

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-06-27

DATE: September 14, 2006

TO: State Survey Agency Directors

FROM: Director
Survey and Certification

SUBJECT: Doctors of Optometry serving as Directors and/or Technical Consultants for
Laboratories Performing Moderate Complexity Testing – Action

Letter Summary

- The Doctor of Optometry (OD) degree is suitable to meet the personnel qualifications for laboratory director of moderate complexity testing provided the testing is limited to tests related to the medical specialty of optometry.
- The individual who has earned an OD degree may also serve as technical consultant and testing personnel for moderate complexity tests.
- Additionally, the laboratory must have a qualified clinical consultant who holds an MD, DO, or Doctoral degree (with applicable board certification, training and experience).

This memorandum provides clarification of Ref: S&C-05-44 dated September 22, 2005, regarding Doctors of Optometry (OD) serving as laboratory directors of moderate complexity testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

The Centers for Disease Control and Prevention (CDC), in collaboration with the Centers for Medicare & Medicaid Services (CMS), 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, an individual who has an OD degree may serve as director of a laboratory performing moderate complexity testing provided the laboratory testing is limited to the medical specialty of optometry and the individual's training/experience meets the requirements stated in §493.1405(b). If the laboratory is performing more extensive testing than that related to optometry, then the director must acquire 20 CME's related to the CLIA laboratory director's responsibilities in order to be qualified. Additionally, §493.1407(a) states the laboratory director may serve as technical consultant, clinical consultant, and testing personnel, if qualified. Thus, an optometrist (limited to the specialty of optometry) who is serving as director of a laboratory performing moderate complexity testing, may also serve as technical

consultant as well as testing personnel. However, the individual must hold an MD, DO, or Doctoral degree in the prescribed sciences and be board certified by a CMS approved board to serve as a clinical consultant.

When testing is beyond the specialty area of optometry the individual serving as technical consultant, clinical consultant or testing personnel would be required to demonstrate compliance with the minimum personnel requirements of education and training or experience for each specialty or subspecialty area of service the laboratory has listed on its CLIA certificate or employ a technical consultant, clinical consultant, and testing personnel that meet the stated qualifications at §§493.1409, 493.1415, and 493.1421, respectively.

Tear duct testing for lactoferrin was the test procedure identified as being performed by optometrists in their specialty area at the time memorandum Ref: S&C-05-44 was issued. It is, therefore, important to reemphasize the significance of the laboratory's test menu and test methodologies listed on the CLIA certificate in providing guidance to the surveyor for determining compliance with personnel qualification requirements for an individual laboratory. The laboratory must notify the accrediting agency or CMS state agency no later than 6 months after making any changes to the listed test menu outside the specialty or subspecialty areas or any changes in test methodologies. [§493.51(b) and (c) and 493.63(b) and (c)]

Form CMS-1557; Survey Report Form (CLIA)

Surveyors should include the qualified optometrist laboratory director/technical consultant/testing personnel on this form.

Examples:

- If the optometrist laboratory director has earned a bachelor's degree and has at least 2 years of laboratory training and 2 years of supervisory laboratory experience in non waived testing under 42 CFR §493.1405, list that individual on Form CMS-1557 under §493.1405(a)(b)(5)(i).
- If the optometrist is acting as the technical consultant and has earned a bachelor's degree and has at least 2 years of laboratory training or experience, (or both) in non waived testing in a designated [laboratory] specialty or subspecialty of service for which the individual is responsible, list that individual on Form CMS-1557 under §493.1411(a)(b)(4).

Form 2567; State of Deficiencies and Plan of Correction

Surveyors should cite a deficiency if the laboratory's test menu includes more than those tests within the subspecialty of optometry and the laboratory director is filling positions without the requisite training/education.

Example:

- If the laboratory is performing testing beyond the specialty area of optometry and the laboratory director has not taken at least 20 CME'/CE's commensurate with the laboratory director's regulatory responsibilities, then document such on Form CMS-2567.

We will re-evaluate this regulatory guidance when the personnel requirements come up for revision. You may contact Judy Yost or CLIA staff at (410) 786-3407 or (410) 786-3531 if you have questions regarding this memorandum.

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 manager, and the State/RO training coordinators.

/s/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management (G-5)
Regional Office CLIA Consultants
CDC
DLS