



FAST FACTS 2

CALIFORNIA REGULATION OF IN-OFFICE TESTING

California's laboratory licensure law became effective January 1, 1996. On this date, clinical laboratories of all types and sizes were required to be state licensed.

Solo-practicing physicians with in-office laboratories and smaller group practices of five or fewer physicians with in-office laboratories were, for the first time, required by law to obtain a state license. However, at that time emergency regulations were enacted which allow the CLIA certificates of these physician office laboratories (POLs) that were already in operation before January 1, 1996, to be accepted in lieu of a state license until California obtains a CLIA exemption. But in 2001, California withdrew their CLIA exemption application from the Centers for Medicare and Medicaid Services (CMS).

Since California enacted a laboratory licensure law, the Department of Health Services (DHS), which would normally enforce this law, has been inconsistent with their oversight and fee collection of these newly regulated laboratories.

In June 2005, DHS began strengthening their oversight of all laboratories in California and enforcing the laboratory licensure law. The law states that all laboratories are required to be state licensed, are subject to state inspections, and must also be in compliance with federal CLIA. New POLs will be required to apply for a state license and submit licensure fees with their application.

Note: Laboratories performing only waived testing and/or provider-performed microscopy do not need a state license, but they must register the laboratory with DHS and pay a small fee. (They must also have the proper CLIA certificate.)

What is a POL?

California defines a POL as a group of five or fewer physicians who do testing only on their own patients, do not perform any testing for other physicians, and do not perform HIV testing or review Pap smears.

Also, the POL must be either owned and operated by

- (a) a partnership or professional corporation, or
- (b) a licensed physician

Note: Unlike in other California laboratories, the testing personnel in a POL are not required to obtain a state personnel license. They must meet the federal CLIA personnel requirements and be supervised by a physician.

How will I know if the POL definition applies to my clinical laboratory?

To determine if the POL definition applies to your clinical laboratory, you will need to examine each partner's ownership interest or role. Under the law, ownership in a laboratory is defined as possessing 5% or more interest. For a POL, a physician or a physician group must have at least a 95% ownership interest or role

When will laboratories need to apply for a state license?

As previously mentioned, all new laboratories, including POLs, that want to begin performing non-waived testing must apply for and obtain a state license before testing begins. DHS has begun enforcing the state licensure law, and POLs that began operating on or after January 1, 1996, will be notified by DHS of the need for a state license at the time their current CLIA certificate expires. POLs that were operating before January 1, 1996, will be allowed to continue to operate with a CLIA certificate in

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lieu of a state license as long as they have not had their certificate suspended or revoked throughout this period or until California changes the existing laws.

What do laboratories have to pay to the state?

All California laboratories must pay the state \$978 annually for the state license, which includes the cost of a state inspection. However, until the state receives its CLIA exemption, laboratories are also still subject to CMS fees and, if applicable, accreditation program fees for purposes of CLIA compliance.

Is accreditation still valid under the laboratory licensure law?

Accreditation is always acceptable for compliance with federal CLIA regulations, and until California obtains a CLIA exemption, laboratories must still be in compliance with CLIA. When California obtains a CLIA exemption, then laboratories must comply with the California laboratory regulations instead of CLIA.

Until such time as DHS can review accreditation programs for equivalence to the California laboratory requirements and grant official approval to accrediting organizations, California laboratories must continue to be state licensed as well as in compliance with CLIA.

California Exemption Status

In June 2005, the California DHS informed CMS that it wishes to re-apply for CLIA exemption. This process could take three years to complete.

What does a CLIA exemption mean to my laboratory?

Under the federal CLIA requirements, states with their own laboratory licensure programs can apply to CMS for what is commonly called a "CLIA exemption." In order to obtain an exemption, the state laboratory standards must be reviewed by CMS and evaluated to determine equivalency to the federal CLIA requirements. Should the state be awarded a CLIA exemption, laboratories would comply with the state standards only and would no longer be required to comply separately with CLIA.

Will the DHS recognize COLA under the state's laboratory licensure program?

COLA currently accredits California laboratories for compliance with CLIA. In the meantime, the California law allows POLs to use their CLIA certificate (including a certificate of accreditation for COLA labs) instead of a state license. This caveat applies to POLs with five or fewer physicians operating before 1/1/96 that have not had their certificates suspended or revoked throughout this period.

California laboratory licensure law requires the DHS to recognize private, non-profit accreditation programs for purposes of state licensure. As soon as the formal review process by DHS is finalized, COLA will seek immediate recognition and official approval. COLA has strong commitment to a high quality laboratory environment, and continues to work to service the needs of its more than 7,350 laboratories nationwide. COLA will work to ensure that laboratories in California have the same educational, quality-focused, private sector, peer-review alternative that other laboratories in the country enjoy. COLA has been approved by CMS as well as by all CLIA-exempt states that regulate physician-directed laboratories.

To obtain official approval, an accrediting organization must demonstrate that its standards meet or exceed state regulations. Once COLA is approved, laboratories will be able to comply with state licensure standards through COLA accreditation. California laboratory licensure law helps ensure that laboratories continue to have the important choice of COLA's physician-directed accreditation program under the California laboratory licensure program and CLIA exemption.

What happens to accredited labs after the state gets exemption?

Under a CLIA exemption, the laboratory will no longer pay any CLIA certificate fees. If laboratory accrediting organizations are approved by the state, then laboratories accredited by that organization will be deemed to be in compliance with state law. The laboratory will pay accreditation programs fees to their accrediting organization and a \$100 fee to California DHS. Accredited laboratories will continue to be inspected by the accrediting organization, not by the state.

Should the state obtain an exemption how would my laboratory be regulated under the revised state requirements?

Federal CLIA would no longer apply to laboratories in California. Obviously, there are uncertainties as to what the final regulatory language will look like, but the state requirements will be equivalent to, or possibly more stringent than, CLIA. The DHS is continuing the rulemaking process to craft and implement the regulations. Laboratories that are not accredited will be inspected by the state.

COLA intends to obtain official approval under the state law. This will ensure that laboratories have COLA's private peer-review as a choice, as intended by legislature in its construction of the new California laboratory licensure law.