CLIA: What You Need to Know

Facilities and practitioners that perform testing require certification, with the level of certification commensurate with the complexity of testing performed.

BY BRYAN BECHTEL, CONTRIBUTING EDITOR

In an attempt to codify laboratory testing outcomes, Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1998 to serve as a universal set of quality standards by which all US laboratories must abide.

Although the financial management of the CLIA program falls under the auspices of the Centers for Medicare & Medicaid Services (CMS), the assignment of diagnostic tests to predesigned categories (waived, moderate complexity, high complexity) is subject to a ruling by the FDA. Meanwhile, state agencies are responsible for surveying laboratory applicants and approving registration, unless the laboratory in question is in a state with a CMS-approved program that exempts it from participating in CLIA. Currently, Washington and New York have such programs, although the exemption in the latter does not apply to physicians' office laboratories.

Even the Centers for Disease Control and Prevention is involved in the CLIA program: it oversees an advisory committee that makes suggestions regarding laboratory standards.

With so many state and federal agencies involved, it is easy to get lost in the complex process of certification. Is the test you wish to perform considered waived or not? Does your facility have to register with the CLIA program if only nonwaived tests are to be performed? How much of the CLIA program is relevant to the practice of ophthalmology anyway?

The following is a brief overview of the CLIA program. Additional information may be found on the CMS website (www.cms.gov/regulations-and-guidance/legislation/CLIA/index.html?redirect=/CLIA), on the FDA website (www.fda.gov/medicaldevices/deviceregulationandguidance/ivdregulatoryassistance/ucm124105.htm), and on the website of the Centers for Disease Control and Prevention (www.cdc.gov/clia/default.aspx).

CLIA LABORATORY CERTIFICATION

According to the CMS, under the law passed by Congress in 1998, all facilities that perform testing on "materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings" must apply for and receive certification under the CLIA program. The level of laboratory certification must correspond with the level of complexity of the tests to be performed.

The FDA has established a checklist of seven criteria upon which each diagnostic test is reviewed, with lower scores indicating less complexity in each category: level of knowledge needed to perform the test; training and experience required; the sophistication of the reagents and materials preparation; characteristics of operational steps; level of required calibration, quality control, and proficiency to operate the testing materials; test system troubleshooting and equipment maintenance; and interpretation and judgment. A total score of less than 12 is designated as moderate complexity, and a score higher than 12 indicates a highly complex test.

Manufacturers may also apply for a CLIA waiver, which allows practitioners to perform simple laboratory examinations and procedures that have a low risk of false outcomes and/or pose minimal risk to the patient in the result of a testing error. The category was created to reduce the regulatory and statutory requirements needed to perform rote or routine examinations (eg, urine dip stick analysis) and to facilitate the use of rapid-result point-of-care tests, such as those used for HIV testing, in facilities outside the traditional health care setting.

Currently, two tests in ophthalmology may be performed with a CLIA Certificate of Waiver: the TearLab Osmolarity Test (TearLab Corporation) and the AdenoPlus adenovirus test for conjunctivitis (Rapid Pathogen Screening, Inc.). Facilities or individuals interested in performing these tests must still complete an application to the CMS and local/

state agencies, and they are subject to a biennial fee. Those facilities with a CLIA Certificate of Waiver may only perform the test(s) specified in the application, but they would not be subject to the requirements of facilities performing more complex testing.

WAIVED VERSUS NONWAIVED TESTS

All testing facilities must apply for a CLIA certificate even if only one test is to be performed. Applicants can go to the CMS website to find form CMS-116, which is then sent to a representative state agency for review. Certification is awarded in four categories:

- Laboratories with a Certificate of Waiver may perform only the designated waived test(s).
- Laboratories with a Certificate for Provider-Performed Microscopy (PPM) Procedures may perform waived tests or microscope-based diagnostics requiring moderately complex preparation and interpretation.
- Laboratories with a Certificate of Compliance may perform waived, PPM, and moderately or highly complex tests, depending on whether CLIA quality standards are met.
- Laboratories with a Certificate of Accreditation may perform waived, PPM, and moderately or highly complex tests after being reviewed for designation by certain partner organizations.

CONCLUSION

Some state laws may dictate a more involved certification process, whereas others may impose additional fees to the biennial CMS fee. Rules governing a party's ability to receive certain levels of certification may also differ from state to state. For example, optometrists practicing in California, Nevada, and New York may not obtain a CLIA Certificate of Waiver. ■