

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850



Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-05-44

DATE: September 22, 2005

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Doctors of Optometry and/or Ophthalmology serving as Laboratory Directors under the Clinical Laboratory Improvement Amendments (CLIA)

Letter Summary

Individuals who have earned a Doctor of Optometry degree are qualified to serve as a laboratory director of certain moderate complexity testing under CLIA.

Background

This memorandum is in response to inquiries concerning whether individuals holding a Doctor of Optometry degree qualify as laboratory director under the CLIA program.

The Centers for Disease Control and Prevention (CDC), in collaboration with the Centers for Medicare & Medicaid Services, reviewed the qualifications for optometrists, including their education, training, and experience, and concluded that the course work that optometrists obtain during their professional training adequately focuses on their diagnostic specialty. Therefore, these individuals would qualify as directors of moderate complexity laboratories, but only for test procedures performed in their specialty area.

Optometrists are required to obtain 20 continuing medical education (CME) credits/hours in laboratory practice in order to qualify as directors of laboratories performing moderate complexity procedures that are not within their specialty area.

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Ophthalmologists with a doctor of medicine (MD) degree are qualified to direct moderate complexity laboratories, provided they have had at least one year of experience directing or supervising moderate complexity laboratories, **or** have obtained at least 20 CMEs in laboratory practice commensurate with the laboratory director's responsibilities under CLIA at 42 CFR 493.1407.

If you need additional clarification, please contact Judy Yost at (410) 786-3531.

Effective Date: Immediately. The State survey agency should disseminate this information within 30 days of the date of this memorandum.

Training: This information should be shared with all appropriate survey and certification staff, their managers, and the state/RO training coordinators.

/s/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management (G-5)
Regional Office Laboratory Consultants