CLINICAL LABORATORY TECHNOLOGY ADVISORY COMMITTEE (CLTAC)
Minutes of the Meeting held on May 25, 2018
Meeting held on videoconference from CDPH Richmond campus, KP Regional Laboratory, North Hollywood, and the Telephone Bridge Line

CLTAC Members Participating

Former CLTAC Members Participating
Lorri Dean-Yoakum, Tim Hammill, Carmen Maldonado

California Department of Public Health (CDPH) Staff Participating
Dolapo Afolayan, Dolly Barrica, Toynia Brown, Karen Demby, Elsa Eleco, Elaine Flores, Robert Hunter, Paul Kimsey, Ted Lee, Nema Lintag, Donna McCallum, Donald Miyamoto, Martha Obeso, Jan Otey, Lynnea Rappe, Robert Thomas, Asraf Tootla, Nga Tran, Clint Venable, Hugo von Bernath, Aaron Webb

Public Members Participating
Michael Aidan, Mark Birenbaum, Angela Castillo, Irene Chen, Amy Daniels, Eureka Denning, Denise Driscoll, Theresa Dunning, Diana Dupuy, Brett Holmquist, Elma Kamari Bidkorpeh, Susan Kazarian, Julie Kingery, Shiuland Kwong, Lois Langs, Katya Ledin, Jamie Marks, Cecilia Mui, Liam Port, Shannon Smith-Crowley, Fernando Torres

Welcome and General Announcements (Rebecca Rosser)
- Meeting opened at 9:00AM.
- Rebecca Rosser conducted roll call and determined that a quorum was present.
- Dr. S. Robert Freedman was introduced as the newest CLTAC member; he will be representing California Medical Association (CMA).

Approval of March 2, 2018, CLTAC Minutes (Rebecca Rosser)
- No changes suggested.
- No one objected to approving the meeting minutes; meeting minutes approved.

Department News (Dr. Paul Kimsey)
- Thanked Southern California Kaiser Permanente in making this videoconference possible.
• Announced Susan Fanelli, Acting Assistant Director, will become the Chief Deputy Director of Policy and Programs. The Department will be announcing a new Assistant Director soon.
• Introduced the ArcGIS system for laboratory mapping. Hugo von Bernath will provide more details later in the meeting.
• Informed that the Director had asked for an assessment of public health labs. The report was published in April 2018 and mentioned reorganization. The report is currently under review and no decision has been made.

**LFS Update**

**Branch Report** (Robert Thomas)
- Personnel licensing regulations Package 1 will be ready for public comment by the end of the year.
- LFS has convened a subcommittee to review PHM regulations and submit recommendations by February 2019.
- Introduced Hugo von Bernath who will present the ArcGIS system for laboratory mapping.
- Announced the LFS website was updated to include additional information on inducements.

**Administrative Items** (Ted Lee)
- CMS audit update:
  - Succession plan, which includes the LFS staff completing a survey. LFS will report summary at next meeting.
  - Reorganization, which includes updated duty statements and organizational chart.
- Recruitment:
  - CDPH will host a career fair in Sacramento in June 2018.
  - LFS intends to further utilize LinkedIn.
- Staff development and trainings:
  - Business writing.
  - Customer service.
  - Lean white belt.

**Electronic Updates**

**ELLFS** (Nga Tran)
- Tentative launch in July 2018 for internal users.
- Tentative launch in October 2018 for external users.
- Future additions will include facility website update, user manuals, video tutorials, and postcard notifications.
o Certificates will be redesigned and will include QR codes. Certificates will be sent via email and also traditional mail.

o Beta testing
  ▪ Allows volunteers to test the system for functionality and usability.
  ▪ Email Nga Tran at Nga.Tran@cdph.ca.gov.

• PERL 2 Update and Live Presentation (Aaron Webb)
  o New releases:
    ▪ Renewal video tutorial.
    ▪ New application video tutorial.
    ▪ Renewal manual.
    ▪ New application manual.
    ▪ Key demographic change functionality.
    ▪ Decimals are no longer required for CEUs.
    ▪ Cancelling applications functionality.
    ▪ Language to order a duplicate license/certificate.

  o Renewal challenges:
    ▪ Navigation.
    ▪ Password difficulties.
    ▪ Lack of computer knowledge.
    ▪ Creation of multiple renewal applications.
    ▪ Creation of an account.

  o Renewal improvements:
    ▪ Updating online tutorial.
    ▪ Improving password reset process.
    ▪ WebEx training for employees.
    ▪ Redesigning of login page/profile.

  o Technical assistance tracking:
    ▪ Users can submit tickets.
    ▪ LFS program and information technology staff are assigned to tickets. Assigned staff then reach out to system users.
    ▪ LFS management track ticket assignments to ensure completion, and view metrics to determine areas for quality improvement.

  o Future releases:
    ▪ Quiz on California laboratory law integrated into PERL.
    ▪ Improved name change procedure.
    ▪ Training programs.
    ▪ Continuing Education providers.
    ▪ Enhancements to initial applications and renewals.
    ▪ Shopping Cart improvements.

  o Notes from Q&A:
- You cannot use an electronic signature.
- LFS advises people to create an account now so that it is ready when they need to renew.
- Advised LFS to provide more detail on uploading CEs in the user manual.
- Rebecca Rosser appreciated all the changes made to the system and noted complaints have decreased.
- Email Aaron Webb at Aaron.Webb@cdph.ca.gov.

**ArcGIS Laboratory Mapping** (Hugo von Bernath)
- This mapping system allows the public to locate all the labs in California and will be a valuable resource during emergencies.
- Each dot on the map represents a single active facility and each color represents a different facility type.
- The public is able to conduct statistical analyses and export for research.
- Currently working to finalize screening procedures to ensure certain information stays confidential.
- Notes from Q&A:
  - Typically, only labs open to the public are displayed on the map.
  - There is no set launch date yet. We would like comment and suggestions from the public.
  - Users are able to download the data and do specific searches by license type and address. We will look into creating a search specific to specialty type.
  - The information is drawn from ASPEN and HAL but eventually we will want to transfer to Pegasus.
  - Currently updating on a quarterly basis but will change if needed.

**Legislative Update** (Robert Thomas)
- **AB 613** (Total Protein Refractometer Testing)
  - Would authorize people who have specified qualifications to perform total protein refractometer testing in licensed plasma collection facilities.
  - Ordered to inactive file on September 5, 2017.
- **AB 2281** (Medical Laboratory Technicians)
  - Would expand the work scope of MLTs to include blood smear reviews, microscopic urinalysis, and blood typing of moderate complexity.
  - Introduced on February 13, 2018.
- **AB 2684** (Parent and Child Relationship)
  - Provides procedures for use of genetic testing to determine paternity.
  - Introduced on February 15, 2018.
- **AB 2846** (Organ Transplantation)
Would enact provisions that would improve the effectiveness of organ transplantation for the general public and in minority communities and low-income communities in California.

- **SB 43 (Anti-microbial Resistant Infection Reporting)**
  - Would require specified acute care hospitals and clinical laboratories to submit a report to the department containing an antibiogram of the facility for the previous year.
  - Introduced on December 15, 2016 (two-year bill).

- **SB 1371 (Occupational Licensing List)**
  - Would provide a list of certain occupational licenses and would state that it is the purpose of this provision to establish and maintain a complete list of all occupational licenses required by the State of California.
  - Introduced on February 16, 2018.
  - Dead on April 27, 2018.

**Notes from Q&A:**
- When a bill is introduced and may affect our program, we conduct an internal analysis and recommendation and send it forward.
- CLTAC is not part of the legislative process.
- There are a lot of concerns about AB 2281; please email all specific questions to Robert Thomas at Robert.Thomas@cdph.ca.gov.

**CLTAC Subcommittee Reports**

- **Public Health Lab Regulations** (Dr. Zenda Berrada)
  - Purpose:
    - Update references, definitions, reporting requirements.
    - Cross-walk PHL regulations with comparable regulations for clinical laboratories and reference applicable HSC and CLIA.
    - Provide recommendations for regulatory updates that will support future service provision by public health laboratories.
  - Subcommittee members: Zenda Berrada, Dolapo Afolayan, Katya Ledin, Nicole Green, Megan Crumpler, Patricia Dadone, Rachel Reese, Michael Edwards, Marge Braasch, Michael Janda, Rebecca Rosser, ad hoc.

- **California State Auditor (CSA) Audit Response** (Fred Ung)
  - No updates.
  - Remove this from future agendas.

- **Recruitment and Retention** (Jonathan Bautista)
  - No updates.
o Jonathan Bautista proposed to remove this from agenda and touch base with Ted on monthly basis and reconvene when there’s an update. Rebecca Rosser seconded.

- Regulations Subcommittee Documents (Shiu-Land Kwong)
  o Two additional FAQs were sent to LFS for review and approval.
    ▪ These documents will be voted on at the next CLTAC.

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

- AABB Approval (Elsa Eleco)
  o AABB will be recognized as an accrediting organization (AO) approved by the Department beginning May 21, 2018.

- Validation Inspections
    ▪ Complaint investigations.
    ▪ Different laboratory types.
    ▪ Different specialties and subspecialties.
    ▪ Geographical location—urban and rural areas.
    ▪ Out-of-state (OOS) labs are included.
  o Conducted within 90 days of the AO inspection.
  o Sample at least 5% of labs with deemed status certificates.
  o Disparity Rate of 20%.
  o Proportionate to number of labs under each approved AO.
  o Approx. 1,216 labs inspected by the AOs from May 2015 – June 2017.
    ▪ CAP = approximately 51%.
    ▪ COLA = approximately 25%.
    ▪ JC = approximately 24%.

  o 43+ trips were included in the travel blanket for approval for SFY18-19.
    ▪ Across 21 states.
    ▪ At least 120 labs.
  o Mostly routine inspections, but also includes validations, and complaints.
  o Additional trips will be added as needed.

- Inducements (Asraf Tootla)
  o What is a “Roaming Phlebotomist”?
    ▪ Concerns about “Roaming Phlebotomist”:
      • Currently contacting Office of Legal Services to see if they are compliant.
      • Can violate BPC section 650 depending on business agreement between phlebotomist and company.
How does Laboratory Field Services (LFS) view “Roaming Phlebotomist” in regards to BPC section 650?

- LFS views them as grey zone and in violation. After investigation, compliance will be determined on a case by case basis.
- Not compliant with BPC section 650 but pending investigation and analysis on a case by case basis.

Random Convenience Surveys

- LFS will begin performing random “inducement surveys.”
- LFS will develop a criteria and policy on which facilities to visit for the random “inducement surveys.”

New inducement information can be found the LFS website.

Personnel Licensing Section Update (Dolapo Afolayan)

- Introduction of Toynia Brown
- Director Program Update
  - Personnel Licensing Section conducted oral licensing examination for director level applicants on May 7, 2018.
  - As a result, four clinical laboratory director applications have been approved for licensure.
  - Next exam is scheduled for August 16, 2018.
- MLT Training Program Update
  - LFS will send out renewal notices.

Tissue and Blood Banks, Biologics, and Cytology Section Update (Martha Obeso)

- License Application and Renewal Process (Robert Hunter)
  - LFS is moving biologics applications and renewals to Richmond.
  - For reprints and clerical issues, please email Rose Aduviso at Rosemarie.Aduviso@cdph.ca.gov or Edgar Llanza at Edgar.Llanza@cdph.ca.gov.
  - For all other Biologics issues, please contact Robert Hunter at: rhunter@cdph.ca.gov.
- Stem Cell Therapies—FDA SB 512 (Robert Hunter)
  - The legislature passed SB 512, which is currently in effect regarding non-FDA approved therapy.
  - Regulations require physicians to place the following notice in the office if they perform stem cell therapy:
    - SB 512 / § B&PC 684 “THIS NOTICE MUST BE PROVIDED TO YOU UNDER CALIFORNIA LAW. This health care practitioner performs one or more stem cell therapies that have not yet been
approved by the United States Food and Drug Administration. You are encouraged to consult with your primary care physician prior to undergoing a stem cell therapy.”

- This does not apply to a practitioner who has an IRB-approved IND (Investigational New Device/Drug).

- **Non-binary Gender Issues for Blood and Plasma Collectors** (Robert Hunter)
  - Allows individuals to self-identify as male, female, or non-binary.
    - Allows birth certificates, driver’s licenses, and potentially other documents to be changed.
  - It involves many sections of CA law including Civil Code, H&S Code, and Vehicle Code.
  - Effective January 1, 2019.
  - Blood and Plasma centers use gender for donor safety screening purposes.
    - Hemoglobin/hematocrit safety limits differ for male and female.
    - The use of plasma from females who have been pregnant or have delivered is severely restricted (HLA typing).
    - Blood and Plasma centers are meeting to discuss how to maintain safety standards, how to compare historical records, etc.

**Laboratory Licensing and Registration Section Update** (Martha Obeso)

- **Exempt Laboratories**
  - Cleaning database by reviewing 9,000 clinical laboratory registration records that qualify for exempt status.
  - Phase 1 (waived or PPMP):
    - 4,000 records.
    - Started sending letters in November 2017 that explained how labs can file for exemption etc. Finished sending letters in January 2018. 2,000 labs did not respond so the third and final notice will be mailed out in June 2018.
    - As of April 19, 2018, 3,000 labs responded.
    - Labs that do not reply will have their licenses terminated.
    - Inquiries can be directed to CNCsp@cdph.ca.gov.
  - Phase 2 (moderate or high complexity):
    - 5,000 records.
    - Start in December 2018.
    - Laboratories will be able to reply through ELLFS.
    - Will create FAQs for clarification.
  - May change the prefix given to exempt labs (CNC) to avoid confusion with “CNC” used in ArcGIS laboratory mapping system.

- **Forfeited Licenses**
Failure to renew will result in a forfeiture of the license or registration after a period of 60 days from the expiration date of the license or registration.

Manual terminations:
- Started in August 2017.
- Discovered 3,000 testing sites failed to renew their licenses.
- These testing sites received:
  - A renewal notice.
  - A delinquency notice.
  - A computer generated termination notice 60 days after the expiration date.
- Manual follow through was required.

LFS forfeitures v. CLIA terminations
- LFS: 86% (2940)
- CLIA: 14% (494)

Many testing sites that forfeited their licenses are trying to reactivate.
With ELLFS, forfeiture of licenses will be timelier.

**CLIA Survey Section Update** (Donna McCallum)
- Announced the new Secretary of the Department of Health and Human Services is Alex Azar.
- CLIA Outreach Program – Academic (COPA).
  - COPA goals:
    - Connect with college and university Medical Laboratory Science programs and their students to increase their knowledge of and visibility of CMS/CLIA.
    - Demonstrate the direct link between compliance with CLIA regulations and high quality laboratory testing and, promote medical laboratory science as an important, dynamic and desirable career.
  - COPA update:
    - The CLIA 101 Presentation has reached 8 campuses, 113 students, and 25 faculty in Maryland and Virginia.
    - In 2018 outreach efforts have expanded to events planned by Healthcare Occupations Students of America (HOSA) in DC at TX.
- FDA Recognition of Public Human Genetic Variant Database:
  - Title Revised:
    - To better reflect scope and content.
    - To acknowledge that currently there are no applicable standards that FDA can recognize.
    - To support community engaging in developing standards.
Scope Revised:
- Clarify that the document only specifically applies to NGS-based tests intended to aid clinicians in the diagnosis of symptomatic individuals with suspected germline diseases.

Next Generation Sequencing (NGS):
- Established a Tri-agency NGS Group.
- Coordinating NGS quality efforts with other offices across CDC and APHL to improve implementation of NGS in public health laboratories.
- NGS session held at last Clinical Laboratory Partners forum (ASM, Nov 2017).
- How best do we serve laboratory needs for assuring the quality of NGS testing?

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<th>CLIA Survey Statistics as of April 2018 (CA)</th>
<th>Total</th>
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<tr>
<td>Initials</td>
<td>35</td>
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<tr>
<td>Recertification surveys</td>
<td>342</td>
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<tr>
<td>Validation surveys (accredited labs)</td>
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<tr>
<td>On-site follow-ups</td>
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<tr>
<td>On-site complaints</td>
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<tr>
<td>PT desk reviews and sanctions</td>
<td>20</td>
</tr>
<tr>
<td>Total</td>
<td>408</td>
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**New Business** (Rebecca Rosser)
- A cohort from SFSU applied for licenses in March 2018 but still experienced delays (e.g. processing applications and LPW).
- Robert Thomas asked for individuals experiencing issues to email Aaron Webb at Aaron.Webb@cdph.ca.gov separately.

**Future Items** (Rebecca Rosser)
- Jonathan Bautista moved to close the meeting. Zenda Berrada seconded.
- Meeting closed at 12:28pm.