CMS Manual System

Pub. 100-07 State Operations Provider Certification

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 234 **Date: September 12, 2025**

SUBJECT: Revisions to State Operations Manual (SOM) Chapter 5 - Complaint Procedures, Sections 5500-5590.

I. SUMMARY OF CHANGES: Revisions have been made to the guidance content of Chapter 5 - Sections 5500 to 5590 which relate to the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

MANUALIZATION/CLARIFICATION -EFFECTIVE: September 12, 2025
IMPLEMENTATION: September 12, 2025

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Chapter 5 - Complaint Procedures Table of Contents
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N	5510.1 - Conducting Investigations in a Laboratory with a Certificate of Waiver
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N	5510.4 - Conducting Investigations in a Laboratory with a Certificate Registration
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R	5520 - Post Complaint Investigation Actions in Non-Accredited, Non-Exempt Laboratories
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R	5570 - Complaint Investigations and Surveys of Accredited Laboratories Under CLIA
N	5570.1 - CMS Direction of Complaint Investigation of an Accredited Laboratory
N	5570.2 - Conducting Complaint Survey of an Accredited Laboratory by CMS or State Agency
N	5570.3 – Forwarding Investigation Report to CMS by the SA
N	5570.4 - Accredited Laboratory Found in Compliance Following a Complaint Survey
N	5570.5 - Accredited Laboratory Found Not in Condition-Level Compliance Following a Complaint Survey
R	5580 - Accredited Laboratories Post Investigation Actions
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III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

IV. ATTACHMENTS:

	Business Requirements
x	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	One-Time Notification -Confidential
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

State Operations Manual
Chapter 5 - Complaint Procedures

Table of Contents
(Rev. 234; Issued: 09-12-25)

Sections 5500 to 5590 relate *to the Clinical Laboratory Improvement Amendments of 1988 (*CLIA*).*

Sections 5500 to 5590 relate *to* CLIA.

5500 - Complaint *Investigations in Non-Accredited, Non-Exempt* Laboratories

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

NOTE: This section applies to complaints against laboratories that hold a CLIA certificate of compliance *(CoC)*, certificate of waiver (CoW), and certificate *for Provider-performed Microscopy (*PPM*) procedures.* See *sections* 5540-5590 for complaints regarding accredited laboratories*, and sections 5510-5530 for State laboratory licensure program (SLLP).*

A complaint is an allegation that could result in citing noncompliance with CLIA requirements. A complaint may be substantiated or unsubstantiated as a result of an investigation or survey.

- A *substantiated* complaint is one resulting in a finding of noncompliance at the time of the investigation, or a finding that noncompliance was proven to exist, but was corrected prior to the investigation.

- An *unsubstantiated* complaint is an allegation where sufficient evidence could not be found to conclude that noncompliance with CLIA requirements existed during the investigation or at the time of the alleged violation.

A complaint may be received *by* either the *State Agency (*SA*)* or *CMS*. The receiving organization should follow the procedures outlined below.

The SA *or CMS should attempt to* obtain the following information for every complaint:

- Complainant's name, address, and telephone number, unless the complainant requests anonymity;

- Laboratory's name and address;

- *CLIA number; and*

- Description of problem, (e.g., personnel, places, and dates of occurrence). *The SA or CMS should gather as much information as possible to help focus the complaint survey.*

If a laboratory representative refuses to permit a complaint survey, the SA should contact CMS.

There are several entities that may address laboratory complaints including: CMS, SAs, SLLPs, and Accreditation Organizations (AO). Each of these entities share a strong interest ensuring the quality of patient care and the services provided by laboratories. When the complaint involves more than one of these entities, CMS should coordinate communication to ensure an effective and timely resolution of the issue.

***NOTE:** If a SA surveyor identifies potential fraudulent billing activities on a complaint survey, the surveyor should refer the information to CMS so that the information can be*

referred to the State OIG with a copy to CMS. CMS can then refer the laboratory to the federal OIG.

5500.1 - Control

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

The SA establishes a file for the complaint and logs the action in*to the CLIA Data S*ystem. The system may be manual or automated but must facilitate tracking and control of *all* complaint*s*.

***NOTE:** All complaints alleging noncompliance with CLIA requirements must be entered into the CLIA Data System.*

5500.2 - Acknowledgment

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

If the complainant is known, the SA promptly issues written acknowledgment*, e.g., email or letter,* that the complaint is being investigated. The SA should not delay acknowledgment pending an investigation unless the investigation takes place within three working days. The SA must take appropriate precautions to protect the complainant's anonymity and privacy. The SA maintains a copy or record of the notification with the complaint documentation.

5500.3 – Evaluation

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

The SA evaluates any complaint to determine whether it should be investigated by the SA, or whether it should be forwarded to *CMS* for investigation or referral to the appropriate authority (e.g., OCR, OSHA, *CMS*). The SA assesses the complaint to determine if an immediate survey is necessary. While the SA will perform most complaint surveys, complaints involving State-operated facilities are the responsibility of *CMS*. When the SA does not have jurisdiction, it should forward the complaint to *CMS* within three working days. If referral is not necessary, the SA considers whether or not any special notification is appropriate.

If a complaint is especially significant, sensitive, or attracting public or media attention, the SA informs *CMS* immediately.

5500.4 – Scheduling Investigations

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

The SA investigates *complaints involving possible immediate jeopardy (IJ) within three working days of receiving the complaint and focuses on the specific problem area. The SA should notify CMS of a possible IJ complaint*. Otherwise, the SA follows procedures for prioritizing and investigating certification-related complaints *within 45 days*. Laboratories with complaints pending are identified and given priority in scheduling of regular certification surveys.

5510 – *Conducting* Complaint Investigations *in Non-Accredited, Non-*

Exempt Laboratories

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

The SA may contact CMS for guidance on the type of complaint investigation which may include one or more of the following: on-site survey, telephone, electronic communication, letter, or a documentation review depending on the complaint. Complaint investigations are unannounced.

***NOTE:** The SA should contact CMS when an unannounced complaint survey is problematic, such as when a laboratory will not permit an investigation.*

For on-site complaint investigations, the SA performs a full or partial survey based on the allegations. If a complaint alleges generalized inappropriate laboratory practices, the SA evaluates compliance with applicable requirements or conducts a full survey, as needed. If the complaint is of a specific nature, the SA performs a survey focused on areas relevant to the complaint. However, if the SA discovers systemic issues on the focused survey, the survey may be expanded to a full survey.

5510.1 – Conducting Investigations in a Laboratory with a Certificate of Waiver

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

If the SA receives a complaint on a CoW laboratory, CMS authorizes an unannounced complaint survey of a laboratory only if it is based on an allegation of noncompliance. The fact that a deficiency is not at the condition-level does not preclude taking adverse action based on provisions contained in 42 CFR 493.1775.

As with other laboratories, the SA investigates complaints made against laboratories with a CoW by means of an on-site survey, by telephone, letter, or by a review of documents.

The SA performs the on-site investigation based on the allegation and determines whether a laboratory is performing only waived tests and if the laboratory is following the manufacturer's instructions for performing the tests. See SOM Appendix C.

If a survey determines that a laboratory is performing tests that are not waived, the laboratory should cease testing of the non-waived tests that do not qualify under 42 CFR 493.15(c) and 493.39(a). If the laboratory wants to continue performing non-waived tests, they must submit a CLIA application for the appropriate level of testing and designate a qualified laboratory director. The SA should notify CMS so a cease-and-desist letter and/or notice of other adverse actions for testing outside of the current CLIA certificate can be sent by CMS to the laboratory.

5510.2 - Conducting Investigations in a Laboratory with a Certificate for Provider-performed Microscopy Procedures

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

If the SA receives a complaint on a certificate for PPM laboratory, CMS authorizes an unannounced complaint survey of a laboratory only if based on an allegation of noncompliance. If a survey determines that a laboratory is performing tests that do not qualify under 42 CFR 493.19(c), the laboratory should cease testing. If the laboratory

wants to continue performing non-waived tests, they must submit a CLIA application for the appropriate level of testing and designate a qualified laboratory director. The SA should notify CMS so a cease-and-desist letter and/or notice of other adverse actions for testing outside of the current CLIA certificate can be sent by CMS to the laboratory in accordance with 42 CFR 493.47(d).

The survey should not differ from a complaint survey done in any other laboratory performing non-waived testing, as all requirements for moderate complexity testing apply, except the routine survey. Note that there are separate D-tags for PPM personnel (D5980-5995). These specific citations should be used for personnel citations in PPM laboratories. The moderate complexity personnel requirements (D6000-D6075, D6190, D6191) should not be used for PPM laboratories.

If a PPM laboratory's noncompliance with waived testing is found during the survey and the laboratory is not following the manufacturer's instructions when performing the waived tests, cite D1001.

5510.3 – Conducting Investigations in a Laboratory with Certificate of Compliance

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

The SA is responsible for the review and triage of CoC complaints. This does not include federal jurisdictional laboratories within its State.

Note for Transfusion-Related Fatality Investigations: *CMS or the SA will conduct the survey within 45 days of the notice from CMS, with notification to CMS when the survey is complete. A copy of the investigation report should be submitted to CMS within 60 days, including the Form CMS-2567, Statement of Deficiencies, if issued.*

Investigations of transfusion-related fatalities are generally announced, since the facility is aware of the possibility of a follow up after the report is made to the FDA. These investigations are an exception to the general policy that complaint surveys are not announced. However, if the report of the fatality originates with any other source, e.g., media or anonymous complaint, the SA or CMS conducts an unannounced survey. Summary and information from the FDA are considered confidential and may only be shared within CMS or the SA. It may not be shared with any other party, including AOs. See SOM Chapter 6 section 6040.

5510.4 – Conducting Investigations in a Laboratory with Certificate of Registration

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

Certificates of Registration (CoR), regardless of whether it is a pending CoC or Certificate of Accreditation (CoA), will be investigated by the SA or CMS. The SA enters all complaints received into the CLIA Data System and notifies CMS for approval or denial to perform the survey.

Note for Transfusion-Related Fatality Investigations: *CMS or the SA will conduct the survey within 45 days of the notice from CMS, with notification to CMS when the survey is complete. A copy of the investigation report should be submitted to CMS within 60 days,*

including the Form CMS-2567, if issued.

Investigations of transfusion-related fatalities are generally announced, since the facility is aware of the possibility of a follow up after the report is made to the FDA. These investigations are an exception to the general policy that complaint surveys are not announced. However, if the report of the fatality originates with any other source, e.g., media or anonymous complaint, the SA or CMS conducts an unannounced survey. Transfusion-related fatality investigations must not be referred to an AO for action. However, the AO or multiple AOs, as appropriate, will receive a copy of the Form CMS-2567 and the accompanying notification letter from CMS when the investigation is complete. Summary and information from the FDA are considered confidential and may only be shared within CMS or the SA. It may not be shared with any other party, including AOs. See SOM Chapter 6 section 6040.

5510.5 – Conducting Investigations in a Laboratory with Temporary Testing Sites, Regardless of Certificate Type

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

Complaints with No Known CLIA Number:

If the SA receives a complaint on a Temporary Testing Site (TTS) without a known CLIA number, it should be entered into the CLIA Data System as a "No CLIA Number (NOCN)." The TTS location is reviewed and triaged.

The SA performs an on-site complaint survey and gathers evidence about which CLIA number the TTS is operating under, including testing and reporting results. If no CLIA number is identified, the SA notifies CMS.

There may be situations where a complaint crosses multiple states. If the NOCN TTS is operating under a primary site laboratory, the SA contacts CMS. CMS opens an intake in the CLIA Data System and inserts the deficiencies from the referring states. The SA that performed the complaint survey completes the Form CMS-2567 and the NOCN information in the CLIA Data System and notifies CMS when it is complete. Deficiencies in multiple states are combined on one Form CMS-2567, as applicable. CMS is responsible for collecting and combining the information to issue and release the Form CMS-2567. CMS is responsible for any subsequent enforcement actions.

Complaints with Known CLIA Number Operating Under a Primary Site or Home Base:

If the SA receives a complaint on a TTS, it should be entered into the CLIA Data System under the primary site/home base. The complaint is reviewed and triaged.

If a complaint is received and the primary site/home base is not located in the state that receives the complaint, the information should be forwarded by the SA to CMS. CMS may request that the SA perform a complaint survey on the TTS in its state. In this case the SA enters the complaint into the CLIA Data System as a NOCN. If the TTS is performing tests outside the scope of its CLIA certificate (e.g., CoW performing moderate/high complexity tests), the SA notifies CMS. The SA completes the Form CMS-2567 for the NOCN laboratory and notifies CMS when it is complete.

Deficiencies in multiple states are combined on one Form CMS-2567, as applicable. CMS is responsible for collecting and combining the information to issue and release the Form CMS-2567. CMS is responsible for any subsequent enforcement actions.

5520 – *Post Complaint Investigation Actions in Non-Accredited, Non-Exempt Laboratories*

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

Following the investigation, the SA records any deficiencies on a Form CMS-2567 and provides it to the facility. Subsequent actions depend on the severity and nature of the deficiencies cited and the facility's willingness or ability to correct them.

When deficiencies are identified, the SA initiates actions as follows:

1. ***Condition-Level Deficiencies – Immediate Jeopardy*** *– Certifies noncompliance and initiates procedures to recommend imposing alternative and/or principal sanctions. An on-site revisit must be performed before imposing principal sanctions (i.e., limitation, revocation or suspension of the CLIA certificate).*

   When IJ is determined, the SA sends the IJ templates, one for each condition-level deficiency, to the laboratory (on-site or off-site). See SOM Appendix Q and SOM Chapter 6 section 6284 for enforcement procedures.

2. ***Condition-Level Deficiencies – No Immediate Jeopardy*** *– If an Allegation of Compliance (AoC) is not submitted or is not credible – Certifies noncompliance and initiates procedures to recommend imposing alternative and/or principal sanctions. An on-site revisit must be performed before imposing principal sanctions (i.e., limitation, revocation or suspension of the CLIA certificate). See SOM Chapter 6 section 6286 for enforcement procedures.*

3. ***Standard-Level Deficiencies – Facility Provides an Acceptable Plan of Correction*** *– Certifies compliance based upon an acceptable Plan of Correction (PoC) and assembles documentation for CMS to review. See SOM Chapter 6 section 6289.*

4. ***Standard-Level Deficiencies – Facility Unable or Unwilling to Provide Acceptable Plan of Correction –*** *If a laboratory fails to submit an acceptable PoC, and subsequent requests for an acceptable PoC are unsuccessful, CMS may initiate principal sanctions against the laboratory certificate. See SOM Chapter 6 section 6289.*

5. ***No Deficiencies*** *- When no deficiencies are identified, no certification action is required.*

5530 – *Post* Complaint Investigation *in Non-Accredited, Non-Exempt Laboratories Resolution/Closeout*

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

The SA closes out all complaints with a follow-up notice to the complainant noting the complaint was substantiated or unsubstantiated. The SA should send this notice soon after the investigation is completed and retain a copy with the complaint record. Complaints are considered closed when an investigation is complete, and the complainant is notified.

The SA provides follow-up reports, as necessary, to other appropriate parties such as the State Medicaid agency and/or initial referring agencies. The SA must protect the anonymity and privacy of the complainant.

The SA inputs the investigation information into the CLIA Data System within 45 days of the completion of the complaint survey.

1 – Unsubstantiated

The SA indicates "unsubstantiated" in the CLIA Data System. If no deficiencies are found, the SA notifies the complainant via written correspondence that the complaint is unsubstantiated and sends a Form CMS-2567 to the laboratory stating that it is in compliance. If deficiencies are found that are either related or not related to the complaint, the SA sends a Form CMS-2567 to the laboratory with the cited deficiencies along with a request for PoC or AoC.

2 – Substantiated

The SA logs summary information in the CLIA Data System. The SA enters the "substantiated" in the complaint into the CLIA Data System. The laboratory will be charged a fee to cover the cost of the survey if noncompliance is documented.

The SA notifies the complainant via written correspondence (e.g., letter, email) that the complaint is substantiated. The SA reports substantiated complaints using the Form CMS-2567 and retains any appropriate supporting documentation.

The SA provides follow-up reports, as necessary, to any other appropriate parties such as the State Medicaid agency and/or initial referring agencies. The SA must protect the anonymity and privacy of the complainant.

The SA inputs the investigation information into the CLIA Data System within 45 days of the completion of the complaint survey.

5540 – *State Laboratory Licensing Program Laboratory (SLLP)* Complaint Investigations – *General*

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

NOTE: *State laboratory licensure program is also referred to as exempt state (ES) or CLIA-exempt laboratory.*

Complaints may be from any source, including verbal, written, electronic or in the media.

Complaints are investigated if they meet the following criteria:

- If substantiated, would have an impact on the health and safety of the general public or individuals served by the laboratory, and
- Would raise doubt as to the laboratory's compliance with one or more CLIA conditions and/or requirements.

An attempt to maintain the anonymity of the complainant should always be made.

There are a number of entities that address laboratory complaints including: CMS*, SAs, SLLPs, and AOs.* Each of these entities shares a strong interest in ensuring the quality of patient care and the services provided by laboratories. When the complaint involves more than one of these entities, *CMS* should be *in* coordination and communication to ensure an effective and timely resolution of the issue.

5540.1 – Review of State Laboratory Licensing Program Laboratory Complaints

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

Complaints received by CMS:

If CMS receives a complaint against a SLLP laboratory, CMS determines what action is appropriate. CMS may do any of the following:

- *Determine the severity of the complaint;*
- *Send the information to the approved State for their action;*
- *May conduct a survey (full or partial);*
- *Investigate the complaint during the course of a validation survey (full survey), if it is conducted within 45 days of the laboratory's licensure survey and the complaint does not present IJ concerns.*

NOTE: *Transfusion-related fatality investigations must be conducted by CMS within 45 days of the notice from CMS, with notification to CMS when the survey is complete. They may not be delegated to the approved SLLP; however, the approved SLLP may accompany CMS on the investigation. In either case, there must be coordination and communication between CMS and the SLLP. Investigations of transfusion-related fatalities are generally announced, since the facility is aware of the possibility of a follow up after the report is made to the FDA. These investigations are an exception to the general policy that complaint surveys are not announced. However, if the report of the fatality originates with any other source, e.g., media or anonymous complaint, CMS conducts an unannounced survey. Where State laws apply to transfusion-related incidents, the approved SLLP should follow its established procedures and coordinate with CMS. The SLLP, as appropriate, will receive a copy of the Form CMS-2567 from CMS when the investigation is complete. See SOM Chapter 6 section 6040.*

CMS reviews the approved SLLPs complaint activities as part of the overall annual review. CMS has the discretion to maintain its own complaint tracking system for complaints that have been forwarded to the approved SLLP. However, this information should be an integral part of the SLLPs annual review.

Complaints received by State Laboratory Licensing Program:

If the approved SLLP receives a complaint against a SLLP laboratory, the approved SLLP determines what action is appropriate. If the approved SLLP sanctions a SLLP laboratory in any way (e.g., licensure is withdrawn), it must notify CMS within 30 days.

If the laboratory against which the complaint is alleged is accredited, the SA must also notify the AO.

5540.2 - Conducting Complaint Investigations and Surveys for State Laboratory Licensing Program

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

Complaints Performed by CMS:

CMS will enter a complaint it performs on a SLLP laboratory in the CLIA Data System. When an investigation can be conducted via telephone or electronic communication (e.g., personnel credentials), CMS should do so. CMS attempts to obtain the following information for every allegation:

- *Complainant's name and address, unless complainant requests anonymity. Do not disclose the identity of the complainant to the laboratory;*
- *Laboratory's name and address;*
- *CLIA number; and*

- *Description of problem, involving names, places, and dates.*

CMS follows the same procedures for control and acknowledgement indicated in section 5500. Complaints involving potential IJ will be investigated by CMS within three working days of receipt. Complaints not involving potential IJ are investigated within 45 days. All complaint surveys are unannounced.

If a laboratory representative refuses to permit a complaint survey, CMS contacts the SLLP and requests that it contact the laboratory to explain the protocol and, if necessary, suggest that the SLLP take enforcement action against the SLLP laboratory. CMS conducts the complaint survey in accordance with the outcome-oriented survey process (OOSP) found in SOM Chapter 6.

Initially, CMS focuses the survey only on the condition(s) or requirement(s) related to the complaint area(s). If the complaint is substantiated or if additional deficiencies are found during the course of the investigation, CMS expands the scope of the survey to include additional standards, conditions, and other CLIA requirements. If the complaint is not substantiated, CMS notifies the laboratory that it is in compliance with the CLIA condition(s). CMS also notifies the approved SLLP of the condition-level compliance.

At the exit conference, CMS informs the laboratory of the deficiencies found. If the deficiencies pose IJ to the health and safety of individuals served by a laboratory or that of the general public, CMS notifies the approved SLLP and the laboratory within three working days by electronic mail and includes a copy of the Form CMS-2567. CMS directs the SLLP to take the appropriate enforcement action. CMS follows-up with the SLLP within 15 working days of its notification to the laboratory to verify that the enforcement action has either been taken against the laboratory or that the laboratory has achieved compliance with CLIA requirements.

5550 - *State Laboratory Licensing Program* Complaint *Post-*Investigation *Actions*

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

If the SLLP fails to take appropriate enforcement action for an IJ case within 23 days of CMS' notification, and the laboratory has not achieved condition-level compliance, CMS may either contact the SLLP or attempt other resolution to eliminate the IJ.

If the deficiencies do not pose IJ to the health and safety of individuals served by a laboratory or that of the general public, CMS prepares a Form CMS-2567 and forwards a letter along with the Form CMS-2567 to the laboratory and to the SLLP within 10 working days of completing the survey. The SLLP is responsible for taking any enforcement action, if necessary, monitoring the correction of the deficiencies, and providing a report to CMS.

CMS completes a Survey Team Composition and Workload Report (Form CMS-670) for all complaint surveys and related activity.

5560 - *State* Laboratory *Licensing Program* Complaint *Resolution/Closeout*
(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

If the SLLP fails to take appropriate enforcement action in non-immediate jeopardy situations, CMS documents its files accordingly. Failure to take and document the necessary enforcement action may subsequently jeopardize the current or future approval of the SLLP.

5570 - *Complaint* Investigation*s and Surveys of Accredited Laboratories*
(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

The statutory basis for conducting surveys of accredited laboratories based on allegations of noncompliance is found in §353(e)(2)(D) of the Public Health Service Act (PHSA).
Since AO requirements are equivalent to CLIA requirements at the condition level, a complaint may affect the laboratory's accreditation status as well. Complaints are investigated if they meet the following criteria:

- *If substantiated, would have an impact on the health and safety of the general public or individuals served by the laboratory, and*

- *Would raise doubt as to the laboratory's compliance with one or more CLIA conditions and/or requirements.*

CMS should evaluate the complaint and take appropriate investigatory action. Every effort should be made to secure a written form of the complaint, while maintaining anonymity, if requested.

All complaint surveys are unannounced and conducted according to OOSP. See SOM Chapter 6. If an investigation can be conducted by letter, electronic communication, or telephone, in lieu of an on-site survey, those means should be utilized.

Upon receipt, all complaints are logged and tracked in the same manner as CMS certified laboratories is collected, monitored and maintained. See section 5500.

5570.1 - CMS Direction of Complaint Investigation of an Accredited Laboratory
(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

CMS has primary responsibility for the coordination of all activities involving complaints relating to an accredited laboratory when a complaint is received by CMS or SA.

If a laboratory representative refuses to permit a complaint survey, the SA should contact CMS.

Complaints related to an accredited laboratory must be investigated by CMS or SA, as directed by CMS.

This includes:

- *Ensuring that all pertinent information concerning the complaint is obtained;*
- *Assessing the level of severity of the complaint;*
- *Determining actions required for investigation;*
- *Determining whether multiple AOs may be involved; and*
- *Informing and coordinating with all affected parties, including AOs, SAs and CMS when warranted (e.g., in cases potentially involving media coverage, Federal/State Congressional or political interest, legal intervention, etc.).*

Although CMS has the lead role in directing the investigation of complaints involving accredited laboratories, all affected entities (i.e., SAs, AOs, CMS) share responsibility in ensuring timely and effective action is taken.

Complaints received by the SA:

If the SA receives an allegation of noncompliance directly from a complainant about an accredited laboratory, it promptly acknowledges receipt of the complaint and advises the complainant that it is being forwarded to CMS for action. The SA forwards a copy of the acknowledgment letter and the complaint to CMS.

Complaints received by CMS:

If the complaint is received directly by CMS, CMS will promptly send a letter to the complainant acknowledging the complaint and advising the complainant of the intended course of action.

In either case (complaint received by SA or CMS), CMS evaluates the complaint and has the lead in determining the course of action. CMS determines whether CMS, the SA, or the AO, including multiple AOs if circumstances so warrant, will investigate the complaint. If CMS determines that the AO will investigate the complaint, CMS promptly sends a letter to the complainant acknowledging the complaint and informing the complainant to contact the AO with any further questions.

If CMS determines that the SA should investigate the complaint, CMS approves the SA performing the complaint survey in the CLIA Data System and forwards the complaint information electronically, including the approval and notifies the AO when the investigation is complete. If CMS authorizes the SA to perform a full survey (all specialties and subspecialties covered by the certificate), and the survey can be performed within 90 days of the AO's inspection, the survey can be counted in the SA's validation workload.

If CMS determines that the complaint involves a potential IJ to the individuals served by the laboratory, or to the general public, the SA investigates the complaint within three working days of receiving it from CMS. Otherwise, CMS will direct the SA to investigate non-

immediate jeopardy complaints within 45 days and report their findings to CMS and AO at the conclusion of the survey.

Complaints investigated by AOs:

If CMS determines that the AO should carry out its own investigation, it promptly forwards the complaint to the AO for immediate attention. CMS will request to be notified of the results of any investigative action taken. CMS will then notify the SA.

NOTE: *Transfusion-related fatality investigations must be conducted by CMS or SA within 45 days of the notice from CMS, with notification to CMS when the survey is complete. Investigations of transfusion-related fatalities are generally announced, since the facility is aware of the possibility of a follow up after the report is made to the FDA. These investigations are an exception to the general policy that complaint surveys are not announced. However, if the report of the fatality originates with any other source, e.g., media or anonymous complaint, the SA or CMS conducts an unannounced survey. Transfusion-related fatality investigations must not be referred to an AO for action. However, the AO or multiple AOs, as appropriate, will receive a copy of the Form CMS-2567 and the accompanying notification letter from CMS when the investigation is complete. Summary and information from the FDA are considered confidential and may only be shared within CMS or the SA. It may not be shared with any other party, including AOs. See SOM Chapter 6 section 6040.*

Complaints received by AOs:

Complaints received directly by AOs will be investigated under each AO's own standards and procedures. If multiple AOs are potentially impacted, the AO receiving the complaint will promptly inform the other AOs and a determination should be reached regarding the need for coordinated action. In cases potentially involving media coverage, Federal/State, Congressional or political interest, legal intervention, etc., CMS should be promptly alerted by the AO receiving the complaint and consulted concerning appropriate action.

5570.2 - Conducting Complaint Survey of an Accredited Laboratory by CMS or State Agency

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

If an on-site survey is warranted, CMS or SA will conduct an unannounced survey of an accredited laboratory based on the allegation of noncompliance. CMS or the SA conducts the complaint survey in accordance with OOSP. See SOM Chapter 6 section 6100-6101.

If the SA is performing the survey, the SA conducts a focused complaint survey, as instructed by CMS. CMS will approve Form CMS-2802A in the CLIA Data System prior to the survey. If the SA finds additional deficiencies during the course of the complaint investigation, it may expand the scope of the survey with CMS approval.

At the exit conference, CMS or the SA informs the laboratory director of the deficiencies found and the procedures to respond to them. If deficiencies are found, a Form CMS-2567 is

prepared. The laboratory is informed that the Form CMS-2567 will be made available to the public under the disclosure of survey information provisions. The surveyor should advise the laboratory that the official report of deficiencies is Form CMS-2567.

Standard-level deficiencies: *If the deficiencies are at the standard-level, a PoC is requested. However, it is optional for the laboratory to submit a PoC to CMS. For standard only deficiencies, responsibility rests with the AO to follow up and pursue corrective action.*

Condition-level deficiencies, non-immediate jeopardy: *If the deficiencies are at the condition-level, the laboratory must submit an AoC to CMS. Condition-level deficiencies* ***must*** *be corrected. CMS or the SA indicates to the laboratory that the Form CMS-2567 will be forwarded to the laboratory within 10 working days and that the AoC must be returned to CMS and the SA within 10 calendar days. Upon receipt of the survey information and AoC, CMS, in coordination with the SA, determines whether or not the AoC is credible, and if sanctions will be imposed against the laboratory. CMS notifies the laboratory and AO.*

Condition-level deficiencies, immediate jeopardy found: *If the deficiencies are at the condition-level and pose IJ to the health and safety of individuals served by a laboratory, or to the general public, an AoC is requested. Condition-level deficiencies must be corrected, so the accredited laboratory must submit an AoC to CMS. CMS or SA indicates to the laboratory that the Form CMS-2567 will be forwarded to the laboratory within three working days of the survey exit date and that the credible AoC and evidence of correction must be submitted to CMS and the SA within 10 calendar days. The IJ template should be given to the laboratory at the time that IJ is determined (see SOM Appendix Q). Upon receipt of the survey AoC and evidence, CMS, in coordination with the SA, determines whether or not the AoC is credible, and if sanctions will be imposed against the laboratory. CMS notifies the laboratory and AO.*

If CMS determines that the deficiencies pose IJ, an IJ template must be given to the laboratory at the time IJ is determined (on-site or off-site). See SOM Appendix Q.

5570.3 – Forwarding Investigation Report to *CMS by the SA*

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

If non-immediate jeopardy is found, the SA will submit the appropriate information*, including but not limited to, Form CMS-2567, Form CMS-116, Form CMS-209, and surveyor notes* to *CMS*, or through an update to *the CLIA Data System* within 45 days of completing the survey and notifies *CMS* of the entry. If the laboratory chooses not to submit a P*o*C when *standard-level* deficiencies are found, the SA reports any known information about the laboratory's efforts to correct deficiencies to *CMS* and AO. *If the laboratory does not submit an AoC for condition-level noncompliance, the SA should refer the case to CMS who may begin enforcement actions.*

5570.4 - Accredited Laboratory Found in Compliance Following a Complaint Survey

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

If after review of the documentation, CMS determines that the accredited laboratory is in

compliance with all CLIA condition-level requirements, it officially notifies the laboratory and forwards a copy of this letter to the SA and the AO. This letter advises that the AO may contact the laboratory about correcting any deficiencies below condition-level, i.e., standard-level deficiencies only. If no deficiencies are found, a Form CMS-2567 should be issued stating that the accredited laboratory is in compliance with CLIA condition-level requirements.

5570.5 - Accredited Laboratory Found Not in Condition-level Compliance Following a Complaint Survey

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

If the deficiencies found pose an IJ to the health and safety of individuals, the SA prepares the Form CMS-2567, IJ template, and letter notifying the laboratory of the condition-level noncompliance with IJ and requests an AoC. The SA copies CMS when notifying the laboratory and requesting an AoC. The Form CMS-2567 is sent to the laboratory within three working days. CMS will notify the AO and forward the letter and Form CMS-2567 to the AO when the investigation is complete. Based on the laboratory's submitted AoC and evidence of correction, CMS determines if sanctions are to be imposed against the laboratory.

For condition-level noncompliance that is not IJ, the same process is followed except the timeline is 10 working days and no IJ template is required.

5580 - Accredited Laborator*ies Post Investigation Actions*

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

CMS will notify the AO about a potential CMS enforcement action.

The laboratory continues to be accredited by its AO and retains its CLIA Certificate of Accreditation. However, it temporarily comes under the jurisdiction of CMS and becomes subject to the same CLIA requirements, survey, and enforcement procedures as applied to non-accredited laboratories found out of compliance. The laboratory remains under the jurisdiction of CMS until either it comes into condition-level compliance, or the certificate is revoked.

Should the condition-level deficiencies, including an IJ situation, be corrected before the adverse action is taken or completed, CMS or the SA will advise the laboratory that it will perform an on-site revisit it to ensure it is in condition-level compliance, and that IJ has been removed. In all cases of condition-level noncompliance, an on-site revisit will be performed before the principal sanctions of revocation or suspension are imposed. This includes, but is not limited to, a credible AoC is not received, or the laboratory does not submit an AoC. CMS will notify the AO.

5590 - Accredited Laborator*ies Resolution/Closeout*

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

The SA will submit the appropriate information to CMS, or through an update to the CLIA Data System within 45 days of completing the survey and notifies CMS of the entry. If the

laboratory chooses not to submit an AoC when condition-level deficiencies are found, CMS will notify the AO that the laboratory is out of compliance, and CMS will move forward with an enforcement action. A copy of all correspondence, as well as the Form CMS-2567 and AoC, is provided to the AO by CMS. Complaints are considered closed when referred to an AO by CMS.