CLINICAL LABORATORY TECHNOLOGY ADVISORY COMMITTEE (CLTAC)
Minutes of the Meeting held on December 1, 2017
Meeting held by videoconference from CDPH Richmond campus, KP Regional Laboratory, North Hollywood, and Telephone Bridge Line

CLTAC Members Participating

Former CLTAC Members Participating
Samuel Chafin, Robert Footlik

California Department of Public Health (CDPH) Staff Participating
Dolapo Afolayan, Elsa Eleco, Ronald Harkey, Robert Hunter, Joselita Joaquin, Tina Kruthoff, Ted Lee, Nema Lintag, Cindy Lloyd, Donna McCallum, Donald Miyamoto, Martha Obeso, Nai Saechao, Robert Thomas, Aaron Webb, Emily Wei, Mary Wogec

Public Members Participating
Michael Aidan, Zenda Berrada, Anna Choi, Amy Daniels, Ilene Dickman, Debbie Ferguson, Nancy Fraize, Nicole Green, Lacey Greene, Brett Holmquist, Susan Kazarian, Susanne Kazailla, Margaret Knapp, Lois Langs, Katya Ledin, Cecilia Min, Valerie Ng, Christine Sabol, Jessica Van Ziffle, Phyllis Walker, Debbie Wilson-Ferguson, Tammy Zinsmeister

Welcome and General Announcements (Rebecca Rosser)
- Meeting opened at 9:00am.
- Rebecca Rosser conducted roll call and determined that a quorum was present.

Approval of September 8, 2017 CLTAC Minutes
- Minor changes were suggested.
- Kathleen Doty moved to approve minutes as amended. Dora Goto seconded.

Department News (Tina Kruthoff)
- New CDPH LFS website design
- California State Auditor Report (remaining issues from 2015 report)
  - Human resources
  - IT resources to replace manual resources (e.g. ELLFS and PERL)
  - Regulations (ongoing)
- Re-accreditation for CDPH
- Legalization of recreational cannabis (effective January 1, 2018)

LFS News (Robert Thomas)
- Branch Report
  - AB 658 (fee holiday for renewal of state licenses) was signed by the Governor (effective January 1, 2018).
Dr. Shohreh Ershadi resigned as Section Chief of Personnel Licensing Section (effective October 31, 2017).
  ▪ LFS is currently working to fill the position.
  ▪ Robert Thomas is serving as interim Section Chief.

Emily Wei, Staff Services Analyst to assist Robert Thomas, was introduced (effective November 15, 2017).

LFS is implementing online systems (e.g. ELLFS and PERL).

- **2018/2019 License Renewal Fees**
  - Martha Obeso will discuss this later in the CLTAC meeting.

**Administrative Items** (Ted Lee)

- **Hiring**
  - LFS is proactively fostering a positive environment and maintaining a strong relationship to keep long-term employees (e.g. vertical growth).
    ▪ LFS promoted two Program Technicians, Lori Marquez and Aaron Webb to Staff Services Analysts.
  - Dolly Luong will attend conferences throughout the state to help fill positions.

- **Website Update**
  - LFS will hold customer service and business correspondence trainings for LFS staff in January and February 2018.

**Electronic Updates**

- **PERL Update** (Aaron Webb)
  - **New functionality:**
    ▪ The renewals system will allow customers to
      - Create, pay for, and submit renewals online.
      - Upload CE certificates and transcripts.
      - Respond to application deficiencies.
      - Order reprints/duplicate licenses and certificates.
      - Receive application updates via email.
    ▪ The initial applications system will allow customers to
      - Upload all required documents (excluding transcripts).
      - Respond to application deficiencies.
      - Pay via MasterCard and electronic check.
      - View all associated “constituent” information including licenses, certificates, and applications.
      - Improve functionality for LFS staff.
  - **Procedural changes**
    ▪ Applications cannot be submitted unless all required documents have been uploaded (excluding transcripts).
    ▪ LFS will conduct quality assurance reviews of renewal applications.
    ▪ LFS no longer issues qualification letters to applicants for certifying examinations.
    ▪ Training programs are no longer required to submit LAB 147-150 forms.
• Notifications of completion will be issued to trainees.
• Trainees will upload documents to their applications.
  o Technical assistance tracking (“Cherwell”)
    ▪ Users can submit online tickets if assistance is needed with account creation and/or application process.
    ▪ LFS IT staff are assigned tickets to assist customers.
• ELLFS Update (Nga Tran)
  o LFS is developing an online application system (ELLFS) to streamline the Laboratory Licensing and Registration section’s paper-based process.
  o ELLFS will allow laboratories to
    ▪ Submit new applications and renewals online.
    ▪ Pay online.
    ▪ Verify license and registration statuses.
    ▪ Review and obtain application statuses.
    ▪ Submit updates online for changes of directorship, ownership, address, license type, testing type, and/or name.

Legislative Update (Mary Wogec)
• AB 613 (Total Protein Refractometer Testing)
  o Authorizes people who have appropriate qualifications to conduct refractometer testing in qualified locations
  o Extensive support with opposition from two groups
  o Ordered to inactive file September 5, 2017
• AB 658 (Clinical Laboratory Licensing Fees)
  o Temporarily suspends the annual renewal fee for clinical laboratory licenses until January 1, 2020
    ▪ Does not affect renewal fees, CLIA fees, or personnel fees
  o Extensive support, no opposition
  o Signed and chaptered September 28, 2017
  o Effective January 1, 2018
• SB 43 (Anti-microbial Resistant Infection Reporting)
  o Requires specified general acute care hospitals and clinical laboratories to submit a report to the department containing an antibiogram of the facility for the previous year
  o Two-year bill

CLTAC Subcommittee Reports
• California State Auditor (CSA) Audit Response (Fred Ung)
  o No report at this time.
• Recruitment and Retention (Jonathan Bautista)
  o No updates at this time.
• Regulations (Rebecca Rosser for Lori Dean-Yoakum)
  o Discussion on completing original charge for subcommittee
    ▪ Subcommittee felt the need for more support from LFS for additional tasks such as FAQs.
LFS felt that original charge was completed and that there are limited resources for additional projects.

**ABMGG Training Changes** (Jessica Van Ziffle, PhD)
- **Goal:** Simplify licensing of laboratory genetics director level
- **Current state of laboratory licensing:**
  - In 2000, licensing established for clinical laboratory directors
  - Clinical Cytogenetics and Clinical Genetic Molecular Biology
    - Doctoral level training in American Board of Medical Genetics and Genomics (ABMGG, formerly ABMG) Clinical Laboratory Genetics programs
    - Concurrent training in approved limited license Clinical Laboratory Scientist (CLS) training programs
      - Clinical Cytogenetics (CC)
      - Clinical Molecular Genetics (CGMB)
    - Individuals working as a licensed CLS for two years after receiving an ABMGG board certification are eligible for a Directors license in a specialty area
      - Biochemical Genetics is not recognized in California
  - **New changes:**
    - ABMGG has merged CCS and CGMBS into one specialty, Laboratory Genetics and Genomics
  - **Outstanding issues:**
    - Specialties not recognized in the Business and Professions Code
      - Laboratory Genetics and Genomics
      - Biochemical Genetics
    - Current genetics laboratory director licensing requirements
      - Methodological principles versus biological discipline

**On-site Licensing Section Update** (Elsa Eleco)

Functions of the section:
- Biennial on-site inspections of California-licensed laboratories located:
  - In-State.
  - Out-of-State.
- Approval of Accrediting Organizations (AOs) for deemed status
- Oversight of California-approved AOs
- Initial state inspections and licensure
  - On-site inspections
  - Issuance or denial of state license
- Complaint handling unit of Laboratory Field Services (includes tracking and investigation)
- Enforcement as a result of complaints, validations, and routine biennial on-site inspections

Inspections completed:
100% of surveys were completed as of June 2017 for in-state clinical laboratories requiring routine biennial surveys (2,475 laboratories as of June 2017).
   o 1,120 were the responsibility of an Accrediting Organization (AO).
   o 48 were the responsibility of LFS’ On-site Licensing Section.
   o 1,307 were the responsibility of LFS’ CLIA section.
100% of surveys were completed as of November 2017 for United States (US)-based out-of-state clinical laboratories requiring routine, biennial surveys (472 laboratories as of August 2017).
   o 335 were the responsibility of an AO.
   o 137 were the responsibility of LFS’ On-site Licensing Section.
100% of surveys were completed as of November 2017 for clinical laboratories located outside the US (9 laboratories as of December 2017).
   o 6 were the responsibility of an AO.
   o 3 were the responsibility of LFS’ On-site Licensing Section.

**CLIA Survey Section Update** (Donna McCallum)

- **CLIA Certificate Renewal**
  o Goal: Reduce the number of phone calls at the CMS regional and central offices
  o State renewal versus CLIA renewal
    ▪ CLIA does not send forms to be completed for renewal.
    ▪ CLIA certificate is renewed by laboratory receiving an invoice and payment of the fees as indicated on the invoice.
  o CLIA Certificate of Compliance
    ▪ Laboratories will receive a payment coupon at least 12 months prior to the expiration of current certificate.
    ▪ If payment is not received prior to expiration date, certificate will automatically terminate.
    ▪ If there is an address or director change, the lab needs to complete the California forms LAB 183 and Lab 193 for changes (do not use the CMS 35 attached to the top of the payment coupon).
  o CLIA Certificate of Accreditation, Waiver and Provider Performed Microscopy Procedures (PPMP)
    ▪ Laboratories will receive a payment coupon 6 months in advance.
  o If a laboratory receives a letter of termination and the letterhead is CDPH, it is referring to the state registration/licensure. The issue must be resolved with the Richmond LFS office.
  o Do not contact CMS Regional Office or CMS Central Office with concerns regarding state licensure/registration; contact the Richmond LFS office.

- **Biennial Inspections**
  o See Elsa Eleco’s report for the number of surveys for both CLIA and On-site Licensing.

- **Validation Inspections**
  o 25 validation inspections were completed by the CLIA section as of September 30, 2017.
Validation inspections must be performed within 90 days of the Accreditation Organization (AO) survey.
- Surveys may be performed simultaneously or as a look-behind survey (which must be performed within 90 days of the AO survey).

- **Proficiency Testing Sanctions**
  - Proficiency testing results are monitored on all non-accredited, non-waived laboratories every 30-45 days to ensure CLIA regulatory compliance.
  - 64 proficiency testing sanctions were completed as of September 30, 2017.
- CLIA information is available on the CLIA website, not the CDPH website.

**Tissue Bank, Blood Banks, and Biologics Section Update** (Robert Hunter)
- All applications and renewals will be sent to the Richmond office (effective January 2018) until online licensing and renewals are implemented for this section (approx. mid 2018).
- Licensing seven new plasma centers
- Investigating contaminated platelet products and failure to follow policies and procedures regarding antibody ID and blood products
- Robert Hunter is authoring an article for the Morbidity and Mortality Weekly Report (MMWR) regarding contaminated platelet products in California and Utah.

**Laboratory Licensing and Registration Section Update** (Martha Obeso)
- **Renewal Fee Letter**
  - AB 658 (authorizes fee holiday for renewal of laboratory licenses) was signed by the Governor in late September.
  - LFS was unable to update the fees to $0 and the letter regarding the renewal application prior to sending letters to the laboratories whose licenses expire in early 2018.
    - LFS sent out a follow-up letter explaining that labs are not required to submit a renewal fee, but are still required to submit a renewal application.
    - LFS IT is able to make the fee correction to the system.
    - If LFS receives a check for the renewal fee, it will return the check to the lab.
  - A new application must be submitted when there is a major change of ownership or director.
- **Termination Notices**
  - Reviewing records in preparation for the online system.
  - Already sent out final notice letters regarding termination of lab license
  - There is confusion about state license and CLIA certification
  - Currently working with individuals who want to reactivate
- In late November, letters were sent to labs that have been exempt from state licensure.
  - If the lab meets the criteria for exemption, the lab needs to send the letter back to LFS with response.
If the lab no longer meets the criteria for exemption, the lab must apply for a license.

**Personnel Licensing Section Update** (Dolapo Afolayan)
- **PHM Report**
  - 28 examinees successfully passed the recent exam.
  - PHM certificates were issued within 10 business days from the date of the last exam.
  - LFS is working to approve a certifying organization to conduct the PHM exam in the future.
  - LFS is in the process of providing training certificates (instead of letters) through PERL.
  - LFS is requesting trainees with approval letters issued before September 2017 to complete an application in PERL for their official certificate.
  - LFS is reviewing and updating the PHM training program.
- **Director Oral Exams**
  - LFS conducted four oral licensing exams this year.
    - Sixteen clinical laboratory director applications have been approved for licensure.
  - American Medical Certification Association (AMCA) has been granted approval to administer its Certified Phlebotomy Technician (CPT) examinations for the purpose of California certification.
- **CE Updates Providers**
  - Monthly Continuing Education (CE) participant reports will replace the CE activity provided during annual renewal (effective February 10, 2018).

**New Business** (Rebecca Rosser)
- **Election of CLTAC Chair**
  - CLTAC bylaws allow an individual to serve two consecutive terms.
  - Dora Goto nominated Rebecca Rosser. Lee Hilborne and John Geisse seconded.
  - CLTAC board members unanimously voted for Rebecca Rosser to serve as CLTAC Chair for 2018.
- **2018 Meeting Dates**
  - March 2, June 1 (Rebecca Rosser will send out a range of proposed dates next week to the CLTAC board), September 7, December 7.

**Future Items** (Rebecca Rosser)
- Lee Hilborne proposed to discuss how the Protecting Access to Medicare Act (PAMA) will impact California during the June meeting as the law is effective January 1, 2018.
- Ted Lee introduced the new CDPH and LFS logos.
- Lee Hilborne called for the meeting to be adjourned. Jonathan Bautista seconded the motion.