

CMS Guidance Document	Department of Health & Human Services (DHHS)
Survey and Certification Policy Letter	Centers for Medicare & Medicaid Services (CMS)
	Date: July 26, 2007
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PROGRAM AREA: Survey and Certification

SUBJECT: Clarification and Standardization of Clinical Laboratory Improvement Amendments (CLIA) Complaint Closeouts to Complainants

APPLIES TO: State Survey Agency and Regional Office Surveyors, all CLIA-certified clinical laboratories

I. SUMMARY OF CHANGES:

This memorandum provides guidance on standardized information that should be contained in follow-up letters to complainants when the State survey agency or regional office laboratory complaint investigation is completed. A model letter is included that provides the complainant this feedback.

II. CHANGES IN POLICY INSTRUCTIONS:

STATUS: R=REVISED, N=NEW, D=DELETED.

Status	Chapter / Section / Subsection / Title
R	Pub 100-07/Chapter 5, Section 5500.9, Resolution/Closeout

III. CLEARANCES:

Clearance & Point of Contact (POC)	Name/Telephone/Component
Senior Official Clearance	Dennis Smith (410) 786-3870/Center for Medicaid and State Operations (CMSO)
Agency POC	Tracey Mummert (410) 786-3398/CMSO/Survey and Certification Group tracey.mummert@cms.hhs.gov

IV. TYPE (Check appropriate boxes for type of guidance)

<input type="checkbox"/>	Audit Guide
<input type="checkbox"/>	Change Request
<input type="checkbox"/>	HPMS
<input type="checkbox"/>	Joint Signature Memorandum
<input type="checkbox"/>	Manual Transmittal
<input type="checkbox"/>	State Medicaid Director Letters
<input checked="" type="checkbox"/>	Other – Survey and Certification Policy Letter

V. STATUTORY OR REGULATORY AUTHORITY: N/A

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-07-XX

DATE:

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

**SUBJECT: Clarification and Standardization of Clinical Laboratory Improvement
Amendments (CLIA) Complaint Closeouts to Complainants**

Memorandum Summary

- This memorandum provides guidance on standardized information that should be contained in follow-up letters to complainants when the State survey agency (SA) or regional office (RO) laboratory complaint investigation is completed.
- Upon completion of a complaint investigation, the RO/SA should communicate with the complainant regarding the outcome of the investigation.
- A model letter is included that provides the complainant this feedback.

Upon completion of a CLIA-related complaint investigation, the RO/SA should communicate with the complainant regarding the outcome of the investigation. In our continuing efforts to be consistent, the letter to the complainant should include the following information, at a minimum.

- A brief description of the problem;
- The completion date of the investigation;
- The current CLIA compliance status of the laboratory in question (compliant/non-compliant).

This information complements the guidance for complaints found in the Complaint section of the State Operations Manual, Chapter 5, Section 5500.9.

If States have additional or more prescriptive requirements, they should meet those as well.

If you have any questions regarding this memorandum, please contact Jim Cometa via email at: james.cometa@cms.hhs.gov or at 410-786-6720.

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum, and disseminate the information to affected providers.

Training: The information contained in this announcement should be shared with all laboratory surveyors and supervisors.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

Attachment

Complaint Close-Out

[DATE]

[COMPLAINANT NAME]

[ADDRESS]

[CITY], [STATE] [ZIP]

[Complaint ID – If applicable.]

Dear Complainant(s):

We are writing to inform you that the investigation regarding your concerns, specifically, **(BRIEFLY DESCRIBE PROBLEM)** of the [LABORATORY NAME and CLIA #] was completed on [DATE]. The laboratory has been found to be [COMPLIANT or NON-COMPLIANT] with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) requirements that are relevant to your allegation.

We appreciate your concerns and thank you for taking the time to share them with us. It takes a great measure of courage and effort to voice concerns about issues which affect the quality of the health care in a community.

If you have further questions regarding this matter please contact me at [PHONE #].

Sincerely,

[SURVEYOR NAME], [TITLE]

[STATE AGENCY NAME]

Or

[NAME/TITLE]

[BRANCH NAME]

[DIVISION NAME]

cc: