



CALIFORNIA LAW AND YOUR LABORATORY PERSONNEL

COLA continues to receive calls from California physicians and their laboratory staff requesting help in understanding the state's laboratory staffing requirements.

The requirements for laboratory personnel were revised in 1996 with the passage of California Senate Bill 113. Regulations to implement portions of the new law continue to be developed. The law enabled the state to submit its application to the Health Care Financing Administration (HCFA) for a CLIA exemption in April 1996. When the state is granted a CLIA exemption, laboratories will be accountable to state law and regulations only in place of the federal CLIA requirements.

However, as of March 2001, the state has not received a CLIA exemption and it is re-examining its efforts to pursue a CLIA exemption. Furthermore, a number of regulatory changes are being considered by the state. This Fact Sheet will be updated to include such changes when they are finalized.

COLA has developed this "Fast Fact Sheet" to address the state personnel and laboratory staffing requirements as revised by SB 113. This information will be supplemented by a new Fast Facts 32CA that will describe pertinent personnel regulations in detail.

How Does the 1996 Law Affect Staff in Labs Used by Five or Fewer Physicians for Their Own Patient Testing?

Physicians performing testing in their office have contacted COLA to determine if they must hire a licensed medical technologist under state law. Please be advised that this is not the case for all clinical laboratories. Depending on the number of physicians using the clinical laboratory, other individuals and healthcare professionals can perform testing in addition to the well-qualified, state-licensed medical technologists.

Under the law, "physician office laboratories" are defined as those laboratories owned and operated by a partnership or professional corporation that perform clinical laboratory testing only for patients of five or fewer physicians. Laboratories meeting this definition are required to meet laboratory staffing requirements different from all other clinical laboratories, including those laboratories providing testing for the patients of six or more physicians.

Specifically, "any person" within a physician office laboratory as defined above who meets the federal CLIA requirements may continue to perform waived, moderate, or high complexity testing.

When an individual meeting these minimum qualifications performs moderate complexity testing, the testing must be performed under the supervision of the patient's physician. The physician must be accessible to the laboratory to provide on-site, telephone, or electronic consultation, as needed.

For high complexity testing, the physician must provide on-site supervision during all testing. Telephone or electronic consultation is not permitted for high complexity testing in the physician office laboratory.

Similar to CLIA, the physician must ensure that the individual performs test methods as required for accurate and reliable tests. The physician must also have personal knowledge of the test results before they are reported from the laboratory.

When other state-licensed professionals (e.g., state-licensed medical technologists) perform testing in a physician office laboratory as defined above, the extra physician supervision requirements are not necessary.

In other words, a state-licensed medical technologist would not require on-site supervision when performing high complexity testing in a physician office laboratory.

How Does the 1996 Law Affect Staff in All Other Clinical Laboratories?

Under the California state law, all other clinical laboratories, including those performing testing for the patients of six or more physicians, need to continue to staff the laboratory with licensed personnel such as registered nurses, physician assistants, and state-licensed medical technologists.

Personnel who are not licensed by the state can also work in these laboratories, but they are only permitted to perform certain laboratory functions. The revised law does not place significantly new regulatory guidelines on these clinical laboratories because they've been mandated to meet the state's comprehensive personnel and facility licensing requirements for several years. In general, only state-licensed personnel are permitted to perform all aspects of the testing process in these clinical laboratories.

State-licensed medical technologists may perform testing in the specialties for which they are licensed. Other state-licensed healthcare professionals including physician assistants, registered nurses, perfusionists, respiratory care practitioners, etc., can perform certain testing when such testing is authorized by their scope of practice. These professionals should contact their representative organization or Lab Field Services for more information about any limitations on their scope of testing that might apply.

All personnel who are not formally licensed by the state and are performing testing for patients of six or more physicians and other clinical laboratories are considered "unlicensed".

Such unlicensed personnel may perform only limited functions in the laboratory. For example, unlicensed personnel may collect specimens and assist in quality control, but may not record results other than those displayed by automatic testing equipment.

These functions are explained fully in COLA Fast Fact Sheet #7, titled "The Role of Unlicensed Personnel in California Laboratories." Unlicensed personnel must be directly and constantly supervised by the physician or a laboratorian licensed by the state. Licensed trainees are not permitted to supervise unlicensed personnel. All personnel, including unlicensed personnel, need to meet CLIA requirements for testing.

COLA has been asked if medical laboratory technicians (MLTs), who meet the CLIA requirements, can perform all phases of testing in these clinical laboratories. According to Laboratory Field Services, there currently is no licensing process for MLTs although state regulations are being developed to do so.

As such, MLTs are only permitted to perform the functions of unlicensed laboratory personnel when working in a laboratory which does not qualify as a physician office laboratory as defined by the law.

Sound Laboratory Practices

As always, you should take great care to carefully review your laboratory operations, test menu, and size to ensure that you employ the appropriate personnel and supervision for your particular practice. Be sure to keep thorough documentation on the training and experience of all your laboratory personnel.

Call COLA If You Need Assistance

Our technical professionals in the Customer Service Center can help you determine the skills your personnel need to demonstrate to fulfill CLIA requirements. They can also suggest possible sources of training to acquire those skills.

If you have any questions about the state law, other aspects of California laboratory licensure, or CLIA, please call the COLA Information Resource Center toll-free at (800) 981-9883.