

## **CLINICAL LABORATORY TECHNOLOGY ADVISORY COMMITTEE (CLTAC)**

Minutes of the Meeting held on September 6, 2019

Meeting held on videoconference from CDPH Richmond campus, KP Regional Laboratory, North Hollywood, and the Telephone Bridge Line

### **CLTAC Members Participating**

Jonathan Bautista, Zenda Berrada, Marjorie Braasch, Kathleen Doty, S. Robert Freedman, William Gardner, Dora Goto, Gabor Hertz, Daniel Leighton, Rebecca Rosser, Fred Ung

### **Former CLTAC Members Participating**

Carmen Maldonado

### **California Department of Public Health (CDPH) Staff Participating**

Dolapo Afolayan, Patricia Bolivar, Yu-Chen Chang, Megan Cornejo, Karen Demby, Elsa Eleco, Paul Kimsey, John King, Ted Lee, Jerrell Limos, Nema Lintag, Yangzhu Long, Elizabeth Lucas, Lorelie Marquez, Donna McCallum, Greta Nash, Martha Obeso, Paula Schultz, Robert Thomas, Armando Tiong, Nga Tran, Clint Venable III, Hugo von Bernath, Emily Wei, Mary Wogec

### **Public Members Participating**

Angela Aguiluz, Elma Kamari Bidkorpeh, Lauren Bongo, Diana Dupuy, Brett Holmquist, Shiu-Land Kwong, Lois Langs, Jamie Marks, Cecilia Mui, Cinco Plumb, Stacy Ralston, Alden Rivas, Pat Rivas, Rodney Roath, Christine Sabol, Osvaldo Santiago, Laura (Last name),

### **Welcome and General Announcements** (Jonathan Bautista)

- Meeting opened at 9:08 AM.
- Jonathan Bautista conducted roll call and determined that a quorum was present.

### **Approval of June 7, 2019, CLTAC Minutes** (Jonathan Bautista)

- Minor changes made:
  - Page 1 “July 1, 2021” → “July 1, 2020” (date)
  - Page 2 “March 27, 20” → “March 27, 2019” (date)
- Motion to approve by S. Robert Freedman
- Seconded by Zenda Berrada

### **Department News** (Paul Kimsey)

- Dr. Karen Smith resigned as Director of CDPH effective July 1, 2019.
- Susan Fanelli is the current acting Director.

- Dr. Charity Dean is the current acting State Public Health Officer.
- Laboratory reorganization project is scheduled to become effective July 1, 2020.

## **LFS Update**

### **Branch Report** (Robert Thomas)

- Thanked Robert Hunter for his service as he retired from LFS.
- Tissue Derived Therapeutics (Stem Cell Therapy).
  - Field of stem cell therapy (regenerative medicine) continues to expand.
  - Dr. Karen Smith and Dr. Charity Dean convened a working group to address issues of stem cell manufacturers, distributors, and clinics.
  - This working group consists of staff from LFS, CDPH Food and Drug Branch, and Healthcare Associated Infections Program.
  - California law requires:
    - A California Biologics license for facilities collecting, producing, storing, or distributing stem cell products derived from circulating blood.
    - A California Tissue bank license for facilities collecting, producing, storing, or distributing stem cell products derived from tissue other than blood.
- LFS Update.
  - BPC section 1228 specifies that CLTAC is convened to assist the Department in issues pertaining to clinical laboratories licensed under Chapter 3 of the BPC.
  - Jonathan Bautista no longer works for a clinical laboratory.
    - Mr. Bautista may serve the duration of his term as he was employed by a clinical laboratory at the time of appointment.
    - Mr. Bautista will not be eligible for reappointment.
  - Tissue banks, blood banks, and biologics production facilities are licensed under the Health and Safety Code, and are not part of CLTAC mandate.
- Annual Response to California State Audit Report of 2015.
  - Three of the ten findings in this report are currently in progress towards full implementation.
  - The three outstanding findings are recruitment and retention and succession planning, information technology improvements, and development of regulations.
  - LFS is currently working to complete a succession plan.
  - PERL (personnel licensing) was fully online November 2017, had some issues in 2018, and as of June 2019 created a new license printing feature.

- ELLFS (Electronic Laboratory Licensing and Registration for Facilities System) will go online internally in September 2019, and will be online for external customers in early 2020.
- LFS completed work on two regulation packages, with eight more in progress.
- LFS continues to work on CLIA Crosswalk Part 2 (DPH-16-002), which retains six sections of California law more stringent than CLIA requirements.
- Independent Phlebotomy.
  - Due to an increase in inquiries from the public, LFS is revisiting this issue.
  - The issue has been discussed by CLTAC before, but no report has been finalized.
  - LFS completed an internet search that identified numerous businesses billing themselves as:
    - “Independent Phlebotomy.”
    - “Mobile Phlebotomy.”
    - “Concierge Phlebotomy.”
  - California law does not allow phlebotomists to work independently.
    - BPC section 1246 refers to the requirements of phlebotomists.
    - 17 CCR section 1034 refers to phlebotomist supervision requirements.
  - BPC section 1228 authorizes LFS to appoint subcommittees.
  - LFS is appointing a subcommittee to study phlebotomists operating independent of a clinical laboratory.
  - The findings reported by the subcommittee will assist LFS with drafting a policy on the issue.
  - This is to be reported before the December 6, 2019, CLTAC meeting.
  - Marjorie Braasch made a motion to accept the subcommittee charge and Zenda Berrada seconded the motion.

#### Administrative Items (Ted Lee)

- The call center relaunched in late March.
- The call center responds to calls made to phone number 510-620-3800.
- Callers have the option to wait on hold or send an email to [LFScc@cdph.ca.gov](mailto:LFScc@cdph.ca.gov).
- The turnaround time is better through email than on the phone.
- Ted Lee provided his email for any pressing issues: [ted.lee@cdph.ca.gov](mailto:ted.lee@cdph.ca.gov).
- Donna McCallum provided her work phone number 213-620-6160 for questions specifically concerning CLIA.

## **Electronic Updates**

### **ELLFS** (Nga Tran)

- LFS is making sure records are not missing information as they are transferred to the new system.
- LFS is currently training staff on ELLFS to ensure there are no bugs.
- ELLFS postcard will be provided to the stakeholders.
- PDF certificates will be emailed to laboratories as LFS staff processes applications.
- The QR code will link directly to the new LFS facility license verification website.
  - This can only be completed using a smart phone.
- Beta testing invitation will be sent out via email.
  - Email Nga Tran at [nga.tran@cdph.ca.gov](mailto:nga.tran@cdph.ca.gov) if interested in participating.

### **PERL** (Dolapo Afolayan)

- Effective June 18, 2019, laboratory personnel can log on to their online account to download and print their license.
- There is no limit to how many times an active license may be printed.
- The licenses will contain a bar code that can be scanned by a smart phone.
  - Scanning the bar code will connect to the LFS personnel license verification website.

## **Legislation Update** (Mary Wogec)

- Of ten bills assigned to LFS this legislative session, five have become two-year bills:
  - AB 601, Health Facilities
  - AB 617, Stem Cell Therapies Notice
  - AB 810, Organ and Tissue Transplantation
  - AB 822, Phlebotomy
  - AB 1271, Licensing Examinations
- Three bills were assigned to LFS as watch bills:
  - AB 476, California Opportunity Act of 2019
  - AB 922, Oocyte Donors
  - SB 180, Gene Therapy Kits (Signed and chaptered July 30, 2019, effective January 1, 2020)
- Two bills assigned to LFS for analysis have been passed:
- AB 785 (Gamete Banks)
  - Would require a gamete bank to collect and maintain, in addition to the identifying information and medical information described above, any other contact information provided by the donor at the time of the donation and records of gamete screening and testing.

- Introduced on February 12, 2019, amended March 21 and March 27, 2019.
- Enrolled August 22, 2019, and presented to the Governor.
- SB 334 (MLT Articulation to CLS)
  - Would require the State Department of Public Health to establish a pathway program that would authorize a licensed medical laboratory technician (MLT) to apply work experience and training from a Department-approved MLT training program towards the completion of a CLS training program. The bill requires the Department to establish a pathway program by January 1, 2022.
  - Introduced on January 19, 2019, amended May 28, 2019.
  - Signed and chaptered July 30, 2019, effective January 1, 2020.

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

- California-licensed laboratories located in state and out of state are to have biennial on-site inspections.
- There must be either an on-site inspection or a desk review conducted by an On-Site Licensing examiner to issue the initial state license.
- OOS laboratory inspections from July 2018 to June 2019:
  - 128 laboratories were scheduled for inspection.
  - 43 laboratories had switched to a Department-approved Accrediting Organization.
  - 12 laboratories had ceased testing California samples.
  - 73 laboratories that required inspections were completed.
- 102 laboratories across 32 states will be inspected from July 2019 through June 2020 involving 53 trips.
- 6 out of the country laboratories are scheduled to be inspected from July 2019 through June 2020.
- On-Site Licensing Section tracks LFS complaints.
  - If the complaint is a personnel licensure complaint, it will be tracked and then forwarded to Personnel Licensing Section to correspond with the complainant.

### **Personnel Licensing Section Update** (Dolapo Afolayan)

- Jerrell Limos has been promoted to Staff Services Analyst.
- Swee Mg Yow has been promoted to Program Technician II.
- New applications:
  - June and July 2019, Personnel Licensing Section (PLS) approved as many new applications as received.

- August 2019, PLS received more applications than approved.
- Renewal applications:
  - June, July and August 2019, PLS approved as many renewal applications as received.
- PERL is improving the efficiency of the application approval process.

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

- Laboratory Licensing and Registration Section (LLRS) welcomes new Program Technician II, Michele Middleton.
- ELLFS user acceptance training allows staff to test out the new online system that will simplify the application process.
- Renewal notices are mailed out 75 days prior to a laboratory's expiration date.
- Laboratories are strongly encouraged to check online for renewal notice information when their expiration date approaches.
- Laboratories will receive a termination notice if they fail to provide requested documents.
  - Laboratories are advised not to contact CLIA should they receive a termination notice.

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

- CLIA Survey Section welcomes two new hires:
  - Examiner I, John King
  - Examiner I, Paula Shultz
- With two examiners, CLIA Survey Section is fully staffed.
- CLIA Survey Activity Report in the state of California (May – July 2019):
  - 23 laboratories had their initial survey.
  - 185 laboratories were recertified.
  - 10 laboratories received proficiency testing review sanctions.
  - 1 laboratory needed an on-site follow up.
- The Tri-Agency Task Force for Emergency Diagnostics (TTFED) was created to promote coordination among three federal agencies; CDC, FDA, and CMS.
- TTFED was established to facilitate rapid authorization of emergency assays and provide timely recommendations for rapid laboratory implementation.
- TTFED has created a draft coordination process for CDC Emergency Use Authorization (EUA), and EUA assays.
- TTFED plans to develop verification panels to help laboratories quickly implement EUA assays at the onset of the next emergency.

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

- Tissue and Blood Banks, Biologics, and Cytology Section is managed by both Robert J. Thomas and Martha Obeso.
- Refractometer Study:
  - AB 613 was signed into law in 2018.
    - Provided authorization to people with specified qualifications to perform total protein refractometer testing.
    - Provided authorization to the Department to collect information from licensed plasma collection centers where such authorized people are performing the testing.
  - A questionnaire was sent to all plasma collection centers that hold a California biologics license.
  - This survey closed on August 31, 2019.
- The group emails for this section are:
  - [LFTissue@cdph.ca.gov](mailto:LFTissue@cdph.ca.gov)
  - [LFSBiologics@cdph.ca.gov](mailto:LFSBiologics@cdph.ca.gov)
  - The staff in this section are cross-training between tissue and blood banks, and biologics to ensure prompt responses to all inquiries.

**New Business** (Jonathan Bautista)

- Accepted a charge to develop the Independent Phlebotomy Subcommittee.
  - Megan will send an email to determine who is interested in joining.

**Future Items** (Jonathan Bautista)

- Future item proposed by Zenda Berrada:
  - To consider reviewing the new title 17 regulation updates and effects on laboratory recording at the next meeting.
- Next meeting December 6, 2019.
- Meeting closed at 11:41 pm.