

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-07-32

DATE: August 24, 2007

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: