

Clinical Laboratory Technology Advisory Committee
Minutes of the September 9, 2011 Meeting
Meeting held by videoconference from Richmond campus, CDPH
KP Regional Laboratory, North Hollywood and
Telephone Bridge

CLTAC members participating

Laurie Armour (Fuller), Michael Borok, Leonard David, Lori Dean-Yoakum, Elizabeth Dequinia, Vickie Finson, Tim Hamill, Lee Hilborne, Jerry Hurst, Lin Kassouni, Donna Kirven, Carmen Maldonado, Peggy O'Toole, Salim Rafidi, Les Revier, Jan Schwartz, Michael Terry, Fred Ung, Mary York.

Former CLTAC members participating

Morton Field, Imre Fischer, Sol Notrica, Jim Ottosen

DPH staff participating

Zahwa Amad, Norma Barocio, Grace Byers, Maria DeSousa, Ron Harkey, Bob Hunter, Nema Lintag, Victoria Maxwell, Donna McCallum, Cassie McTaggart, Don Miyamoto, Karen Nickel, Bea O'Keefe, Jan Otey, Judy Schlosser, Pat Toomer, Clint Venable, Kathy Williams.

Welcome and general announcements

The meeting was called to order by CLTAC chairperson Lori Dean-Yoakum. She thanked Kaiser Permanente for providing the videoconference center in North Hollywood and the telephone bridge. A roll call was conducted of CLTAC members and other participants, and Ms Dean-Yoakum noted a quorum was present.

Approval of the June 24, 2011 meeting minutes

Ms Dean-Yoakum asked if there were any corrections to the June 24, 2011 minutes and a number of corrections were made. After these corrections were made, Salim Rafidi moved that they be accepted as corrected, Elizabeth Dequinia seconded, and the CLTAC voted to approve the minutes as amended.

Department news

Ms Pam Dickfoss, Acting Deputy Director of the Center for Health Care Quality, said the hiring freeze with the state continues but there are hopes that it will be lifted. Many vacancies need to be filled but triggers are in place in case new revenue doesn't come in. Dr. Chapman, the new Director, is trying to get additional resources with the legislature.

Ms Dickfoss said administrative penalties have been imposed on 12 hospitals with \$600,000 being assessed. She noted that the number of violations is going down.

Ms Dickfoss said an update of the personnel licensing regulations would be given. Amendments were not made in time to give them out at today's meeting. She introduced Cassandra McTaggart, Chief of Regulations and Hearings for CDPH to explain.

Ms McTaggart said CDPH is planning to not proceed with the regulations in their current draft. They will be withdrawn. Over 10,000 comments need to be addressed and the new package needs to meet APA requirements. Amendments have been made but they are in draft form, not finalized. Their new number is DPH-011-012. They will be sent to the CLTAC subcommittee today by Bea OKeefe. They have been re-organized, re-structured and hopefully are easier to understand. The new categories have been removed because there is no authority to collect license fees. She asked the CLTAC subcommittee to address the issues, not the minutia.

Questions:

Salim Rafidi asked what is the document they were going to get today. Ms OKeefe said it is just a working draft, not published for comment yet. It has imbedded questions, needs CLTAC input.

Salim Rafidi asked what needs to be done yet before it goes to public comment. Ms OKeefe said it needs to be approved by the regulation project team which includes LFS, Office of Regulations, Office of Legal Services, CDPH Budgets and the Director's office.

Jerry Hurst asked why the biochem geneticist and embryologist categories were removed. Ms OKeefe said CDPH has authority to create new licenses but is told it has no authority to charge new license fees.

Tim Hamill asked how long it would take to get authority to charge fees. Bea OKeefe said LFS has submitted a request for CDPH support for legislation, but status is unknown.

Maria DeSousa asked if language for fees could be added to the new regulation package, or if they could be added later. Ms McTaggart said regulations could not anticipate changes in authority in the law.

Tim Hamill asked if the document being released today would show the deletion of the new license categories proposed. Ms McTaggart said it would and the following have been deleted: biochem geneticist, doctorate embryologist, baccalaureate embryologist, postgraduate fellow, and immunologist.

CLTAC Subcommittee on Personnel Licensing Regulations

Bea OKeefe said this agenda item was included to see if the CLTAC wants to have input on the revised regulations. Salim Rafidi asked why not use the old subcommittee. Bea OKeefe said they could continue if they wanted. Salim Rafidi said he could continue to head up the committee.

Someone asked why not appoint a new chair. Salim Rafidi said the old committee worked together well, had good communication and was large (20+). Michael Borok said it was too hard to get a quorum. Lori Dean-Yoakum asked for a show of hands of subcommittee members who wanted to continue, and all indicated they would. Morton Field said the group needs a parliamentarian. Ms Yoakum asked for a motion. Michael

Borok made a motion that the former subcommittee be retained to review the revised regulation, Peggy OToole seconded. Questions were solicited. Jerry Hurst asked if others could join. Ms Yoakum said the subcommittee was still open. Jim Ottosen again questioned the size of the committee and suggested that it be limited to 6-8 people. The motion was called, and the CLTAC voted to retain the current subcommittee and allow anyone else to participate.

Role of the CLTAC as advisory to the Department of Public Health

The CLTAC has asked that this item be put on the agenda, but LFS was unable to obtain a speaker on the subject. This will be carried over to the next meeting.

Report of the CLTAC subcommittee on CLTAC Bylaws

The full CLTAC meeting was closed and the CLTAC Bylaws subcommittee meeting was opened. Jim Ottosen, chair of the subcommittee presented the minutes of the Bylaws subcommittee meeting. Lori Dean-Yoakum made a motion that they be accepted, Salim Rafidi seconded, and the subcommittee voted to accept the minutes.

The full CLTAC meeting was reconvened and the report of the CLTAC Bylaws subcommittee was heard. Lee Hilborne made a motion to accept the report, Fred Ung seconded and the CLTAC voted to accept the report. Karen Nickel asked whether the CLTAC was accepting or approving the report, and it was decided the CLTAC was “accepting” the report pending further discussion.

Jim Ottosen said a number of changes are proposed to the CLTAC Bylaws, as follows:

- Change the name of Department of Health Services to Department of Public Health wherever the former is mentioned.
- The composition of the CLTAC should not be fixed but “as determined by the Department and appointed by the Director” added.
- The Healthcare (Hospital) Administrator (non-voting) should be removed.
- “Professional constituencies” should be changed to “membership categories”.
- Voting rights should be expanded to include electronic voting by videoconference or by telephone.
- A quorum should be defined as 50% of the membership plus one.
- Once a quorum is established, it should remain for the rest of the meeting.
- A meeting notice should go out in writing or my email within at least 14 days of the next meeting.
- The CLTAC chair may solicit opinions of CLTAC members by telephone, email or mail but they are not official CLTAC opinions until discussed during a scheduled meeting.
- The CLTAC Bylaws should be reviewed every 5 years.
- Remove “standing” and “ad hoc” to committee designation.
- Say the CLTAC may appoint its own subcommittees, as needed.
- Delete as follows: Advice shall be sought from the Committee ~~on all regulations developed by the Department related to clinical laboratory technology and practice.~~ Replace it with: Advice shall be sought from the Committee during the

development of and prior to the filing of work product for all regulations developed by the Department related to clinical laboratory science and clinical laboratory practice.

- Add the following: It shall be documented in the minutes of the final CLTAC meeting of the calendar year the meeting dates for the following (next) year. In addition, a roster of the current membership shall be available to members of the committee and interested parties, which shall include the member's name, the membership category and the expiration date of the term of office.
- The date of the update should be changed from June 2001 to September 2011.

Lori Dean-Yoakum thanked the subcommittee for their work and asked for discussion on the proposed changes.

Morton Field said a quorum could be called at any time, just not at the beginning of the meeting.

Salim Rafidi said there should be a category for phlebotomy interests, so one other should be removed. Dora Goto said both phlebotomy and MLT members should be included. Jim Ottosen said it was LFS' responsibility to set up committee membership. Bea OKeefe said Legal said CLTAC members should be set by DPH with terms and voting or non-voting. Salim Rafidi asked if CLTAC could recommend member categories. Lori Dean-Yoakum said this would be answered at the December meeting. Bea OKeefe said the language "as determined by the department" should be added as a possible override of CLTAC recommendations for member categories. Michael Borok said DPH sets membership categories. Lin Kassouni said DPH should go to professional organizations for nominees and to avoid favoritism. Jim Ottosen said BPC Section 1228 said nominees were "made from lists". Jerry Hurst asked if anything was written in LFS policies about how to get CLTAC nominations. Bea OKeefe was unsure and said nominations were accepted from organizations which included individual's CV. A letter was prepared for the Director and the appointment is made at that level. Imre Fischer said in the 1970s, membership was made by license category through organizations.

Michael Borok said the Bylaws should say when a member is termed out and no new appointment is made, the current member continues. Jim Ottosen said this is included already in the Bylaws.

Lori Dean-Yoakum said the issue of the membership categories would be discussed at the next meeting. Lin Kassouni said the CLTAC is supposed to have 22 members, not 21. Bob Footlik said MLTs have few licensees and need not be represented on the CLTAC. Lori Dean-Yoakum suggested the changes in the CLTAC member categories be removed and "as determined by Department and appointed by the Director" be added. Lee Hilborne said he would accept these changes to his motion to accept. Lori Dean-Yoakum accepted the report of the subcommittee as amended and thanked the subcommittee for their work.

CLTAC appointments

Bea OKeefe said she had solicited nominations to the CLTAC. Twelve members have terms expiring this year. Donna Kirven said the CLTAC roster is the official document, but it is inaccurate and misleading. Ms OKeefe said if a person is completing his or her first term, she would ask them to continue.

LFS update

Bea OKeefe said the furlough of state workers continues after two years of 3 days per month. It has been reduced to 1 day per month now. Furlough of LFS staff plus unfilled vacancies has created backlogs in all sections. LFS currently has a 42% vacancy rate. There is hope for some freeze exemptions to fill high priority vacancies.

Some major clinical laboratories were fined for charging more to MediCal than to private physicians.

LFS biologics program has been involved with an investigation with the FDA on cord blood retrieval from a closed blood bank.

The California legislature has recently asked for a list of training sites for CLS and specialist training with the number of training sites. There is obvious interest in ability of California labs to train new persons for licensing.

Four applications have been received from accrediting organizations applying for approval of their accreditation of clinical laboratories seemed deemed status for licensure purposes. This would replace routine inspections by LFS staff. LFS would do an initial survey, validation and enforcement for these laboratories.

Michael Borok asked who the informant was in the MediCal case. Ms OKeefe said it was handled through the department's Audits and Investigation section and she did not know. Morton Field said a whistle blower filed suit, citing free work for MediCal referral of MediCal. Lee Hilborne thought this was incorrect and said different scenarios were involved.

Donna McCallum asked clarification of CLIA and state "deemed status". Bea OKeefe said this was confusing. CMS gives deemed status to accrediting organizations for their accredited laboratories seeking CLIA certification. CDPH will approve accrediting organizations so their accredited laboratories can get deemed status for state licensure. Jerry Hurst asked whether their license would still be a "CLIF" license. Ms OKeefe said, no, it would be a different license

CLIA update

Donna McCallum said the federal fiscal year ends September 30 and the LFS CLIA staff worked hard to achieve their target workload for the fiscal year. In July, they did 14 initial surveys, 56 recertifications and 9 proficiency testing sanctions. In August, they

did 6 initial surveys, 90 recertifications and 3 proficiency testing sanctions. They performed 843 surveys through August and have met their target of 843 surveys for the year. She thanked the CLIA staff for their hard work.

Michael Borok asked how many physician office labs had been inspected. Ms McCallum said their surveys were not broken down that way and she did not know. She said LFS does not routinely inspect physician offices performing waived tests.

Personnel licensing section update

Zahwa Amad thanked the LFS staff in her section for their hard work despite many vacancies. She said she hoped the hiring freeze would be lifted soon. LFS has made several improvements, as follows. The CLS and MLT training program application forms have been posted online, and Karen Nickel is working on CLS training program applications since Frank Barnes is on medical leave. Doctoral scientist license applications are also online. The phlebotomy certification approval program has reduced its backlog from about 6 to 2 weeks, and the time to print CLS licenses has been decreased to 2 weeks with online verification available after 48 hours.

LFS is working with a contractor on CPT identification cards and is reviewing a mock copy. It is almost ready.

The MLT program is slowly expanding under Nema Lintag's management with 7 training programs approved and one in progress (Diablo Valley College).

Applications are holding steady with about 70 CLS applications per month and about 40 of these licensed. CLS trainee licensing is being managed by Jan Otey now and is getting about 45 applications per month with about half licensed. The phlebotomy section is still getting about 675 applications per month. LFS has received a total of 323 MLT license applications and has licensed 174 (54%). LFS is getting about 1700 phlebotomy renewals a month of about 2000 subject to renewal.

LFS is working to revamp and update its website. Again, Dr. Amad thanked her staff for the efforts.

Elizabeth Dequinia questioned whether there are jobs for 675 new phlebotomists certified every month. She said her hospital had one opening and got 75 applications. Ms OKeefe said LFS cannot limit the number of applications.

Salim Rafidi said phlebotomy training programs should be of good quality and provide practical training. Joseph Musallum said UCSF requires longer training than that required of phlebotomy schools and they have a waiting list for training. He said some private schools charge \$4,000-5,000 for 2 week training. Karen Nickel said the new regulations will put further restrictions on phlebotomy training programs. Bea OKeefe said most new applicants are in a rush to be certified because "they have a job waiting."

Karen Nickel noted that many CPTs do not renew, as many as 40%. If LFS had more staff, it would be able to inspect the operation of phlebotomy training programs. Ron Harkey suggested that training programs post vacancy rates in their areas. Judy Schlosser said vacancies varied with job location.

Kathy Davis asked if CLS training program requirements would change in the new regulations. Dora Goto said if CLS applicants don't qualify for licensure, they should be encouraged to get licensed as MLTs and have their fee applied to that license. Zahwa Amad said they would have to pay an MLT fee.

Joseph Musallum asked the number of CLS trainees licensed and if that was posted. Zahwa Amad said about 200 trainees were licensed in 2010 and their licenses were individually posted online. Bea OKeefe said the Senate Research Committee estimated CA would need 800 new CLSs in the next four years. Jerry Hurst asked whether the new biotechnologies would hire CLSs. Bea OKeefe thought genetic specialists would be needed, but Jerry Hurst thought a generalist is more useful to the lab.

Facility licensing

Kathy Williams said SB 186 for reportable diseases was enrolled and will authorize the department to quickly change reportable disease requirements. Sanctions cannot be imposed for failure to report new tests until after 6 months of imposition, however.

Ms Williams said LFS continues to receive 90 new laboratory registrations per month and 5-10 new license application. The laboratory renewals are caught up through July but out-of-state licensing is severely backlogged. LFS has received 102 complaints this year to date. Of these, 52 are closed, 50 are still open and 21 were referred to Genetic Disease Branch (newborn screening billing), Licensing & Certification (hospitals and nursing homes), Pharmacy Board or CMS. One recurring complaint is phlebotomists working independently of laboratory employment or employing other uncertified phlebotomists. Independent phlebotomy services can only operate under contract and responsibility of a laboratory.

Joseph Musallum asked how a lab in Chicago could draw blood in California. Kathy Williams said an RN could draw blood for them, not a CPT. Mr Musallum asked why a trainee license was issued for one year and not two. Ms Williams this could be changed in the new regulations.

Michael Borok asked if licensed laboratories outside CA paid license fees on a sliding scale. Ms Williams the fee was based on the number of CA specimens performed. Donna McCallum verified that the fee was based only on tests done on CA specimens.

New business

Lori Dean-Yoakum asked that the number and composition of the CLTAC members, voting and non-voting be a topic of discussion at the next CLTAC meeting. Lee Hilborne said the number of categories should be “collapsed”.

Salim Rafidi asked about the subcommittee on review of the new regulations. What is their timeframe? Will the revisions be done by the end of the year? He said he wanted the subcommittee to meet in 3-4 weeks after they get the regulation draft, possibly the first week in October. He asked who would get the draft and who could provide input. Bea OKeefe said only the subcommittee could be involved.

Michael Borok said he thought a physician office lab in CA should be increased from two to three physicians. He said many POLs are increasing their staff physicians. He made a motion that this be recommended by the CLTAC, Fred Ung seconded, there was no further discussion and the motion failed.

Future agenda items

Lee Hilborne said LFS should evaluate online license verification used by the Medical Board of California. Bea OKeefe said LFS uses that source to verify director qualifications for lab licensing already. It is out-of-state laboratories whose state websites do not provide this information that are a problem.

Lori Dean-Yoakum said the next meeting would be on December 2, 2011 and two items would be held over for that meeting:

- Report of the subcommittee on personnel licensing regulations
- Recommendation of the subcommittee on Bylaws on CLTAC composition

Hearing no further business, Ms Yoakum asked for a motion to adjourn. Jerry Hurst moved that the meeting be adjourned, Salim Rafidi seconded, and the CLTAC voted to adjourn the meeting at 12:30PM