CLINICAL LABORATORY TECHNOLOGY ADVISORY COMMITTEE (CLTAC)

Minutes of the Meeting held on March 1, 2019
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
Robert Footlik, Lorri Dean-Yoakum, Lee Hilborne

California Department of Public Health (CDPH) Staff Participating
Dolapo Afolayan, Toynia Brown, Yu-Chen Chang, Elsa Eleco, Robert Hunter, Ted Lee, Nema Lintag, Greta Nash, Robert Thomas, Nga Tran, Hugo von Bernath, Emily Wei, Mary Wogec, Jenny Yun

Public Members Participating
Lauren Bongo, Amy Daniels, Nancy Fraize, Justin Haugenberg, Brett Holmquist, Carola Howe, Shiu-Land Kwong, Lois Langs, Carmen Maldonado, Jamie Marks, Margie Morgan, Cecilia Mui, Cinco Plumb, Rodney Roath, Nancy Stratton, Tammy Zinsmeister

Welcome and General Announcements (Jonathan Bautista)
- Meeting opened at 9:03 AM.
- Jonathan Bautista conducted roll call and determined that a quorum was present.
- Jennifer Schiffgens resigned from the CLTAC board.

Approval of December 7, 2018, CLTAC Minutes (Jonathan Bautista)
- No changes suggested.
- No one objected to approving the meeting minutes; meeting minutes were approved.

Department News (Robert Thomas for Paul Kimsey)
- The Centers for Medicaid and Medicare Services San Francisco Regional Office and the Office of the State Public Health Laboratory Director, and Laboratory Field Services have been meeting regularly for informational purposes.
- The Clinical Laboratory Improvement Advisory Committee (CLIAC) appointed a workgroup to provide advice to CLIAC for consideration in making recommendations to the Department of Health and Human Services on revising
CLIA personnel regulations. Dr. Paul Kimsey represents CDPH while Dr. Lee Hilborne is the chair of the workgroup.

- The goal to complete consolidation of all state laboratories is July 1, 2019.

**LFS Update**

- **Branch Report** (Robert Thomas)
  - Thanked South California Kaiser Permanente for making this videoconference possible.
  - Thanked Jennifer Schiffgens as she resigned from the CLTAC board.

- **Administrative Items** (Ted Lee)
  - LFS has experienced ongoing challenges about how to be responsive to the public while processing applications.
  - Call center opened in December 2018 and closed in late January 2019. LFS is planning on reopening the call center in April 2019.
  - The 510.620.3800 voicemail has been updated and currently instructs constituents to contact us through the LFS website. Designated LFS staff members respond to those inquiries.
  - LFS is hiring Program Technician IIs.

**Electronic Updates**

- **ELLFS** (Nga Tran)
  - Purpose of customer beta testing:
    - Demonstrate the system to our participants.
    - Allow our participants to interact with the application system.
    - Gather feedback.
  - Conducted our first customer beta testing in December 2018.
  - Thanked 10 participants with representatives from Dignity Health, Southern and Northern Kaiser, Solano County, and McKesson.
  - Beta testing schedule:
    - Morning session:
      - Create a business profile.
      - Create a new testing site.
      - Apply for an application.
      - Pay for the application.
    - Afternoon session:
      - Summarize testing experience.
      - Discuss application system.
  - Received 60 suggestions from the beta testing session.

- **ArcGIS** (Hugo von Bernath)
Due to other program priorities, we have not been able to integrate the suggestions proposed during the previous CLTAC meeting.

Map is available at https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/Laboratories-In-State-Map.aspx.

In the future, the information available on the map will be updated on a quarterly basis.

**Legislation Update** (Mary Wogec)

- **AB 476 (California Opportunity Act of 2019)**
  - Introduced on February 12, 2019
  - Would require the Department of Consumer Affairs to create a task force to study and write a report of its findings and recommendations regarding the licensing of foreign-trained professionals, with the goal of integrating foreign-trained professionals into the state’s workforce.

- **AB 617 (Stem Cell Therapies Notice)**
  - Introduced on February 14, 2019
  - Would make nonsubstantive changes to the current requirement that licensed health care practitioners who perform stem cell therapies that are subject to regulation by the United States Food and Drug Administration (FDA), but are not FDA-approved, communicate to their patients specified information regarding the therapies in a notice and in writing prior to providing the initial stem cell therapy.

- **AB 810 (Organ and Tissue Transplantation)**
  - Introduced on February 20, 2019
  - Would require the Department of Public Health to convene a working group to evaluate ways to provide organ transplants to uninsured or undocumented residents of the state who are ineligible for organ transplants due to financial hardship, and submit its findings and recommendations to the Legislature.

- **AB 822 (Phlebotomy)**
  - Introduced on February 20, 2019
  - Would state the intent of the Legislature to enact legislation to authorize trained phlebotomists to utilize new devices or procedures to withdraw blood.

- **AB 844 (License Posting)**
  - Introduced February 20, 2019
  - Would authorize clinical laboratory personnel licenses or renewal permits to be stored in a file or maintained electronically, and would require them to be produced to the department upon request.
• AB 994 (Health Care Practitioner Identification)
  o Introduced on February 20, 2019
  o Would make nonsubstantive changes to provisions requiring a health care practitioner, as defined, to wear a name tag while working that discloses the practitioner’s name and license status.

• AB 1271 (Licensing Examinations)
  o Introduced February 21, 2019
  o Would require the Department of Consumer Affairs to provide a report to the Assembly Committee on Business and Professions and the Senate Committee on Business, Professions and Economic Development that contains specified information relating to licensing examinations for each licensed profession and vocation under the department’s jurisdiction.

• SB 325 (Anatomical Gifts)
  o Introduced on February 15, 2019
  o Would add authorization to allow an anatomical gift to be made to approved nursing schools, in addition to a hospital, accredited medical school, dental school, college, university, or organ procurement organization, for research or education.

• SB 334 (MLT Articulation to CLS)
  o Introduced on February 19, 2019
  o 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, as specified.
  o Contact Marge Braasch at braasch@earthlink.net if you have any comments or suggestions, as she will be able to pass them to the legislator.

**CLIA Personnel Regulations** (Lee Hilborne)
• CLIAC recommended the formation of a working group to advise the committee on how to respond to the personnel questions asked by Centers for Medicare and Medicaid Services (CMS) such as the following:
  o The educational requirements necessary for laboratory personnel, including possible use of competency exams/other key performance indicators, and leveraging the cumulative experience of existing accreditation bodies.
  o The requirements for clinical laboratory directors, supervisory positions, and technical consultants: supervisory experience for laboratory directors and technical supervisors, documentation/verification of training,
experience, and supervisory activities, qualifications “equivalent to board certification,” continuing medical education requirements as a function of degree, on-site requirements, and other clinical laboratory experience.

- The findings of the workgroup are completed and will be presented to the CLIAC in April 2019.
- This topic will be discussed in more detail at the next CLTAC meeting.

**CLTAC Subcommittee Reports**

- **Public Health Lab Regulations** (Zenda Berrada)
  - Completed reviewing existing Title 17 regulations related to Public Health Laboratories and waiting to receive feedback from stakeholders.
  - Gave overview of recommendation to the California Association of Public Health Laboratory Directors (CAPHLD) membership on 12/14/18 and 1/25/19. A follow-up meeting will scheduled in March 2019.
  - Gave overview of recommendation to the California Conference of Local Health Officers (CCLHO) Communicable Disease Control and Prevention Committee. A follow-up meeting is scheduled for April 18, 2019.
  - Plans to submit report to CLTAC by May 7, 2019.

- **Regulations** (Lorri Dean-Yoakum)
  - CLTAC approved regulations documents in December 2018.
  - Thanked Shiu-Land Kwong, co-chair, and all subcommittee members.
  - Rebecca Rosser made a formal motion that work has been completed. Dora Goto seconded. No opposition.
  - Regulations subcommittee will remain active but need not meet again until assigned by LFS. The subcommittee members may change.

**Stem Cells: The Good, the Bad, and the Ugly** (Robert Hunter)

- The use of stem cells for regenerative medicine is promising but also dynamic and complex.

- Human cells, tissues, or cellular or tissue-based products (HCT/P) are articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient.

- Institutional Review Board is the administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated.

- Investigational New Drug is the means by which a pharmaceutical company obtains permission to start human clinical trials and to ship an experimental drug across state lines before a marketing application for the drug has been approved.

- There are 16 FDA-approved cellular and gene therapy products. Eight of those therapies are derived from umbilical cord blood.
In general, there are many, many success stories with these products, especially certain childhood diseases, and other very promising results for a wide variety of conditions (i.e. cancers, blood disorders, bone marrow failure syndromes, metabolic disorders, immunodeficiencies etc.)

There is abundant literature from the medical community warning patients about medical tourism.

The Food and Drug Administration (FDA) approves only umbilical cord blood-derived stem cell products and only for hematopoietic and immunologic reconstitution.

FDA acts to remove unproven, potentially harmful treatment used in ‘stem cell’ centers targeting vulnerable patients.

**Laboratory Licensing and Registration Section Update** (Robert Thomas)
- No update.

**CLIA Survey Section Update** (Daniel Yamasaki)
- Section 353(m) of the Public Health Service Act requires the Secretary to impose two types of fees:
  - Certificate fees
  - Additional fees
- Effective January 7, 2019, the CLIA fees for all certificate types have increased 20% (except for registration certificate fees).

**On-site Licensing Section Update** (Elsa Eleco)
- Surveys conducted by On-Site Licensing Inspection section:
  - Biennial on-site inspections
  - Initial state surveys
  - Validation surveys
  - Complaint surveys
- Submitted paperwork to schedule out-of-state laboratory inspections from July 2019-June 2020.

**Personnel Licensing Section Update** (Dolapo Afolayan)
- Provided updates on how many applications were resolved.

**Tissue and Blood Banks, Biologics, and Cytology Section Update** (Robert Thomas)
- Don Miyamoto, Examiner II, retired on December 14, 2018.

**New Business** (Jonathan Bautista)
• Mary Wogec stated that the Personnel Regulations package has been divided into five packages to make them more manageable.

**Future Items** (Jonathan Bautista)
- Discuss CLIA personnel package when Dr. Kimsey is present.
- The Public Health Regulations Subcommittee will provide a report to CLTAC by May 7, 2019.
- Meeting closed at 12:02pm.