use. If no Dtags are cited, the SA can make a note of it and ensure they were not cited where they were supposed to be cited. CMS may review any of the 2567 where mandatory citations were used.*
PI 2	The SA reviews CMS-2567s for clarity, conciseness and consistency with the POD on an ongoing basis. The SA reviews at least 10 of each surveyor's CMS-2567s prepared during the FY25 and CY25 under review for POD. See the table below for an example.			Oversight	*The SA will provide the process for the review and the relevant documentation. The PI review above can be one of the SOD reviews.*
PI 3	The SA reviews the POC/AOCs for consistency with SOM 6130. The SA reviews at least 10 of each surveyor's POC/AOCs that were accepted by the surveyor during the FY25 and CY25 under review for acceptability of POC/AOCs.			Oversight	*The SA will elaborate on how they perform this review.*
PI 4	CMS DCLIQ will review at least one Form CMS-2567 for each surveyor for adherence to POD. Did CMS' review of Form CMS-2567s (Review Tool Crit 4, POD Pr 3) meet POD?	NA		Survey & Enforcement	*An example of a table that can be used for each of the SA's surveyor(s) is at the end of this table.*
PI 5	The SA review process includes participation by all surveyors as an opportunity for skill improvement.			Oversight	*This is applicable to a SA with multiple surveyors*
PI 6	The SA review process must include at least quarterly review and must track the progress of surveyor improvement or document sustained proficiency.			Oversight	*The SA review of CMS 2567's should be spread out to meet the quarterly review requirement*
PI 7	Specific area(s) of improvement identified in DCLIQ feedback (FMS Assessment, DCLIQ POD reviews, and any other DCLIQ reviews), if any, are incorporated by the SA into their review process. The SA will provide documentation showing how they have incorporated DCLIQ feedback into their process.			Survey & Enforcement	*The Survey Branch will provide available information on any SA FMS, as applicable.*

PI 8	The SA review process quantifies* and documents the state-wide results annually so that the State can compare results across FY25 and CY25 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 and CY 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 and CY 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.			Oversight	*An example of a table that can be used for each of the SA's surveyor(s) is at the end of this table.*
PI 9	Did the CMS DCLIQ review of at least one POC or AOC, accepted by each surveyor, meet acceptability (see CR #4 POD/POC/AOC References)?	NA		Survey & Enforcement	

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, POD Principle 3, on the review tool. If all D-Tags in the CMS-2567 being reviewed meet POD, enter "Yes" 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.

Completion of the "CLIA SAPR Criterion #4 D-tag DCLIQ review tool" is **Required**

Review Tool Criterion #4, POD Pr 3 and Tool Criterion #4 have been moved up next to Criterion #4 for the convenience of completing this information. References remain at the end.

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

EXAMPLE OF A TEMPLATE FOR STATE AGENCY - USE A SEPARATE TABLE FOR EACH SURVEYOR (SEE PI 4 & 8 ABOVE)

SURVEYOR ID OR NAME:

Date (To cover Q1 - Q4)	CLIA Number (2567)	POD requirements met?	POC/AOC requirement met (optional)?	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

To calculate the Quarterly Overall Results for the SA Internal Review:
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.

# Dtags meeting PoD	# Dtags meeting PoD		
Total # D-Tags Reviewed	Total # D-Tags Reviewed		
# D-tags PoC/AoC was acceptable	# D-tags PoC/AoC was acceptable		
Total # D-Tags Reviewed	Total # D-Tags Reviewed		

Criterion 4 - POD PR 3 __REVIEW TOOL

CLIA Number:	Facility Name:	
State Agency	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. Personally Identifiable Information including patient names/sex/age/DOB is referred to by a coding system so they remain confidential. 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		
General		
The D-Tag is applicable to the requirement cited		
The deficiency citation is free of extraneous remarks and advice		

Enter the number of acceptable fields based on the review above	
Overall Score (Number of Acceptable fields/Total number of fields (17*100)	0 %

FY 2025 CLIA SAPR CRITERIA 4 D-TAG, POC/AOC REVIEW TOOL

CLIA Number:	
Facility Name:	
State:	
Survey Date:	
Review Date:	
CRITERION 4, PI #4, POD/POC/AOC	
Identify D-tag(s) which do not meet POD	
Identify principle(s) of POD not met	
Enter total number of D-tags which met POD	
Enter the total number of D-tags cited in the CMS 2567	
POC : Overall, is the POC acceptable?	select Yes or No
AOC: Overall is the AOC credible?	select Yes or No
Total # of acceptable and or credible D-tags	
% D-tags which meets POD:	
% D-tags which meet requirements:	

CRITERION 4, PI #4, POD/POC/AOC Requirements	**Evaluation Result (Yes, No, (n/a, if Std only))**
The **POC/AOC** addressed actions that will be taken or actions that have been taken for patients found to have been affected.	select Yes or No
The **POC/AOC** addressed how the laboratory will identify or has identified other patients having the potential to be affected by the same deficient practice and what applicable corrective action(s) have been taken.	select Yes or No
The **POC/AOC** addressed measures that will be or has been put into place or what systemic changes will be made or made to ensure that the deficient practice does not recur.	select Yes or No
The **POC/AOC** addressed how the corrective action(s) will be monitored to ensure the deficient practice does not recur	
The laboratory **AOC** showed evidence of actions taken for patient and other patients affected or having the potential to be affected by the deficient practice.	
The **AOC** reviewed indicated that the problem(s) has been resolved and is adequate to ensure that the deficient practice will not recur.	
Note: Evaluation of Credible Allegation of Compliance	
The labs's statement or documentation: -- Is it made by a representative of a laboratory with a history of commitment to compliance and taking action when required? -- Is it realistic; is it possible to accomplish corrective action(s) by date of AoC? -- Does it indicate that the problem has been resolved?	
Additional Comments, Reason why D-tag does not meet POD OR Why PoC/AoC was not acceptable/credible	

FY 2025 CLIA SAPR CRITERIA 4 D-TAG CMS DCLIQ REVIEW TOOL

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

CRITERION 4, PI #4, POD/POC/AOC				
A	B	C	D	E
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
CRITERION 4: % D-tags which meet POD		#DIV/0!		

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
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

SAPR FY25 Criterion #5: Survey Workload and Outcome-Oriented Survey Process (OOSP)

Performance Threshold:	**85%**	**Evaluator:**	
State Agency:		**Date:**	
Quantified Performance:	FALSE		
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:** This Worksheet is intended for use by CMS DCLIQ for its review. However, the SAs are welcome to use the template if it will help them track their compliance with the CLIA requirements. CMS staff will complete the necessary fields with the appropriate information.		
2025 Changes	PI 4, 5, and 6 : SAs must provide multiple CASPER reports with evidence of review within 30 days of quarter completion, and states with survey backlogs (>10% overdue COC laboratories) must submit quarterly plans to address them.		

Performance Indicator	Requirements	SA Response	CMS use only: Requirements Met (Yes or No)	Responsible Branch	Comments
PI 1	The SA completes all initial surveys within 3-12 months. (Quarterly SAS Viya SVY A report) Additionally, all SAs who have a backlog of overdue surveys must submit, quarterly, their plan to complete all overdue surveys. NOTE for PI #1: If the SA can demonstrate that all expired Certificates of Registration (CoR) listed on this report 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.			Oversight	*Refer to Attachment 2 of the SAPR FY 25 Memo for additional information on this data related criterion.*
PI 2	The SA completes all recertification surveys timely so that no Certificates of Compliance expire. (Quarterly SAS Viya SVY B). Additionally, all SAs who have a backlog of overdue surveys must submit, quarterly, their plan to complete all overdue surveys. NOTE for PI #2: If all expired Certificates of Compliance (CoC) listed on this report 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.			Oversight	
PI 3	The SA completes budgeted validation surveys within 90 days of the AO survey date. **(Quarterly SAS Viya SVY C)** NOTE for PI #3: If zero or one of the time intervals between AO and CLIA surveys exceed 90 days, enter "Yes." If two or more of the time intervals exceed 90 days enter "No". EXCEPTION: If the SA can demonstrate that all the intervals which exceed 90 days were due to survey scheduling changes by the **accreditation organization/laboratory**, 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.			Oversight	
PI 4	The SA must demonstrate that they have generated, evaluated, and acted on the CASPER 0080D reports every 30-45 days. The SA must submit evidence of review and all follow-up actions taken and the 0080D report generated in the quarter, within 30 days of the completion of the quarter.			Oversight	
PI 5	The SA has generated and utilized the CASPER 0850D quarterly reports to address expired certificates (CoR and CoC). *The SA must submit evidence of review and all follow-up actions taken and the 0850D report generated in the quarter, within 30 days of the completion of the quarter.* 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 report each quarter even if the reports show that the SA has no expired certificates. If the SA has generated the CASPER 0850D report and has no expired certificates, enter a "Yes"; however, if the SA has no expired certificates and has NOT generated the CASPER 0850D report, enter a "No".			Oversight	*The SA must demonstrate that they have generated, evaluated and acted on the CASPER 0850D reports each quarter o for the period under review.*

PI 6	All surveys are uploaded in a timely manner (within 45 days). (**Quarterly SAS Viya SVY - D)**. *The SA must submit evidence of review and all follow-up actions taken, SAS Viya SVY D report generated in the quarter, within 30 days of the completion of the quarter.* 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 review period by the CMS DCLIQ (e.g., for the purpose of FMS Assessments, Condition-level non-compliance) can be incorporated into the CMS DCLIQ 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 OOSP and interview surveyors to determine whether they are familiar with them. If, during the period under review, no new directives or changes were issued, interview surveyors, including newly hired, to ascertain their familiarity with SOM directives in the OOSP.			Oversight & Enforcement	*Note, in addition to reviewing the SA SAS Viya report, the SA must generate and act on the ASPEN Tracking Report for Failed and Overdue Certification Kit Uploads at least quarterly.*

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

SAPR FY25 Criterion #6: Complaints

Performance Threshold:	**90%**	**Evaluator:**	
State Agency:		**Date:**	
Quantified Performance:	FALSE		
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.

Instructions for Completing Data Fields associated with Performance Indicators:
This Worksheet is intended for use by CMS DCLIQ for its review. However, the SAs are welcome to use the template if it will help them track their compliance with the CLIA requirements. CMS staff will complete the necessary fields with the appropriate information.
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 OR review the SA SOP for complaints and complete PI #2 - #9 based upon the interview or review.
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	SA Response	CMS use only: Requirements Met (Yes or No)	Responsible Branch	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.			Oversight	
PI 2	The SA has a process to track, evaluate for CLIA applicability, and triage all complaints as required. *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 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 .*			Oversight	
PI 3	The SA adheres to the SOM instructions for complaints.			Oversight	
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.			Oversight	
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, and 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.			Oversight	
PI 6	Complaints are scheduled in accordance with established procedures/priorities.			Oversight	
PI 7	Complaint investigations are: a. Conducted in accordance with established timeframes. b. Unannounced.			Oversight	
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. The SA is not required to perform the post-investigation actions. Enter a "Yes".			Oversight	
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.			Oversight	

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 FY25 Criterion #7: Quality Assessment

Performance Threshold:	**100%**	**Evaluator:**	
State Agency:		**Date:**	
Quantified Performance:	FALSE		
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 based on written guidance from CMS, to include the applicable portions of the State Operations Manual (SOM) and all CMS memos (QSO & AdminInfo). 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:** This Worksheet is intended for use by CMS DCLIQ for its review. However, the SAs are not prohibited from using the template if it will help them track their compliance with the CLIA requirements. CMS staff will complete the necessary fields with the appropriate information.		
2025 Changes	PI 2 now requires SA procedures to follow all CMS written guidance.		

Performance Indicator	Requirements	SA Response	CMS use only: Requirements Met (Yes or No)	Responsible Branch for the Review	Comments
PI 1	The SA has documented evidence of the implementation of CAP (Corrective Action Plan) and/or QIP (Quality Improvement Process).			Oversight	
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 These procedures must follow all written guidance from CMS, to include the applicable portions of the State Operations Manual (SOM) and all CMS memos (QSO & AdminInfo).			Oversight, Enforcement, Logistics, & Survey	
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 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.			Oversight, Enforcement, & Survey	
PI 4	The SA runs quarterly monitoring reports (See AdminInfo Memo Attachment #2: Data Reports) and when indicated, corrects problems identified in the reports. The quarterly reports include the ASPEN Tracking Report for Failed and Overdue Certification Kit Uploads, CASPER 0074D, and CASPER 1400D.			Oversight	

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.			Oversight	

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

SAPR FY25 Criterion #8: Budget			
Performance Threshold:	**80%**	**Evaluator:**	
State Agency:		**Date:**	
Quantified Performance:	FALSE		
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.** Instructions for Completing Data Fields associated with Performance Indicators: This Worksheet is intended for use by CMS DCLIQ for its review. However, the SAs are not prohibited from using the template if it will help them track their compliance with the CLIA requirements. CMS staff will complete the necessary fields with the appropriate information.		
2025 Changes	PI 4: Submission of CMS Form 105, and PI 5: Submission of Workload reports are no longer required.		

Performance Indicator	Requirements	SA Response, if applicable	CMS use only: Requirements Met (Yes or No)	Responsible Branch	Comments
PI 1	The SA submits an "activity plan" to the Logistics Branch in accordance with the SOM within the specified time limit.				
PI 2	The budget forms are submitted for formulating the SA 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) quarterly into SCCLIA for review by the Logistic Branch. **Evaluate for the four quarters.**				

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

Performance Indicator		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) quarterly into SCCLIA for review by the Logistics Branch.				

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 §6137 Budget Call Letter 1864 Agreement – Article V-C
3. Proficiency Testing Desk Review	SOM §§6042-6063 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 §§6100 – 6140 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 §§6400 – 6486