

Clinical Laboratory Technology Advisory Committee

Minutes of the September 7, 2012 Meeting

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

CLTAC members participating

Michael Borok, Anthony Butch, Elizabeth Dequinia, Laurie Fuller, Tim Hamill, Lee Hilborne, Jerry Hurst, Lin Kassouni, Carmen Maldonado, Peggy OToole, Les Revier, Fred Ung, Lorri Dean-Yoakum (chair),

Former CLTAC members participating

Sam Chafin, Imre Fischer, Robert Footlik, Jim Ottosen.

DPH staff participating

Zahwa Amad, Alan Ankerstar, Norma Barocio, Kama Brockman, Grace Byers, Ron Harkey, Robert Hunter, Paul Kimsey, Nema Lintag, Yangzhu Long, Victoria Maxwell, Donna McCallum, Don Miyamoto, Karen Nickel, Martha Obeso, Bea O'Keefe, Jan Otey, Tammy Pahland , Judy Schlosser, Robert Thomas, Clint Venable, Kathy Williams, Mary Wogec.

Welcome and general announcements

The meeting was called to order by CLTAC Chairperson Lorri Dean-Yoakum. Ms. Dean-Yoakum 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 that a quorum was present for the meeting.

Approval of the June 1, 2012 meeting minutes

Corrections were made to the minutes from the June 1, 2012 meeting. After correction, Tim Hamill moved for approval, Lin Kassouni seconded, CLTAC approved as amended.

Department news

Dr. Paul Kimsey, Deputy Director of the Office of State Public Health Laboratory Directors (OSPHLD), gave an update for the department. Dr. Kimsey said the oversight of LFS had been changed from the Center for Health Care Quality (CHCQ) to the OSPHLD under him. This was effective July 1, 2012. Dr. Kimsey said that he had overseen LFS' activities for ten years as it was part of the Division of Laboratory Science previous to LFS reporting to the CHCQ for five years. Dr. Kimsey said he had experience with LFS and the federal CLIAC, and reports to Dr. Kathleen Billingsley, former Deputy Director of CHCQ and now Deputy Director of CDPH.

Dr. Kimsey said the state passed its budget on time this year, and Governor Brown needs to get his tax initiative passed and to continue to make cuts in spending to achieve the budget goals. Among the concessions were union negotiations which resulted in loss of retired annuitant staff, one day non-pay per month for CDPH staff (not a "furlough"), and loss of the Lab Aspire program funding. The latter program

provided \$2.25 million to train public health laboratory directors.

Dr. Kimsey said that for the last 10-15 years, CDPH has been talking about consolidating departmental IT activities and that is finally taking place. We are anticipating some rough spots for the now de-centralized IT program as it becomes centralized.

CDPH is starting a 2-3 year process to achieve public health accreditation as a part of the national Public Health Accreditation Board (PHAB) program. Dr. Chapman, CDPH Director, has incorporated accreditation into a strategic map for the department that strives for continuous quality improvement.

Michael Borok asked what the source of funding was for the Lab Aspire program. Dr. Kimsey said it was the General Fund.

Status of the regulation package

Tammy Pahland, Staff Counsel for LFS, gave the CLTAC an update on the regulation package under development. She said LFS was making great strides, meeting every two weeks to review and modify sections. Consideration is being given to CLTAC, and to public comments made to the earlier submission. LFS hopes to have the draft completed in two months and it will be made available to the CLTAC before it goes out for public comment.

Jim Ottosen asked how CLTAC comments would be taken. Bea O'Keefe said she was unsure of the format but hoped the new version will be easier to follow, understand, and enforce. She hoped it would reduce questions and concerns from the public.

Tim Hamill asked if the draft would be ready prior to the December meeting and how the CLTAC would be involved. Karen Nickel said she hoped it would be ready, and that the CLTAC should focus on 5-6 major issues. Jerry Hurst asked when the regulations would be finalized. Tammy Pahland said she thought it would be six months before the public would see them. She said a timeline would be developed that would accommodate a fast turnaround, if possible. Lorri Dean-Yoakum asked that the CLTAC be "kept in the loop".

LFS Update

Bea O'Keefe said LFS had been very busy this legislative session with many bills, all requiring a quick turnaround time on analyses and technical assistance to the authors, department, agency, and governor's office. She hopes next year will be better. Karen Nickel pointed out that since this was the second year of this legislative session, next year should be all new bills "testing the waters".

Ms. O'Keefe said that the imposition of one day off without pay per month effectively cuts staff pay by five percent and may impact turnaround time. She said that the negotiated agreement between the Governor and the SEIU resulted in review of "mission critical" positions. LFS unfortunately lost 17 retired annuitants on August 31. Many of these people had been employed part time at LFS for ten years and they are sorely missed. She noted that some professional level retired annuitant positions, such as those for Bob Thomas and Karen Nickel, were not eliminated.

Bea OKeefe said LFS was dealing with several cases involving fraudulent certificates and licenses used by phlebotomy services, home health agencies, hiring agencies, and others. She encouraged everyone to check the authenticity of personnel certificate and licenses on the LFS website.

CLTAC comments Lee Hilborne said the law required licenses to be posted and said employees should always check the website. Tim Hamill agreed. Jerry Hurst asked if facilities were checking for the watermark on the licenses. Bob Thomas said a printout of the website licensing information was valid for 90 days only. Lin Kassouni said the accrediting organizations require primary source verification.

Robert Footlik said certified phlebotomists were not authorized to work for home health agencies because of lack of supervision. Ms. OKeefe said phlebotomists are contracting with a clinical laboratory or working for a business that has a laboratory registration. Sometimes these businesses obtain a lab registration just to be able to operate a phlebotomy business.

Robert Footlik said LFS had higher license fees due to legislation and this should support staffing to provide better oversight. He said LFS is still restricted from hiring inspectors and asked Ms. OKeefe to comment. Ms. OKeefe said that budgetary restrictions impact all programs and if layoffs are imposed, it is done across the department. Dr. Kimsey said this is always a struggle and few exceptions are allowed. All programs and funds are treated the same, without logic, at the direction of the HHS agency, Department of Finance, and Governor's office.

Lorri Dean-Yoakum asked where the LFS special fund was. Dr. Kimsey said it is secure but sometime special funds can be borrowed. He said LFS' special fund has not been expended by LFS or anyone else. Dora Goto asked if LFS got confirmation of its reserves. Robert Footlik asked if LFS earned any interest from its fund. Bea OKeefe said she gets monthly reports and that it earns interest. However, LFS has expensive projects that don't necessarily involve hiring new staff during the hiring freeze. The main need is to replace the HALS, the licensing database for labs and lab personnel. HALS is used by LFS, Radiologic Health branch, the Certified Nurse Assistant program, and the Drinking Water program. The reserves in the LFS special fund could be used for this need (and others).

Legislative reports

AB 761 Jan Otey reported that this bill passed. It authorizes optometrists to direct a waived lab and perform specified waived tests as part of their practice.

Someone asked if optometrists could do moderate complexity testing. Ms. Otey said they were restricted to waived tests on tears and urine glucose.

AB 2356 Jan Otey said this bill also passed. It defines "sexually intimate partner," and gives immunity to a physician when a recipient waives repeat testing of HIV from a donor known to the recipient.

Clint Venable said this bill had seven amendments and credited Bea OKeefe and

staff on response to questions about the bill.

SB 1267: Kathy Williams said SB 1267 was called the Genetic Information Privacy Act. She said this bill failed to pass the legislature, but the federal government was going forward with legislation.

SB 1481: Ms. Williams said this bill was sponsored by the California Association of Pharmacists and would exempt pharmacists and pharmacies from clinical lab law entirely. Currently pharmacists are authorized to perform procedures that a patient could, with or without a prescription, perform for himself or herself, or clinical laboratory tests that are classified as waived, provided they have a physician and surgeon as their waived laboratory director. This bill changed many times and passed without a NO vote. In the final bill, pharmacies must be registered with the state and the pharmacist in charge can serve as director, performing glucose, hemoglobin A1C and cholesterol. Ms. Williams expects continued legislation from the pharmacists.

Robert Footlik said pharmacists don't want to be lab directors. They want to be exempt from the law. Who will be the director on the CLIA certificate? Ms. Williams said the final version of SB 1481 authorizes the pharmacist-in-charge to be director.

Karen Nickel asked whether testing done by pharmacies would be paid by third party payers, such as Medicaid. Ms. Williams thought maybe this would be reimbursable, but only for these three tests. If they did any other tests, the pharmacy would have to get a fully qualified laboratory director.

Michael Borok noted that retail health clinics would be interested in this. Ms. OKeefe said there were 50 over-the-counter diagnostic tests available for sale, but not all are available at a pharmacy. Ms. Williams said LFS currently has registered 120 pharmacies as "laboratories" and there are about 6000 pharmacies in California. These 120 pharmacies have medical doctors as directors at this time. Dora Goto said CAMLT opposed this bill as it will open the door wide open for more testing. Karen Nickel said that immunizations were available at pharmacies now, too.

Lee Hilborne said California law restricts pharmacies, but what about other states' pharmacies? Ms. Williams said over 35 other states allow pharmacies to offer any test that is sold over-the-counter, including coagulation tests. Dr. Hilborne asked about impact on patients, access to testing and restriction of trade. Ms. OKeefe asked Donna McCallum to update CLTAC on CMS findings on waived lab compliance. Ms. McCallum said there were many problems with waived labs, such as not following manufacturer's instructions, no competency testing, interchange of reagents, and other problems. These facilities get a "letter of recommendation" for actions to take to regain compliance, and there is training in other states, but not California. Jerry Hurst said the CLIA study showed non-compliance was rampant. Ms. McCallum agreed and said compliance has increased, and only 5-10 percent continue in violation of the law. Jan Otey asked if pharmacists had the background and training to be a lab director. Kathy Williams said they are getting training. Karen Nickel noted that many are PharmDoctors now. Robert Footlik said the degree didn't matter. Lee Hilborne said there should be a study like the old POL study years ago.

SB 289 Robert Thomas reported that this bill would have affected training programs but was amended many times, removing reference to NAACLS and clinical training sites. As passed, it allows CLS training programs to use multiple training sites in any percentage as long as certain requirements are met and each clinical lab is approved by the department.

AB 1976 Robert Thomas said this bill did not pass the legislature and would have impacted acceptance of military experience for licensure purposes.

AB 2214 Robert Thomas said this bill did not pass and would have required all licensed persons to provide information which would be aggregated and posted on the website. There was no funding to implement this bill.

Office of AIDS program

Bea OKeefe introduced Dr. Kama Brockmann, Specialist for HIV testing in a Healthcare Setting at the CDPH Office of AIDS. Dr. Brockmann said she was relieved that analysis of AB 2356 (discussed previously) was transferred to LFS from her program. She said she had been working with LFS since 2005 on HIV testing laboratory approval, and subsequently on the HIV testing regulations.

In 2010 the United States implemented an HIV strategy that is the same as the Office of AIDS goal to (1) reduce new HIV infections, (2) increase access to HIV care, and (3) improve HIV treatment disparities. Dr. Brockmann said there are currently about 120,000 persons with active HIV infection in California, with 5000 new cases diagnosed each year. Current treatment is viral suppression that can reduce or eliminate the risk of transmission. In the US, about 1.2 million persons are HIV-infected and of these, about 80% know their diagnosis, about 62% are linked to HIV care, and 36% are on retroviral therapy. These statistics are similar in California. Dr. Brockmann presented the HIV diagnostic testing algorithms proposed by the CDC. These algorithms cannot be adopted in California until adopted and published in the MMWR.

Michael Borok had several questions. What does it mean that a patient is “linked to HIV care”? Dr. Brockmann says that means he or she sees a physician three times a year. Where is the testing done? Most testing is done in clinical settings such as a physician’s office or hospital. Only 4 percent are done in HIV counseling and testing sites. What is the date on the new HIV algorithm? 2011. What about fourth generation testing? Office of AIDS and LFS agree that labs can use fourth generation technology for screening, but due to California regulations, labs cannot use the new testing algorithm until it is published in the MMWR.

Robert Footlik said a lab can use the HIV-1,-2 test but it must be confirmed by Western Blot or IFA. Dr. Brockmann agreed.

Dr. (missed the name) from KP said a lab can use a fourth generation HIV test as screening, but the issue is confirmation. Dr. Brockmann agreed.

Jerry Hurst said a manufacturer needs FDA approval to change a kit insert and that

is a huge hurdle. Dora Goto said other states are using the new algorithm. Jerry Hurst said using a test “off label” requires test validation. New HIV home test kits sell for \$60. Will a person get a confirmation test? Where will he or she get it? The test may be used by sexual partners prior to sexual activity.

Robert Hunter said the new over the counter HIV test is listed on the CLIA database as a waived test. Bea OKeefe said state law allows any test available OTC to be self-ordered at a laboratory, but a laboratory is not obligated to accept the test order without a physician's order. A physician would advise a patient about the need to confirm a home HIV test.

Facility licensing

Kathy Williams said LFS continues to get about 100 new laboratory registration applications each month and about 50 new laboratory license applications. There are currently about 400 laboratories licensed by LFS outside the state and about 4-6 new out-of-state license applications are received each month. LFS gets about 20-30 complaints each month about personnel issues (mostly phlebotomy), laboratory, and technical matters. Some are referred to the responsible programs. Ms. Williams said her section has been hampered by the loss of the retired annuitants for activities such as backup for the phones, mail room, filing, copying, organizing documents, and so on.

Personnel licensing.

Zahwa Amad thanked her staff for their hard work. She said the personnel licensing section has two new examiners and six new support staff, but has also been hampered greatly by the loss of the retired annuitants and mandatory furloughs. She encouraged people to renew their licenses and certificates as early as possible to avoid delays in licensing. Dr. Amad said LFS currently has licensed about 252 MLTs and 39,622 phlebotomists. There are three new CLS training programs and several new clinical microbiologist scientist training programs. Martha Obeso will be assuming responsibility for training programs.

Lorri Dean-Yoakum asked for statistics on the pass rate of California applicants taking an approved certification examination. She asked this be put on the agenda for next meeting.

Someone asked if it would be possible to redesign the blue continuing education form. Dr. Amad said she would look into that. Ms. OKeefe said any changes would cost money as EDD prints the license forms.

Elizabeth Dequina said there were no jobs for phlebotomists in her area. She encouraged LFS to make changes in the regulations to strengthen training requirements.

Biologics and tissue bank programs

Ron Harkey said the tissue bank presentation by Clint Venable had to be postponed because he was too busy with AB 2356. Mr. Harkey said stem cells and stem cell typing was a link between biologics and tissues. Cord blood is being used for stem cell production and adipose stem cells are now used for reconstructive surgery.

Michael Borok said fat injection done on-site may not require banking. He said some tissue was stored but doesn't last. A skin biopsy can be sent out, grown up, and sent back for patient use. He asked whether a physician needed a tissue bank license for that. Mr. Harkey said that would not require a tissue bank license, but Clint Venable said if any processing was done on-site, a license would be required. Mr. Harkey said this would have to be evaluated on a case-by-case basis.

Robert Footlik asked whether autologous tissue stored for later use requires a license. The answer was no. Clint Venable said if one person's tissue was used for another patient, it would have to be tested for sexually transmitted diseases first. He said that the federal legislation HSS 1634 was unclear and should be put on the CLTAC agenda for next time.

Mr. Harkey said there are about 600 licensed tissue banks in California now with about 8 percent growth per year. He said he would meet with the Blood Centers of California Medical Technology Advisory committee to discuss biologics standards. They need to be harmonized with FDA standards regarding donor deferrals following travel to other countries and exposure to malaria, West Nile virus, and TB.

CLIA section update

Donna McCallum said the end of the federal fiscal year is September 30 and her update today would not include the current month. LFS CLIA section is on target to complete 819 surveys in the current fiscal year for CMS, 96 percent of its goal. LFS has inspected 37 waived labs this year and 10 percent (4) had compliance problems.

Ms. McCallum said the EP23 publication, called the IQC Plan, will replace EQC. She also said the Interpretive Guidelines have allowed electronic test records in CLIA. There is no CLIA requirement for pre-approval by the FDA of IVD-MIA tests done for single patient result or condition. Ms. McCallum said there are no new guidelines for genetic testing by CMS.

Jerry Hurst requested more time to discuss IVD-MIA testing. Would they all be referred to CMS? Ms. McCallum said they would be referred to the CMS Regional Office or the Central Office, not to the FDA.

New business

Chairperson Lorri Dean-Yoakum asked if there was any new business. She also asked that future agenda items be sent to her before the next meeting.

- Jerry Hurst asked that genetic testing, laboratory-developed tests and genetic versus chemistry tests be discussed.
- Robert Hunter asked for clarification of the waived HIV laboratory test and its ramifications.
- Lorri Dean-Yoakum wants to discuss the phlebotomist workscope versus unlicensed person's workscope.

- Michael Borok wants clarification of when a person needs a tissue bank license.

Next meeting

Ms. Dean-Yoakum said the next meeting of the CLTAC would be December 7, 2012.

Adjournment

Lin Kassouni made a motion that the meeting be adjourned, Elizabeth Dequina seconded, and the CLTAC voted to adjourn at 12:20 PM.