Legislation Affecting CA Clinical Laboratory Professions and Laboratories

Past, Present and Future

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April 7, 2019
Topics Discussed

- Differences between statutes and regulations
- “Popular” codes and regulations
  - [http://leginfo.legislature.ca.gov/faces/codes.xhtml](http://leginfo.legislature.ca.gov/faces/codes.xhtml)
  - [https://govt.westlaw.com/calregs/Browse/Home/California/CaliforniaCodeofRegulations?guid=I4EFB82E0D60511DE88AEDDE29ED1DCoA&originationContext=documenttoc&transitionType=Default&contextData=(sc.Default)](https://govt.westlaw.com/calregs/Browse/Home/California/CaliforniaCodeofRegulations?guid=I4EFB82E0D60511DE88AEDDE29ED1DCoA&originationContext=documenttoc&transitionType=Default&contextData=(sc.Default))
- The Life Cycle of Legislation – From Idea into Law
- How to read a bill
- How to look up bill language and status: [http://leginfo.legislature.ca.gov](http://leginfo.legislature.ca.gov)
  - Legislation affecting CA Clinical Laboratory Professions
- Corresponding with elected officials
- CAMLT website – [www.camlt.org](http://www.camlt.org)
What’s the difference between a statute and a regulation?

### Statute
- Governing bodies such as the CA State Senate and Assembly enact statutes (aka laws)
- CA Lab Law can be found in:
  1. CA Business and Professions Code; Division 2 Healing Arts; Chapter 3 Clinical Laboratory Technology: BPC 1200-1327
  2. CA Health and Safety Code; Division 2 Licensing Provisions; Chapter 4 Human Whole Blood, Human Whole Blood Derivatives, and other Biologics: HSC 1600-1648
- Only Governing bodies can adopt, amend and repeal CA Lab Laws.

### Regulation
- Rules or requirements imposed by a governmental agency (such as LFS) responsible for carrying out a statute’s provisions adopts regulations to enforce the statute.
- CA Lab Regulations can be found in:
  1. CA Code of Regulations (CCR); Title 17 Public Health (Biologics, Clinical Laboratories, HIV, Reportable Diseases); Division 1 State Dept. of Health Services; Chapter 2 Laboratories; Subchapter 1 Service Laboratories; Group 2 Clinical Lab Regulations
- LFS can adopt, amend and repeal CA Lab regulations under the authority granted to them by statutes.
California Law Code and Text Searches

- Website: [http://leginfo.legislature.ca.gov/faces/codes.xhtml](http://leginfo.legislature.ca.gov/faces/codes.xhtml)

- “Popular” Codes:
  - BPC 1206.5 (a) – Who can perform waived tests
  - BPC 1206.5 (b) – Who can perform moderately complex tests
  - BPC 1206.5 (c) – Who can perform highly complex tests
  - BPC 1209 – Who can direct clinical laboratories
  - BPC 1241 – Clinical laboratories exempt from CA lab law
  - BPC 1260.3 – MLT licensing requirements and scope of practice
  - BPC 1261 – CLS licensing requirements
California Code of Regulations and Text Searches

- Website:  [https://govt.westlaw.com/calregs](https://govt.westlaw.com/calregs)
- “Popular” Regulations
  - **CCR 1031** – Licensure requirements for CLS specialists
  - **CCR 1032** – Licensure requirements for CLS generalists
  - **CCR 1032.5** – Licensure requirements, scope of practice, license renewal and supervision for MLTs
  - **CCR 1034** – Certification requirements, scope of practice, certificate renewal and supervision for LPTs and CPTs
  - **CCR 1040** – Forfeited licenses
The Life Cycle of Legislation – From Idea into Law

Assembly
1) Idea to Assembly Member
2) Assembly Bill prepared
3) Assembly Bill introduced
4) Pass Assembly Committee Hearings
5) Pass 2nd and 3rd Assembly Readings and vote
6) 1st Senate Reading
7) Pass Senate Committee Hearings
8) Pass 2nd and 3rd Senate Readings and vote

Senate
1) Idea to Senate Member
2) Senate Bill prepared
3) Senate Bill introduced
4) Pass Senate Committee Hearings
5) Pass 2nd and 3rd Senate Readings and vote
6) 1st Assembly Reading
7) Pass Assembly Committee Hearings
8) Pass 2nd and 3rd Assembly Readings and votes

Governor
1) Sign: Bill is chaptered by Secretary of State
2) Veto: Legislature has 60 days to override veto; if not, veto prevails
3) No signature after 12 days (or 30 days at the end of a legislative session):
   Bill is chaptered by Secretary of State
What A Bill Looks Like

CALIFORNIA LEGISLATURE—2015-16 REGULAR SESSION

ASSEMBLY BILL No. 528

Introduced by Assembly Member Baker
(Coauthors: Assembly Members Bigelow, Grove, Harper, Lackey, Olsen, and Wilk)

February 23, 2015

An act to amend Section 3616 of, and to add Section 3616.1 to, the Government Code relating to the San Francisco Bay Area Rapid Transit District.

LEGISLATIVE COUNSEL'S DIGEST

AB 528, as introduced, Baker. San Francisco Bay Area Rapid Transit District: strikes: prohibition.

Existing law creates the San Francisco Bay Area Rapid Transit District and establishes provisions regulating the collective bargaining of the employees and the board of directors of that district. Existing law prescribes procedures specifically relating to the collective bargaining of transit districts, and authorizes the Governor, when it appears a strike will significantly disrupt transportation services and endanger public health, safety, and welfare, to appoint a board to investigate issues in connection with these labor negotiations and make a report. Existing law prohibits a strike during the period of investigation and permits the Governor, upon receiving a report from a board of investigation, to request the Attorney General to petition a court to enjoin the strike, as specified.

This bill would prohibit employees of the San Francisco Bay Area Rapid Transit District from engaging in a strike or work stoppage if the transit district board maintains the compensation and benefit provisions of an expired contract and an employee or employee organization has agreed to a provision prohibiting strikes in the expired or previous written labor contract. The bill would provide that an employee whom the transit district employer finds willfully engaged in a strike or work stoppage in violation of these provisions is subject to dismissal if that finding is sustained upon conclusion of the appropriate proceedings necessary for the imposition of a disciplinary action.


The people of the State of California do enact as follows:

SECTION 1. Section 3616 of the Government Code is amended to read:

3616. Except as expressly provided by subdivision (b) of Section 3612 and Section 3614, 3612, and Sections 3614 and 3616.1, nothing in this chapter shall be construed to grant or deprive employees of a right to strike.

SEC. 2. Section 3616.1 is added to the Government Code, to read: 3616.1, (a)
CLS as Waived Lab Directors 2013

- **AB 1215 (Hagman & Holden) Clinical Laboratories**
  - CAMLT co-sponsored AB 1215 with the Engineers and Scientists of California, IFPTE, Local 20.
  - In the wake of attempted legislation over the years to allow various allied health professionals to do laboratory testing without a lab director, AB 1215 will permit Clinical Laboratory Scientists, both generalists and specialists, to be laboratory directors for purposes of clinical laboratory tests classified as waived under CLIA.
  - Signed into Law in 2013.
AB 761 (Hernandez) Optometrists – Oppose to Neutral

- An optometrist serves as laboratory director to only a laboratory that performs authorized clinical laboratory testing waived under CLIA, and
- Performs only those tests that optometrists are permitted to order, designated in 3041 (e) (9): “smears, cultures, sensitivities, complete blood count, mycobacterial culture, acid fast stain, urinalysis, and X-rays necessary for the diagnosis of conditions or diseases of the eye or adnexa.”
- Signed into law September 28, 2012.
Optometrist Scope Expansion 2014

- **SB 492 (Hernandez) Optometric Corporations – OPPOSE**
  - This bill would significantly expand the scope of practice for optometrists and was opposed by the California Medical Association and the California Academy of Eye Physicians and Surgeons.
  - Of particular interest to CAMLT was that the bill at one point would have authorized an optometrist to perform and/or order any laboratory and diagnostic imaging tests.
  - The bill outright repealed the agreements reached in 2013 restricting optometrists to perform CLIA waived tests necessary for the diagnosis of conditions and diseases of the eye or adnexa from a short list of tests that they are authorized to order.
  - SB 492 died on the Assembly floor.
Optometrist Scope Expansion 2015

• SB 622 (Hernandez) – Optometry - OPPOSE
  • Introduced in 2015, SB 622 continued the optometric agenda to pursue scope expansion into clinical laboratory science.
  • Similar to SB 492 (Hernandez) which died on the Assembly Floor in 2014, SB 622, would have expanded the scope of practice for optometrists to perform all (CLIA) waived tests; not just those they are legally permitted to order.
  • SB 622 failed to progress out of committee and died in 2017.
AB 443 (Salas), Healing Arts: Optometry - WATCH

- Amended language with regard to diabetes testing to allow optometrists to collect blood specimen by the finger prick method.
- AB 443 would also allow an optometrist to perform skin testing to diagnose ocular allergies limited to the superficial layer of skin, collect blood through skin puncture for diabetes testing, treat eyelid inflammation/inadequate eyelash growth and eliminates the protocols that specify when an optometrist must refer a patient to another provider.
- This bill was signed into law on 10/7/17.
Chiropractor Scope Expansion 2014

- **AB 2143 (Williams) Clinical Laboratories – Neutral**
  - Following up on their original intent with AB 722, this bill was introduced at the request of the Chiropractors to allow them to do waived clinical laboratory tests without having to have a laboratory director.
  - While the chiropractors wanted more, they really needed a bill to allow them to do four dip stick urine tests (urine specific gravity, urine protein, urine blood, and urine sugar tests) listed on the National Registry of Certified Medical Examiners, for the sole purpose of completing the DMV medical examination report to determine if an individual is fit to have a commercial driver’s license.
  - CAMLT proposed amendments that would allow chiropractors to do only these four tests as long as they held a CLIA Certificate of Waiver.
  - AB 2143 was signed into law on 8/22/14.
AB599 (Bonilla) – Cytotechnologists – Watch

- This bill, co-sponsored by the California Association of Cytotechnologists and the California Society of Pathologists, authorized a licensed cytotechnologist to perform all tests and procedures pertaining to cytology, including, but not limited to, microscopic and nonmicroscopic methodologies and tests and procedures that utilize molecular or genetic methodologies as well as other methodologies and diagnosis.

- AB599 allows Cytotechnologists to perform molecular tests for infectious agents such as HPV from a PAP specimen.

- This bill was signed into law on 9/21/15.
Clinical Laboratory Fees 2017

- AB 658 (Waldron) Clinical Laboratories – NEUTRAL
- This bill suspends annual renewal licensure fee for clinical laboratories for two years (2018 & 2019)
- This measure is a result of the release on September 10, 2015 from the office of the State Auditor a report on the Laboratory Field Services (LFS) branch of the Department of Public Health which noted in its audit findings that since 2008 LFS has collected more than $12 million in lab fees that it has not spent.
- AB 658 proposes that by requiring LFS to suspend the annual renewals licensure fee for clinical laboratories for two years (2018 & 2019), this will allow the Department to spend down the surplus in funds to an appropriate operating level.
- AB 658 passed from the Legislature and was signed by the Governor.
Total Protein Refractometer 2018

- **AB 613 (Nazarian), Healing Arts: Clinical Laboratories — OPPOSE**
  - 2017; this measure is the reintroduction of AB 757 (Gomez) that CAMLT opposed and was ultimately vetoed by the Governor in 2015.
  - Would allow Unlicensed High School graduates to perform the moderately complex total protein refractometer test on potential plasma donors at plasma collection centers.
  - Standards outlined in the bill for unlicensed personnel/assistants performing this test do not ensure the health and safety of plasma donors.
  - Unlike AB 757 (Gomez), AB 613 does not allow Unlicensed High School graduates to perform calibration of the total protein refractometer test.
  - Bill sunsets on January 1, 2021.
  - CAMLT had asked for a veto but the Governor signed AB 613 into law on September 27.
AB 1627 (Chen) Clinical Laboratories: Certified Phlebotomy Technicians: - OPPOSE

- AB 1627 was gutted and amended in late June 2018.
- Authorizes CPTs to withdraw blood for laboratory tests from a peripheral venous catheter.
- This bill poses a threat to the health and safety of patients in an effort to expand the use of the PIVO device for blood withdrawal.
- This bill was sponsored by Velano Vascular, maker of PIVO device.
- CAMLT does not feel that the proposed revisions in the statutory or regulatory language could prepare CPTs for the care and management of peripherally inserted intravenous catheters.
- AB 1627 was sent to the Senate Appropriations Suspense file due to the measure’s fiscal component, where it failed to advance. The measure died on August 16, 2018.
CPT Scope Expansion 2019

• AB 822 (Irwin & Arambula) – Watch
  • Authorizes CPTs to withdraw blood for laboratory tests using devices for blood collection authorized by the clinical laboratory employing the CPT.
  • As technological innovations continue, such as needle-free blood collection via peripheral venous catheter with a PIVO device, CAMLT will remain open to new techniques only if sufficient measures are in place to ensure for education, training and competency of CPTs.
  • The decision to use new technology to collect blood should be a practice level decision. As such, the clinical laboratory (in collaboration with clinical staff and device manufacturer) must ensure for education, training and competency before implementation.
  • This bill is sponsored by Velano Vascular, maker of PIVO device.
MLT Scope Expansion 2018

- **AB 2281 (Irwin) Clinical Laboratories: Licensed Medical Laboratory Technicians – WATCH**
  - Would expand Medical Laboratory Technician scope of practice to include moderately complex blood smear reviews other than manual leukocyte differentials, microscopic urinalysis, blood typing (ABO/Rh testing) and antibody screen.
  - Does **NOT** expand MLT scope of practice to include Gram stains or immunohematology procedures if such results are used for compatibility testing.
  - **AB 2281 was enrolled and signed by the Governor; this law will be effective January 1, 2019.**
BPC 1260.3 (b) A licensed medical laboratory technician may perform clinical laboratory tests or examinations classified as waived or of moderate complexity under CLIA, *but not high complexity*, and may report the test results. However, a licensed medical laboratory technician shall not perform microscopic analysis or immunohematology procedures, except for blood smear reviews other than manual leukocyte differentials, microscopic urinalysis, and blood typing of moderate complexity such as automated ABO/Rh testing and antibody screen testing. The medical laboratory technician shall work under the supervision of a licensed physician and surgeon or a baccalaureate, masters, or doctoral level person licensed pursuant to this chapter. The supervision shall be required during the entire time a medical laboratory technician performs clinical laboratory tests or examinations.
MLT Scope of Practice

- Is limited to select moderately complex tests
- FDA test complexity data base can be found at: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm
- Perform phlebotomy, supervise LPT & CPT1
- Report test results after training and competency has been documented
- MLT Regulations include:
  - Supervisory CLS : MLT ratio of 1:4 be maintained in the clinical laboratory
  - Onsite supervision when testing is being done by an MLT
  - MLTs are required to complete 24 units of continuing education every two years and pay biannual fees to the state
MLT to CLS Articulation 2019

- SB 334 (Pan) Healing Arts: Clinical Laboratories – WATCH

- Would require LFS to establish a pathway program that would authorize a MLT to apply their work experience and training from a CDPH approved MLT training program towards the completion of a CLS training program.

- CAMLT prefers not to legislate a MLT to CLS articulation since duplicative regulation is currently part of the LFS Personnel Update Regulation Package.
Corresponding With Elected Officials

**Do:**
- Arrive on time or earlier
- Be brief and to the point, courteous and reasonable
- Include your name, address and CAMLT Brochure for Legislators
- Come prepared – clearly spell out what needs to be done and what bill is involved
- Be direct about identifying the current problem and how existing laws affect the problem
- Written communication (including email) is free from grammatical and spelling errors

**Don’t:**
- Do not be late
- Address an elected official with an incorrect title; for example, confusing a State Senator with a United States Senator
- Forget to include your address and phone number with your correspondence, including with e-mail correspondence
- Come unprepared – be vague, just complain, or address a legislator in broad generalities
- Wait until the last minute before a bill is heard or is on the floor before contact/writing
Talking Points with Legislators

Purpose:

- It is imperative to educate legislators about clinical laboratory science and the patients who rely on educated, qualified laboratory personnel for accurate and reliable testing results before bills effecting laboratory science are heard in committee or voted on. We want legislators to come to CAMLT first to access the impact of bills to the quality of patient test results before bills are introduced or amended.
Talking Points with Legislators cont’d

Who is CAMLT?

• The California Association for Medical Laboratory Technology is a voluntary, not-for-profit professional organization representing dedicated laboratory professionals throughout the State of California.

Our mission

• Part of CAMLT’s mission is to maintain and improve high quality in laboratory testing by fostering education and working to ensure that legislators understand the impact of new bills in maintaining high quality laboratory results.
Talking Points with Legislators cont’d

What is a clinical laboratory test?
- Laboratory tests take human biological samples such as whole blood, urine, spinal fluid and other body fluids and perform various analytical tests ranging from urine pregnancy through DNA analysis requested by physicians.

Why is it important to maintain high quality laboratory tests?
- Over 80% of clinical and diagnostic decisions are based on the results of laboratory testing.
- Accurate and timely laboratory test results directly correlates with better patient outcomes.
- Maintaining the integrity of the lab personnel standards is essential for accurate and timely laboratory test results.
Who works in the laboratory?

- Laboratory tests are classified as waived, moderate, or high complexity based on the necessary skill and educational level of the testing personnel needed to perform a particular test.
- Most testing personnel are Clinical Laboratory Scientists (CLS) who have at the minimum, a bachelor’s degree and have completed a post-graduate training program in a DPH (Dept of Public Health) approved laboratory. After passing a licensure examination, they perform waived, moderate and high complexity laboratory testing, including analyzing body fluids, cells, and tissue samples.

Who represents CAMLT in Sacramento?

- Public Policy Advocates (PPA) engage in the legislature on CAMLT’s behalf.
CAMLT Website: www.camlt.org

- Legislation tab
  - Legislative Update – Quarterly summary
    - List of bills we are currently tracking:
      - Bill language, amendments and impact
      - CAMLT’s position
      - Bill status
  - Meet Your Legislator
    - Link to CAMLT Grassroots Guide
    - Link to Laboratory Brochure for Legislators
    - Lists of Senators and Assembly Members by Committee and District
    - Link to Lab-PAC information and donation form
    - Link to CAMLT membership information and application