

CLINICAL LABORATORY TECHNOLOGY ADVISORY COMMITTEE (CLTAC)

Minutes of the Meeting held on June 7, 2019

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

CLTAC Members Participating

Jonathan Bautista, Richard Bennett, Zenda Berrada, Marjorie Braasch, Dan Dominguez, Kathleen Doty, William Gardner, John Geisse, Dora Goto, Daniel Leighton, Tula Nieva, Armand Robert Parada, Rebecca Rosser, Fred Ung

Former CLTAC Members Participating

Lee Hilborne, Carmen Maldonado

California Department of Public Health (CDPH) Staff Participating

Dolapo Afolayan, Yu-Chen Chang, Patricia Dadone, Elsa Eleco, Paul Kimsey, Ted Lee, Nema Lintag, Donna McCallum, Greta Nash, Martha Obeso, Robert Thomas, Nga Tran, Clint Venable III, Hugo von Bernath, Emily Wei, Mary Wogec

Public Members Participating

Rose Edwards, Margaret Knapp, Peggy Kollars, Julie Kingery, Shiu-Land Kwong, Cinco Plumb, Brian Reuwer, Osvaldo Santiago, Tammy Zinsmeister, Denise Driscoll, Jamie Marks, Angela Aguiluz

Welcome and General Announcements (Jonathan Bautista)

- Meeting opened at 9:05 AM.
- Jonathan Bautista conducted roll call and determined that a quorum was present.

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

- Minor changes and then approved
 - Page 4 “201” → “21” (date)
 - Lee Hilborne is a former CLTAC member

Department News (Paul Kimsey)

- Enterprise risk assessment
 - The Enterprise Risk and Accountability Unit is requiring all Centers and Offices of CDPH to complete a risk assessment of their programs. Items identified are monitored on an ongoing basis. This new process will be ongoing into the future.
- Dr. Charity Dean continues to be involved in LFS operations and OSPHLD programs.
- The reorganization of the Richmond state laboratories under one center is ongoing and is scheduled to become effective July 1, 2020.

- Stem cells
 - FDA issued a warning notice to Genetech, which is posted on the CDPH website.
 - Federal judge ruled in favor of the FDA in a lawsuit against a Florida-based stem cell company whose treatments have blinded at least four patients.

LFS Update

- **Branch Report** (Robert J. Thomas)
 - New CLTAC board member, Dr. Gabor Hertz, effective May 15, 2019.
 - CLTAC currently has two positions open on the board:
 - One position is for an RN, bedside testing.
 - The other position is for a laboratory instrument manufacturer (non-voting position).
 - Megan Cornejo is the new staff services analyst who will be organizing all CLTAC meetings.
- **Administrative Items** (Ted Lee)
 - Call center originally opened in December 2018 and reopened in mid-April 2019.
 - Call center updates
 - Phone number: 510.620.3800
 - If constituents are unable to reach a staff member, the voicemail provides instructions to email us.
 - Staff currently answer approximately 60% of all calls.
 - The call center receives 200 inquiries each day: 50% phone calls and 50% emails.
 - The call length is around 7 minutes while the wait time is around 8 minutes.

Electronic Updates

- **ELLFS** (Nga Tran)
 - Upcoming activities to prepare for launch
 - Data migration - ensuring the records being transferred are not missing any pertinent information.
 - Internal user training and testing - utilizing the opportunity to test the ELLFS system as the staff are being trained to use it.
 - Customer outreach - continue using beta testing.
- **PERL** (Dolapo Afolayan)
 - Effective mid-June, laboratory personnel will have access to download and print their licenses.
 - There is no limit for the number of licenses that can be printed.

- Laboratory Field Services will no longer mail laboratory personnel licenses or certificates.
- ArcGIS (Hugo von Bernath)
 - Map is available at <https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/Laboratories-In-State-Map.aspx>
 - Incorporated all suggestions, including adding subspecialties that you can filter by.

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

The remaining bills are:

- AB 476 (California Opportunity Act of 2019) (Watch)
 - 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.
 - Introduced on February 12, 2019.
- 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.
- AB 922 (Oocyte Donors) (Watch)
 - Would require individuals who provide human oocytes for research to be compensated for their time, discomfort, and inconvenience in the same manner as other research subjects.
 - Introduced on February 20, 2019.
- SB 180 (Gene Therapy Kits) (Watch)

- Would prohibit a person from selling in this state a gene therapy kit, as defined, unless the seller includes a notice on the seller's internet website that is displayed to the consumer prior to the point of sale, and on a label on the package, stating that the kit is not for self-administration.
- Introduced on January 19, 2019, amended March 27 and May 2, 2019.
- **SB 334 (MLT Articulation to CLS)**
 - Would 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 re requires the Department to establish a pathway program by January 1, 2022.
 - Introduced on January 19, 2019, amended May 28, 2019.

CLIA Crosswalk Part Two (Mary Wogec)

- The second part of the CLIA Crosswalk has been reviewed and approved by the CDPH Office of Legal Services and is now moving forward for review by the Budget Office and the Director's Office.
- Part I of the Crosswalk adopted as California law subparts of the 2003 updates to the federal CLIA that were determined to be equivalent to or more stringent than California law.
 - The subparts included in Part I became effective by operation of law 60 days after the publication in the California Regulator Notice Register on October 7, 2016. (California Regulatory Notice Register 2016, No. 41-Z, pages 1825-1826; see Bus. & Prof. Code, § 1208, subd. (b).)
- Part II of the Crosswalk addresses subparts of 2003 CLIA determined to be less stringent than California law.
 - This regulation package will complete the process of adopting into state law the 2003 CLIA updates by making stringency determinations for and rejecting the six subparts of 2003 CLIA found to be less stringent than California law. (42 CFR § 493.1105(a)(1), (2), (3), (3)(i), (5), and (6))
- The California Business and Professions Code section 1265, subdivision (j)(2) requires clinical laboratories to retain the lab records listed in Business and Professions Code section 1265, subdivision (j)(2), for three years.
 - The records listed include test requisition and authorization records, test procedure records, quality control and patient test records, test system performance specifications, quality systems assessment records, and test reports.
 - The federal requirement for these types of records under CLIA of 1988, effective January 24, 2003, is to retain the records for two years.

- The proposed regulations will reject the six subparts of federal regulations pertaining to clinical laboratory record retention requirements that are less stringent than California law and clarify that laboratories must follow the state law requirements, retaining these records for three years.

CLTAC Subcommittee Reports

- **Public Health Laboratory Regulations** (Zenda Berrada)
 - Subcommittee drafted recommendations in January 2019.
 - General recommendations
 - Standardize format to include content/details, definitions, licensure of personnel, training continuing education as it is available for clinical laboratory personnel regulations.
 - Update definitions of Public Health Microbiologist, Public Health Laboratory Director, Approved Public Health Laboratory, “laboratory of the State Department of Health.”
 - Update “State Department of Health” to “California Department of Public Health.”
 - Motion to accept the recommendations of the Public Health Laboratory Regulations subcommittee was submitted May 7, 2019.
 - No opposition by CLTAC members.
 - Recommendations were accepted.

CLIA Personnel Regulations (Lee Hilborne)

- CLIA has submitted recommendations to the federal Health and Human Services Department on revising the CLIA personnel regulations.
- These recommendations will be reviewed through the Health and Human Services Department.
- Overall, CLIA has accepted the workgroup’s recommendations, which regard
 - Educational background
 - Training, experience, supervision
 - Laboratory director qualifications
 - Laboratory director continuing education
 - Laboratory director on-site requirements
 - Laboratory director qualifying experience
 - Technical consultant
 - Midlevel practitioners
 - Histopathology
- The details of these recommendations can be found at https://www.cdc.gov/cliac/docs/spring-2019/5a_Personnel-Workgroup-Report.pdf

CalREDIE Protocol (Robert J. Thomas)

- CDPH has established a protocol for follow-up when laboratories do not meet infectious disease reporting requirements.
- CALREDIE brochure provided
 - CalREDIE , otherwise known as California Reportable Disease Information Exchange, allows healthcare/lab facilities to comply with public health reporting requirements as stated in the California Health and Safety Code section 120130 subdivision (g) and California Code of Regulations Title 17, Section 2505, pursuant to HSC 120130 subdivision (a).

CLIA Survey Section Update (Donna McCallum)

- The total number of laboratories is 263,705
 - The total number of non-exempt laboratories is 254,160
 - Of these non-exempt laboratories:
 - 17,655 are compliance
 - 15,794 are accredited
 - 189,451 are waived
 - 31,260 are provider performed microscopy
 - The total number of exempt laboratories is 9,545
- CMS and CDC collaborated to develop the proposed rule:
 - Proficiency testing regulations related to analytes and acceptable performance (CMS-3355-P).
- CMS is proposing to add 29 analytes to Subpart 1 of the CLIA regulations.
- CMS is proposing to delete 5 analytes from Subpart 1 of the CLIA regulations
- Additional proposed changes
 - Removing lists of specific example organisms from each microbiology subspecialty
 - Amending definitions for target value, acceptance limit, unacceptable score, and peer group
 - Amending the regulations to reflect moderate and high complexity laboratories that may perform waived tests
 - Amending requirements for PT programs

On-Site Licensing Section Update (Elsa Eleco)

- Most frequently asked questions during the last 6 months (December 2018- May 2019) were addressed.
 - Do nurses qualify as technical consultants?
 - Can nurses supervise moderate complexity testing?
 - Do perfusionists qualify as technical consultants?
 - Can perfusionists supervise moderate complexity testing?
- Out-of-State (OOS) inspections from July 2018- June 2019
 - 43 trips completed

- 21 states
- 120 laboratories inspected
- 40 of the laboratories identified and scheduled for inspections had switched from state oversight to an accrediting organization (AO)
- As of June 7, 2019
 - LFS is expected to complete 76 on-sight inspections of OOS laboratories, across 21 states

Personnel Licensing Section Update (Dolapo Afolayan)

- No additional updates

Tissue and Blood Banks, Biologics, and Cytology Section Update (Robert J. Thomas)

- Following up on the stem cell therapies report, LFS has been working to identify facilities that collect, process, store, or distribute these products and may need a California license.
- LFS is in the process of sending notification letters to several facilities registered in the FDA Human Cell and Tissue Establishment list that may require California licensure.
- LFS is in the preliminary stages of creating an electronic facility licensing system.
- There is a new vacancy in this section.

Laboratory Licensing and Registration Section Update (Martha Obeso)

- LLRS website updates will be shown in this link
<https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/ClinicalLaboratoryFacilities.aspx>
- Facilities are able to check the current processing date of applications, view current instructions for contacting LFS, and download and print all LFS forms.
- Effective June 1, 2019, a CMS 116 form is required for all changes to CLIA certificates including Certificate of Waiver (COW) and Provider Performed Microscopy Procedure (PPMP).
- LFS will still accept the LAB 193 form, but facilities are required to complete the CMS 116 form in order to update the CLIA certificate.
- Processing times for all laboratory license and registration applications have decreased significantly from January 2018 through April 2019.

New Business (Jonathan Bautista)

- None

Future Items (Jonathan Bautista)

- Send an email to Megan Cornejo if you have ideas about future topics for CLTAC meetings, and/or the confirmation of your presence at CLTAC meetings.

- Meeting adjourned at 12:28 pm.