



Center for Medicaid and State Operations/Survey & Certification Group

Ref: S&C-09-48

DATE: July 31, 2009

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Clinical Laboratory Improvement Amendments (CLIA) Policy on November 2009 CLIA Basic Training

Memorandum Summary

This memorandum further defines and clarifies the Centers for Medicare & Medicaid Services (CMS) policies for attendance at the CLIA Basic Training scheduled for November 16 – 20, 2009 in Baltimore.

The purpose of this memorandum is to clarify related CLIA policies and provide guidance for preparation and attendance at the 2009 CLIA Basic training.

The CLIA policy for Basic training is that all surveyors must attend a basic training, regardless of how long they have been employed. CLIA Basic training is a very detailed training that gives a comprehensive overview of the application of the regulatory requirements to surveyors. This includes their interpretation, compliance assessment using the Outcome Oriented Survey Process, Principles of Documentation for legally defensible citation of deficiencies and enforcement options and protocols, as well as a Pre and Post test. Additionally, there will be plenty of opportunities for questions and interaction with the faculty.

Therefore, the Basic and Beyond training held in 2006 does not qualify as a suitable Basic training under CLIA. This training focused on limited topics where specific problems were identified in response to the Government Accountability Office's (GAO) Report on Laboratory Quality. However, if your surveyor(s) attended a Basic training provided by a regional office (RO), then those individuals do not have to attend the Basic.

Anyone who is employed as a surveyor or a surveyor's supervisor since 2004 and has not attended a CLIA Basic training should attend this training in Baltimore the week of November 16, 2009. In addition, if a RO identifies surveyors that have had a Basic training, but still need to attend due to certain surveying criteria and/or polices, then those persons should also attend. **This training is mandatory and will be conducted full days on Monday through Thursday and one-half day on Friday.**

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Please include in your FY'10 budget an allotment for the number of individuals who will attend. An agenda and hotel information will be forthcoming in the near future. We will notify you when the information for registration is available in the Learning Management System (LMS).

Prerequisites for this training are attached to this memo and we will assume that all attendees reviewed the suggested materials sufficiently to have a working knowledge of that information prior to attending the Basic training.

If you have further questions, please contact Clarissa Weaver at (410) 786-3406 Clarissa.Weaver@cms.hhs.gov or Judy Yost at (410) 786-3407 Judith.Yost@cms.hhs.gov.

Thomas E. Hamilton
Director

Attachment

Prerequisites for CLIA Basic Training

These items or tasks should be accomplished prior to attending a CLIA Basic training; as they establish the foundation for that training & facilitate its effectiveness.

A. General

1. Learn the information in the State Orientation Manual
2. Complete the orientation program in your state, if possible
3. Read and understand the CLIA Law and Regulations at 42 CFR 493
4. Become familiar with how to use the Interpretive Guidelines (IG) and Survey Process
5. Review the State Operations Manual (SOM) CLIA sections, including Chapter 5, Complaints
6. Review Admin. Info/S&C Letters
7. Coordinate with your RO for a final acceptance on surveying and knowledge base, if feasible

B. Group I Background, History & Achievements; Application, Certificate, Billing, Data Systems' Processes

1. Access

- QIES
- OSCAR
- PDQ

2. Materials to Review

- QTSO on-line training; e.g., Web-Exs & e-learning modules
- SOM, Orientation Manual/IG/Regulations—applicable sections
- Review Admin/S&C letters/Forms related to CLIA Data

3. Training

Attend ASPEN CLIA data system training in Longmont, Colorado

C. Group II Quality Systems Concepts & CLIA Surveys; Analytic Systems

1. **Observe at least one CLIA survey**

D. Group IV Cytology/Histology/Cytology PT

E. Group V Principles of Documentation; Overview of Regulations & D-tags; Enforcement

1. General:

- CLIA Statute (brief review)
- 42 C.F.R. 493.1800-1850, Subpart R
- SOM 6250-6299

Prerequisites for CLIA Basic Training

Specific:

- Purpose of enforcement
- Timelines for Conditions out, IJ, Standards
- Types of sanctions available
- CLIA model letters (Web site reference)
- PT desk review (Policy Letter)
- Role in enforcement of RO/SA/CO[?]

2. Review CLIA Principles of Documentation document