

Date of Hearing: April 3, 2018

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS

Evan Low, Chair

AB 2281 (Irwin) – As Introduced February 13, 2018

SUBJECT: Clinical laboratories: licensed medical laboratory technicians.

SUMMARY: Expands the scope of practice of licensed medical laboratory technicians (MLTs) to include blood smear reviews, microscopic urinalysis, and moderate complexity blood typing.

EXISTING FEDERAL LAW:

- 1) Provides for the regulation of human medical laboratory testing by the Centers for Medicare & Medicaid Services (CMS). (Clinical Laboratory Improvement Amendments (CLIA), Title 42 United States Code (USC) § 263a; Title 42 Code of Federal Regulations (CFR) §§ 493.1-493.2001)
- 2) Defines “laboratory” or “clinical laboratory” as a facility for the biological, microbiological, serological, chemical, immune-hematological, hematological, biophysical, cytological, pathological, or other examination of 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. (42 USC § 263a(a); 42 CFR § 493.2)
- 3) Classifies laboratory tests into three categories: waived, moderate complexity, and high complexity and prohibits a clinical laboratory from soliciting or accepting materials derived from the human body for laboratory examination or other procedure unless certified to perform the category of testing that includes the examinations or procedures. (42 USC § 263a(b); 42 CFR §§ 493.5, 493.1351)
- 4) Requires laboratories that perform moderate complexity testing to have a laboratory director who is qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests. (42 CFR §§ 493.1403, 493.1405)
- 5) Requires laboratories that perform moderate complexity testing to ensure that personnel performing moderate complexity tests possess a current license issued by the state where the laboratory is located, if a license is required, and meet one of the following requirements: (42 CFR § 493.1423)
 - a) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution.
 - b) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution.

- c) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician).
- d) Have earned a high school diploma or equivalent, and have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

EXISTING STATE LAW:

- 1) Provides for the licensure, registration, and regulation of clinical laboratories and clinical laboratory personnel by the California Department of Public Health (CDPH). (BPC § 1200-1327)
- 2) Defines, for purposes of state regulation of clinical laboratories, the following:
 - a) “CLIA” means the federal Clinical Laboratory Improvement Amendments of 1988 and the adopted regulations. (BPC § 1202.5(a))
 - b) “Clinical laboratory” means any place used, or any establishment or institution organized or operated, for the performance of clinical laboratory tests or examinations or the practical application of the clinical laboratory sciences. That application may include any means that applies the clinical laboratory sciences. (BPC § 1206(a)(8))
- 3) Requires a clinical laboratory performing laboratory tests or examinations classified as moderate or high complexity under CLIA to obtain a state clinical laboratory license from the CDPH. Licensed laboratories must ensure that laboratory personnel meet CLIA requirements for moderate or high complexity, or both. (BPC § 1265(a)(1))
- 4) Prohibits a person from performing a test classified as of moderate complexity test under CLIA unless the test is performed under a laboratory director, as specified, the laboratory director provides documentation of the adequacy of the qualifications and competency of the personnel, and the test is performed by one the following individuals: (BPC § 1206.5)
 - a) A licensed physician and surgeon;
 - b) A licensed podiatrist or a licensed dentist;
 - c) A person licensed to engage in clinical laboratory practice or to direct a clinical laboratory;
 - d) A certified local health officer.
 - e) A licensed physician assistant if authorized by a supervising physician and surgeon.
 - f) A registered nurse.
 - g) A perfusionist if authorized under BPC § 2590.

- h) A respiratory care practitioner.
 - i) A person certified to perform nuclear medicine technology under CDPH if authorized.
 - j) Any person if performing blood gas analysis in compliance with BPC § 1245.
 - k) A certified or licensed emergency medical technician II or paramedic while providing prehospital medical care.
 - l) A person licensed as a psychiatric technician, as a vocational nurse, or as a licensed midwife, or certified by the CDPH as a nurse assistant or a home health aide, who provides direct patient care, if the person meets the following:
 - i) Is performing the test as an adjunct to the provision of direct patient care by the person.
 - ii) Is utilizing a point-of-care laboratory testing device at a site for which a laboratory license or registration has been issued.
 - iii) Meets the minimum clinical laboratory education, training, and experience requirements set forth in regulations adopted by the CDPH.
 - iv) Has demonstrated to the satisfaction of the laboratory director that the person is competent in the operation of the point-of-care laboratory testing device for each analyte to be reported.
 - v) Has participated in a preceptor program until they are able to perform the clinical laboratory tests or examinations with results that are deemed accurate and skills that are deemed competent by the preceptor. For the purposes of this section, a “preceptor program” means an organized system that meets regulatory requirements in which a preceptor provides and documents personal observation and critical evaluation, including review of accuracy, reliability, and validity, of laboratory testing performed.
 - m) Any person within a physician office laboratory if the test is performed under the supervision of the patient’s physician and surgeon or podiatrist who is accessible to the laboratory to provide onsite, telephone, or electronic consultation as needed, as specified.
 - n) A pharmacist, if ordering drug therapy-related laboratory.
- 5) Provides for the licensure of medical laboratory technicians by the CDPH. (BPC § 1260.3)
- 6) Requires applicants for a medical laboratory technician license to do the following:
- a) Meet state law requirements for clinical laboratories and any reasonable qualifications established by regulations of the CDPH, including, but not limited to, any of the following:

- i) Holds an associate degree or an equivalent or higher degree in chemical, physical, biological, or clinical laboratory science, which includes a minimum of 36 semester units of physical or biological sciences. (BPC § 1260.3(a)(1)(A))
 - ii) Completed 60 semester (90 quarter) units from an accredited college or university, with 36 semester units in physical or biological sciences. (BPC § 1260.3(a)(1)(B))
 - iii) Graduated from an MLT training program accredited by the National Accrediting Agency for Clinical Laboratory Sciences or other recognized accrediting program approved by the CDPH. (BPC § 1260.3(a)(1)(C))
 - iv) Graduation from an advanced military medical laboratory specialist program approved by the department. (BPC § 1260.3(a)(1)(D))
- b) Apply for the license on forms provided by the CDPH. (BPC § 1260.3(a)(2))
 - c) Pay the license fee established by the CDPH. (BPC § 1260.3(a)(3))
- 7) Authorizes a licensed MLT to perform clinical laboratory tests or examinations classified as waived or of moderate complexity under CLIA and report the test results, but provides that: (1) the licensed MLT may not perform microscopic analysis or immunohematology procedures; (2) the MLT must work under the supervision of a licensed physician and surgeon or a baccalaureate, masters, or doctoral-level clinical laboratory license; and (3) the MLT is supervised the entire time the MLT performs clinical laboratory tests or examinations. (BPC § 1260.3(b))

THIS BILL:

- 1) Authorizes an MLT to perform three microscopic analysis and immunohematology procedures: (1) blood smear reviews, (2) microscopic urinalysis, and (3) blood typing of moderate complexity, such as ABO/Rh testing.

FISCAL EFFECT: Unknown. This bill is keyed fiscal by the Legislative Counsel.

COMMENTS:

Purpose. This bill is sponsored by the **California Society of Pathologists**. According to the author, “California is currently experiencing a shortage of laboratory personnel that has been worsened by the growing demand for health care services. Clinical Laboratory Scientists (CLS) are individuals with bachelor’s degrees who are licensed to perform the most complex tests in a laboratory. Considering that 42% of current CLSs are quickly nearing retirement, our state can anticipate a drastic shortage in clinical laboratory personnel. We must prepare for this reality while ensuring that we can continue to provide quality health care services. This bill will alleviate the workforce shortage by allowing [MLTs], or individuals with associate degrees and extensive training, to assist CLSs with three moderately complex tests.”

Background. MLTs are licensed professionals that perform clinical laboratory tests. Clinical laboratory tests are healthcare services that involve the examination and analysis of human tissue

and fluid, such as blood tests and biopsies. Clinical laboratories are regulated under the federal law known as CLIA.

CLIA establishes the minimum federal standards for laboratory testing and personnel to ensure accuracy, reliability, and timeliness of laboratory tests. States may require laboratory and personnel standards that exceed CLIA standards. All laboratories that perform tests on human specimens for diagnostic or assessment purposes must be certified under CLIA and comply with state-specific requirements.

The laboratory and personnel requirements for CLIA certification vary depending on the complexity of the laboratory tests performed. Clinical laboratory tests are categorized as waived, moderate, or high complexity. The federal Food and Drug Administration (FDA) determines the complexity of laboratory tests under CLIA. Waived tests are simple tests with a low risk for an incorrect result. They include tests listed in the CLIA regulations, tests cleared by the FDA for home use, and tests approved for waiver by the FDA using the CLIA criteria. Tests not classified as waived are assigned a moderate or high complexity category based on seven criteria given in the CLIA regulations, including ease of use, knowledge required, and materials being tested.

In general, the more complicated the test, the more stringent the education, training, supervision requirements for laboratory personnel. At a minimum, all laboratories must have a licensed laboratory director who supervises and trains personnel.

Under both CLIA and California law, anyone may perform a waived test in a licensed laboratory. However, California law imposes additional requirements for moderate complexity testing. The minimum requirements under federal law require that personnel have (1) at least a high school diploma or equivalent and (2) documentation of training appropriate for the testing performed prior to analyzing patient specimens. In California, only specific categories of licensed or certified individuals may perform moderate complexity tests.

Medical Laboratory Technicians. MLTs are one of the licensees that may perform moderate complexity tests. MLTs generally have two years of education in a community college setting (Associate Degree). In California, MLTs work under the close supervision of CLSs and other licensed laboratory personnel.

Under CLIA and in states that license MLTs (other than California), MLTs are authorized to perform up to high complexity tests. California only authorizes MLTs to perform moderate complexity tests except for microscopic analysis or immunohematology procedures. This bill would authorize MLTs to perform two immunohematology procedures (blood smear reviews and moderate complexity blood typing) and one microscopic analysis procedure (microscopic urinalysis).

Blood Smear Reviews. A blood smear or film is a drop of blood that is spread onto a glass slide and is stained so it can be examined under a microscope. It is a snapshot of the cells that are present in the fluid portion of the blood (plasma) at the time the sample is obtained. The blood smear allows for the evaluation of blood cells.

The observer can compare their size, shape, and general appearance to the established appearance of "normal" cells. Abnormal numbers or appears can suggest a variety of diseases

and conditions. Examination of a blood smear can also be used to support findings from other tests.

Microscopic Urinalysis. Urinalysis is the analysis of urine. A microscopic examination of urine is typically done when there are abnormal findings on the physical or chemical examination. A microscopic exam is performed on urine sediment — urine that has been centrifuged to concentrate the substances in it at the bottom of a tube. The fluid at the top of the tube is then discarded and the drops of fluid remaining are examined under a microscope.

Blood Typing. Blood typing is a procedure to determine blood type. It can also show whether there is a substance called Rh factor on the surface of red blood cells. Blood typing is done to determine whether it is safe to donate blood or receive a blood transfusion. Incompatible blood types can result in an adverse immune response called hemolytic reaction. Rh incompatibility may cause complications for newborns.

Prior Related Legislation. SB 1809 (Machado), Chapter 356, Statutes of 2002 established the MLT license category, authorizing licensed MLTs to perform waived and moderate complexity clinical laboratory tests except for microscopic analysis or immunohematology procedures.

ARGUMENTS IN SUPPORT:

The **California Society of Pathologists** (sponsor) writes in support, “[p]athologists are physicians who specialize in laboratory medicine and under California law are directors of hospital clinical labs and many freestanding labs. They are acutely aware of the shortage of qualified clinical laboratory personnel and the need to allow the greater utilization of existing personnel to staff clinical laboratories. [This bill] would help allow the appropriate use of MLTs who are already trained to perform these three lab procedures.”

The **California Clinical Laboratory Association** writes in support, “[e]very clinical laboratory operating in California and various clinical laboratory personnel are licensed and regulated by the [CDPH]. Existing law requires an MLT to be licensed by the [CDPH] and sets for the duties that a licensed MLT is authorized to perform.

[This bill] expands the law to allow MLTs to perform 3 additional moderately complex tests. This will greatly help with the difficulty California health care employers have faced over the last decade in confronting the workforce shortage.”

The **California Hospital Association** (CHA) writes in support, “[i]n 2015, the CHA-sponsored Healthcare Laboratory Workforce Initiative collaborated with the University of California, San Francisco Healthforce Center to conduct a national study comparing California's MLT workforce supply and scope of practice to the rest of the country's. The study found that:

- The scope of practice limitations on MLTs in California are the most restrictive in the nation when compared to other states that license MLTs.
- In California, MLTs are trained to perform moderately complex tests.
- In other states that license MLTs, laboratory personnel support MLTs practicing to their highest level of training.

- In other states that regulate MLTs, laboratory directors perceive MLTs as beneficial to productivity and quality.
- Many states do not license MLTs; instead, state statute allows the lab director to determine the MLT's competence to perform moderately complex testing. In fact, some states only require a high school diploma.

In addition, according to a 2016 survey of 223 hospitals, more than 39 percent of the CLS workforce is over the age of 55; 10 percent of that group is over the age of 65. MLTs will be vital in helping support the laboratory as CLSs begin to retire in large numbers. However, their current scope presents a challenge when fitting them into the workforce mix.

If MLTs can perform the high-volume tests specified in [this bill], for which they have received training, clinical laboratory efficiencies will improve. Labs will be able to more quickly provide patients with test results, and will improve their capacity to meet the increased demands for services. Furthermore, allowing MLTs to perform the tests specified in the bill reserves the CLS for highly complex testing, thereby mitigating the impact of the CLS shortage.”

The **Folsom Lake College Medical Laboratory Technician Program** writes in support, “[this bill] does not grant high complexity testing to MLTs, however it does away with several of the items preventing MLTs from having a meaningful impact in hospital laboratories. It is a good compromise amongst all the stakeholders, and it will ensure MLTs have value in California. Several MLT training programs have closed down recently, and this is because hospitals are not willing to train MLTs if they cannot utilize them effectively. Hospitals have limited resources and are not willing to train an MLT if they can only be utilized in one area due to scope limitations set by current California law. Without hospital participation, programs will continue to close, and the laboratory staffing crisis will worsen.”

Quest Diagnostics writes in support, “[this bill] authorizes an MLT to perform blood smear reviews, urinalysis, and blood type tests. These are tests that all MLTs are trained to perform and they do so in other states. However, California law and regulation has not kept pace with the training requirements of MLTs and does not currently allow MLTs to perform these moderately complex tests.

[This bill] will improve the efficiency and flow of laboratory operations with no sacrifice in test accuracy. In doing so, this bill will also free the higher trained and educated CLS to perform the higher complexity tests for which only they are trained and educated to perform.”

ARGUMENTS IN OPPOSITION:

The **Engineers and Scientists of California** write in opposition, “[w]e fear that by allowing MLTs to perform clinical lab tests normally performed by a CLS, [this bill] will steer hospitals toward picking the “cheaper” option without regard to patient safety. Indeed, in the 2010 *Biochemia Medica* report “Overview on patient safety in healthcare and laboratory diagnostics” authors noted that, “Owing to the volume and complexity of testing, a large number of errors still occur in laboratory diagnostics, especially in the extra-analytical phases of testing.” Lab tests such as blood smear reviews, microscopic urinalysis and blood typing require a certain amount of discretionary judgment. We believe that these tests are best performed by licensed

professionals who are properly educated, trained, and experienced. In our view, it's the CLS that best serves the patient here.”

REGISTERED SUPPORT:

California Society of Pathologists (sponsor)
California Clinical Laboratory Association
California Hospital Association
Folsom Lake College Medical Laboratory Technician Program
Quest Diagnostics
13 Individual MLTs

REGISTERED OPPOSITION:

Engineers and Scientists of California
3 Individual CLSs

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