CLINICAL LABORATORY TECHNOLOGY ADVISORY COMMITTEE (CLTAC)
Minutes of the Meeting held on September 7, 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
Tim Hammill, Carmen Maldonado

California Department of Public Health (CDPH) Staff Participating
Andre Alexander, Toynia Brown, Karen Demby, Elsa Eleco, Joselita Joaquin, Paul Kimsey, Ted Lee, Nema Lintag, Araceli Liu, Yangzhu Long, Lorelei Marquez, Donna McCallum, Donald Miyamoto, Greta Nash, Martha Obeso, Robert Thomas, Nga Tran, Clint Venable, Aaron Webb, Emily Wei, Mary Wogec, Jenny Yun

Public Members Participating
Michael Aidan, Amy Daniels, Denise Driscoll, Nancy Fraize, Brett Holmquist, Carola Howe, Alejandra Ibarra, Susan Kazarian, Margaret Knapp, Shiu-Land Kwong, Lois Langs, Cecilia Mui, Cinco Plumb, Osvaldo Santiago, Matt Silverman, Shannon Smith-Crowley, Debbie Wilson-Ferguson

Welcome and General Announcements (Rebecca Rosser)
- Meeting opened at 9:20AM.
- Rebecca Rosser conducted roll call and determined that a quorum was present.

Approval of May 25, 2018, CLTAC Minutes (Rebecca Rosser)
- No changes suggested.
- No one objected to approving the meeting minutes; meeting minutes were approved.

LFS Update
- Branch Report (Robert Thomas)
  - Thanked all for patience with the technical difficulties.
  - Personnel updates:
    - Five new employees LFS who will be introduced later in the meeting.
Ron Harkey, previous Section Chief of Blood & Tissue Bank Licensing, Cytology Surveillance Section, passed last month.
Martha Obeso is now serving as interim-Section Chief of Blood & Tissue Bank Licensing, Cytology Surveillance Section.

- California Reportable Disease Information Exchange (CalREDIE)
  - CalREDIE is a “secure system that CDPH has implemented for electronic disease reporting and surveillance.”
  - LFS is collaborating with Division of Communicable Disease Control within CDPH to formalize a procedure regarding CalREDIE.

- Medical Laboratory Technician law
  - Will go into effect January 1, 2019.
  - Will discuss corresponding impact at the December 7, 2018, CLTAC meeting.

- 2018 AAB Public Health Microbiologist Examination Results
  - This exam is composed of two parts: (1) basic knowledge and (2) PHM.
  - This exam was tailored to California certification.
  - There were a total of 23 examinees in San Francisco and Los Angeles. 20 passed and 3 failed.
  - The next exam is scheduled for December 16, 2018.

- Administrative Items (Ted Lee)
  - State Audit Response
    - Regulations package
      - Recently hired someone from UC Davis to conduct the fiscal and economic analysis.
    - Electronic systems
      - Nga Tran will present on ELLFS.
      - Aaron Webb will present on PERL.
  - Recruitment and retention
    - LFS promoted 21 employees (10 within Examiner series, 6 within the analyst series, and 5 within the program technician series.)
  - Workload Assessment
    - LFS is currently understaffed and working with the Director’s Office and HRB on a solution that may be presented at the next CLTAC meeting.

Electronic Updates
- ELLFS (Nga Tran)
  - Live demonstration of ELLFS (i.e. new application)
- Web page
  - (1) Apply (for clinical laboratory registration or clinical laboratory license), (2) Renew, (3) Account, (4) Look-up, (5) Help, and (6) More
- Features
  - Auto verification
  - Auto populates license type, complexity, fee depending on type of tests selected
  - Integration with LPW (auto populate information from LPW)
  - Payment and corresponding receipt (PDF and emailed)
- Email Nga.Tran@cdph.ca.gov
- **PERL 2** (Aaron Webb)
  - New releases:
    - “Remove” button added to “Shopping Cart” section of application.
    - Security feature added in duplicate order process.
    - “Help” link created in profile banner.
  - Technical challenges:
    - Navigation of the system.
    - Creating an account.
  - Technical improvements:
    - Redesigning of user profile page is near completion.
    - Certificates, licenses, permits, and registration portal (CLPR) is near completion.
  - Technical assistance tracking:
    - Use of Cherwell technical assistance tracking program.
    - Users submit tickets online if assistance is needed with account creation and/or application process.
    - Users can submit tickets by visiting the “Contact Us” link within the application, or by visiting [https://accountportal.cdph.ca.gov/ContactUs.aspx](https://accountportal.cdph.ca.gov/ContactUs.aspx)
    - LFS program and information technology staff are assigned to tickets; assigned staff reach out to system users to provide assistance
    - LFS management track ticket assignments to ensure completion, and view metrics to determine areas for quality improvement of system and/or website information
  - Future releases:
    - New Personnel Licensing Search page
    - Quiz on California state law integrated into PERL
    - CLPR
Training programs
Continuing Education providers
Enhancements to initial applications and renewals

- Email Aaron.Webb@cdph.ca.gov

**Legislative Update** (Mary Wogec)

- **AB 613 (Total Protein Refractometer Testing)**
  - Would authorize people who have specified qualifications to perform total protein refractometer testing in licensed plasma collection facilities.
  - Effective for a two-year trial period (2019-2021)

- **AB 1627 (Certified Phlebotomy Technicians)**
  - Would authorize a certified phlebotomy technician to withdraw blood from, and flush, a peripheral intravenous catheter upon authorization from a licensed physician and surgeon, if he or she meets certain requirements.
  - Introduced on February 17, 2017.
  - Dead on August 17, 2018.

- **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.
  - Effective on January 1, 2019.

- **AB 2684 (Parent and Child Relationship)**
  - Provides procedures for use of genetic testing to determine paternity.
  - Introduced on February 15, 2018.
  - Effective on January 1, 2019.

- **AB 2846 (Organ Transplants)**
  - Would declare the intent of the Legislature to enact provisions that would improve the effectiveness of organ transplantation for the general public and in minority communities and low-income communities in California.
  - Introduced on February 16, 2018.
  - Dead on May 25, 2018.

- **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.
  - Dead on June 29, 2018.

- **SB 1371 (Occupational Licensing)**
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.

**CLTAC Subcommittee Reports**

- **Public Health Lab Regulations** *(Dr. Zenda Berrada)*
  - Projected dates:
    - Finalize review and draft report by December 2018.
    - Submit report with recommended updates to CLTAC for review by February 2019.
    - Receive comments from CLTAC at March 2019 meeting.
  - Short-term goals:
    - Cross-walk PHL regulations with comparable regulations for clinical laboratories
    - Reference applicable HSC and CLIA to see where there may be need for alignment.
    - Work through regulatory sections that are still pending
  - Subcommittee members:
    - Zenda Berrada, PHM, CLS(M) – Chair, Dolapo Afolayan, PHM, CDPH-LFS, Katya Ledin, PHM, CDPH-IDBL, Nicole Green, PHM, CLS(M), Megan Crumpler, PHM, Patricia Dadone, PHM, Rachel Reese, PHM, CLS, Michael Edwards, PHM, Marge Braasch, CLS, Michael Janda, PHM *(ad hoc)*, Rebecca Rosser, CLS *(ad hoc)*
  - Twice monthly calls (Thursdays from 1:30PM-3:00PM)
    - [https://global.gotomeeting.com/join/608662245](https://global.gotomeeting.com/join/608662245)
    - United States: +1 (786) 535-3211
    - Access Code: 608-662-245

- **Regulations Subcommittee Documents** *(Shiu-Land Kwong)*
  - California Lab Directorship FAQs
    - Original document was approved by CLTAC in September 2016.
    - FAQ revision was completed in March 2018:
      - LD Responsibilities
      - Differentiation between CLIA LD & California LD
      - Delegation of Responsibilities
      - Lab Director Change: Notification Requirements
  - Medical Laboratory Technicians (MLT) in California FAQ
    - Document was drafted based on existing law and regulations on MLT
New duties permitted under AB 2281 are not included.
Test Complexity of Tests and Examinations
Examples of Test complexities - Various bacteriology and microbiology procedures
Supervision Requirements for MLTs
  o Requests CLTAC to approve the documents or provide directions for next steps.
      ▪ Bob Thomas provided feedback and comments based on concerns expressed by LFS’ legal counsel.

Personnel Licensing Section Update (Toynia Brown)
  • Introduced Andre Alexander and Greta Nash, PhD, as new staff in the Personnel Licensing Section.
  • Personnel Licensing Section conducted oral licensing examination for director level applicants on August 6, 2018.
      o Four clinical laboratory director applications have been approved for licensure
      o Clinical Cytogeneticist: 2
      o Clinical Genetic Molecular Biologist: 1
      o Clinical Chemist: 1

Tissue and Blood Banks, Biologics, and Cytology Section Update (Clint Venable)
  • Tissue Bank Update
      o Policies and procedures project
        ▪ Goal: To create comprehensive policies and procedures for the Tissue Bank Licensing Section
        ▪ Task: To gather information and diagram all daily and monthly activities performed by the section.
        ▪ Status: The information has been assembled and diagrammed.
        ▪ The information will be used to assemble a narrative Policies and Procedures Manual for the program.
      o Regulation project
        ▪ Task: To review statutes and pertinent guidelines and standards and outline a draft text.
        ▪ Status: The regulations writing team has been assembled and is meeting twice weekly.
        ▪ The team plans to complete regulations and supporting documentation for submission to the Office of Regulations by the end of 2020.
**Laboratory Licensing and Registration Section Update** (Martha Obeso)

- Introduced Maria Quitugua and Maria Lizza Ronquillo Orante as new staff in the Laboratory Licensing and Registration Section.
- Announced Nai Saechao had been promoted to an Associate Governmental Program Analyst.
- Manual Terminations:
  - Project started in August 2017 to manually terminate licenses in our database
  - 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.
  - Termination is a continuous project.
- Final revised notice of termination (rev. 8/23/18)
  - Added the following information:
    - Disregard this notice if you have already submitted the required forms and fees.
    - Attn: Box 500 Reactivations
    - Do not contact the Centers for Medicare & Medicaid Services (CMS) offices.
    - Visit our website [http://cdph.news/reactivations](http://cdph.news/reactivations) or emails us at LFSReactivations@cdph.ca.gov
    - Required Forms for Reactivation of Terminated License or Registration (page 2)
- Schedule of notice:

<table>
<thead>
<tr>
<th>Response type</th>
<th>1&lt;sup&gt;st&lt;/sup&gt; batch total (July 12, 2018)</th>
<th>2&lt;sup&gt;nd&lt;/sup&gt; batch total (August 2, 2018)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivation received</td>
<td>70</td>
<td>54</td>
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<tr>
<td>Inquiry</td>
<td>49</td>
<td>21</td>
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<tr>
<td>Returned mail</td>
<td>73</td>
<td>29</td>
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<tr>
<td>Closure</td>
<td>2</td>
<td>0</td>
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<tr>
<td>No response from the lab</td>
<td>281</td>
<td>381</td>
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<tr>
<td>Grand total</td>
<td>475</td>
<td>485</td>
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  - 3<sup>rd</sup> batch is scheduled for September 2018
- Summary:
  - Termination project is ongoing
  - Both State registration/license and CLIA certification is required.
  - Many testing sites that have forfeited their licenses are trying to reactivate.
o When we transition to the new online system, terminations will occur automatically.
  o For more information, visit our website at http://cdph.news/reactivations

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

- CLIA waiver by application decision summaries pilot
  - Under CLIA the FDA categorizes in vitro diagnostic (IVD) tests by their degree of complexity waived, moderate and high complexity testing. Test are waived under 42CFR 493.15 (c), or cleared or approved for home use or for over the counter use are automatically categorized as waived following clearance approval.
  - A manufacturer of a test categorized as moderate complexity testing may request categorization of the test as waived through a CLIA Waiver by Application (CW) (/MedicalDevices/DeviceRegulations and Guidance /IVDRegulatoryAssistance/ucm393233.htm) submission to FDA. In a CW the manufacturer provides evidence to the FDA that the tests meets the CLIA statutory criteria for waiver, 42USC 263a (d)(3).

- 1st CLIA waived complete blood count (CBC) analyzer
  - **Sysmex XW-100 Automated Hematology Analyzer:**
    - Reports 12 hematology parameters including 3-part WBC differential
    - Cleared and CLIA waived through the Dual Submission pathway
    - For more info, see the K172604 and CW170012 Decision Summaries and the April 2018 CLIA Meeting FDA Update Slides

<table>
<thead>
<tr>
<th>CA laboratories by certificate type</th>
<th>July 2018</th>
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<tbody>
<tr>
<td>Waived</td>
<td>17,070</td>
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<tr>
<td>PPMP</td>
<td>3,055</td>
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<tr>
<td>Compliance</td>
<td>1,509</td>
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<tr>
<td>Accreditation</td>
<td>1,193</td>
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<tr>
<td>Total</td>
<td>22,827</td>
</tr>
</tbody>
</table>

- CLIA survey statistics as of July 2018

<table>
<thead>
<tr>
<th>State: California</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initials</td>
<td>44</td>
</tr>
<tr>
<td>Recertification surveys</td>
<td>474</td>
</tr>
<tr>
<td>Total initial and recertification surveys</td>
<td>518</td>
</tr>
<tr>
<td>Validation surveys—accredited labs</td>
<td>8</td>
</tr>
<tr>
<td>On-site follow ups</td>
<td>3</td>
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<tr>
<td>On-site complaints</td>
<td>3</td>
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<tr>
<td>PT desk reviews &amp; sanctions</td>
<td>27</td>
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<tr>
<td>Total CLIA surveys</td>
<td>559</td>
</tr>
</tbody>
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**On-site Licensing Section Update** (Elsa Eleco)

- Biennial on-site inspections of California-licensed laboratories located in-state and out-of-state
- Combined in-state and out-of-state survey summary report from May 2016-June 2018

<table>
<thead>
<tr>
<th>In-state and OOS</th>
<th>AO</th>
<th>LFS on-site</th>
<th>LFS CLIA</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total facilities</td>
<td>1622</td>
<td>165</td>
<td>1682</td>
<td>3469</td>
</tr>
<tr>
<td>Required surveys</td>
<td>1496</td>
<td>140</td>
<td>1209</td>
<td>2845</td>
</tr>
<tr>
<td>Survey not required June 2018 quarter*</td>
<td>126</td>
<td>25</td>
<td>473</td>
<td>624</td>
</tr>
<tr>
<td>Completed surveys</td>
<td>1496</td>
<td>140</td>
<td>1209</td>
<td>2845</td>
</tr>
<tr>
<td>% completed</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

- *Survey not required June 2018 quarter: new closed, withdrawn, denied, merged

<table>
<thead>
<tr>
<th>In-state</th>
<th>AO</th>
<th>LFS on-site</th>
<th>LFS CLIA</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total facilities</td>
<td>1267</td>
<td>31</td>
<td>1682</td>
<td>2980</td>
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<tr>
<td>Required surveys</td>
<td>1153</td>
<td>29</td>
<td>1209</td>
<td>2391</td>
</tr>
<tr>
<td>Survey not required June 2018 quarter*</td>
<td>114</td>
<td>2</td>
<td>473</td>
<td>589</td>
</tr>
<tr>
<td>Completed surveys</td>
<td>1153</td>
<td>29</td>
<td>1209</td>
<td>2391</td>
</tr>
<tr>
<td>% completed</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

- *Survey not required June 2018 quarter: new closed, withdrawn, denied, merged

<table>
<thead>
<tr>
<th>Out-of-state</th>
<th>AO</th>
<th>LFS on-site</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td>Total facilities</td>
<td>355</td>
<td>134</td>
<td>489</td>
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<tr>
<td>Required surveys</td>
<td>340</td>
<td>111</td>
<td>451</td>
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<tr>
<td>Survey not required June 2018 quarter*</td>
<td>15</td>
<td>23</td>
<td>38</td>
</tr>
<tr>
<td>Completed surveys</td>
<td>340</td>
<td>111</td>
<td>451</td>
</tr>
</tbody>
</table>
*Survey not required June 2018 quarter: new closed, withdrawn, denied, merged

- Other survey types performed by On-Site Licensing Inspection section
  - Initial state surveys
  - Validation surveys
  - Complaint surveys

- “Comments” received from in-state and OOS licensed laboratories:
  - Inspection scheduled earlier, even though inspections are only required every two years.
  - Inspector took photographs…
  - Unannounced complaint investigation was performed. Was this legal?
  - We had a ‘surprise’ (one week notice) inspection.

- **California Business and Professions Code section 1225.**
  - (a) In order to carry out this chapter, any duly authorized representative of the department may do any of the following:
    - (1) Enter or inspect on an announced or unannounced basis any building, premise, equipment, materials, records, or information at any reasonable time to secure compliance with, or prevent a violation of this chapter or the regulations adopted pursuant thereto.
    - (2) Inspect, photograph, or copy any records, reports, test results, test specimens, or other information related to the requirements of this chapter or the regulations adopted pursuant thereto.
    - (3) Secure any sample, photograph, or other evidence from any building or premise for the purpose of enforcing this chapter or the regulations adopted pursuant thereto.

**New Business** (Rebecca Rosser)
- 2019 CLTAC Chair Nomination
  - Kathleen Doty nominated Jonathan Bautista.
  - Dora Goto, Zenda Berrada, John Geisse and others seconded.

**Future Items** (Rebecca Rosser)
- Meeting closed at 12:35pm.