

Clinical Laboratory Technology Advisory Committee
Minutes of the June 10, 2005 Meeting
Meeting held by videoconference from Kaiser Permanente Oakland and
North Hollywood, and by telephone bridge.

CLTAC members participating: Michael Borok, Teresa Bryant, Greg Clark, Paul Fu, Tim Hamill, Tim Huston, Curtis Johnson; Lin Kassouni, Donna Kirven, Carmen Maldonado; Salim Rafidi, Les Revier; Peggy Tessier-Otoole, David Yong, Mary York, David Zingmond.

Former CLTAC members: Vicki Bello, Morton Field, Imre Fischer, Robert Footlik, Jim Ottosen

DHS staff present: Alan Ankerstar, Wenn Chen, Maria de Sousa, Ron Harkey, Paul Kimsey, Shiuland Kwong, Howard Manipis, Donna McCallum; Don Miyamoto; Karen Nickel, Bea O'Keefe, Jan Otey, Tom Tempske, Robert Thomas, Kathy Williams

Public Members: 21 persons signed in in Oakland, 30 persons, in North Hollywood, 30 lines called in on the telephone bridge and 14 persons reviewed the digital replay of the meeting.

Introduction and General Announcements: Teresa Bryant opened the CLTAC meeting, welcomed the participants and asked the participants to identify themselves at both videoconference sites and on the telephone bridge. She reminded the audience that CLTAC members would be heard first, than the others. She also noted that the telephone bridge participants were all on "mute" and could only access the meeting through the operator. This was done to eliminate background noise of phones left on.

Approval of March 4, 2005 Meeting Minutes: Teresa Bryant asked for any corrections to the minutes of the March 4, 2005 meeting of the CLTAC. The following changes were made: (1) "Medi-Cal" on page 2 was corrected to California "Medical" Association, (2) The time period of phlebotomy certification on page 4 was changed from 3/1/04 to "3/1/05", (3) Morton Field said that his name should be included among those CLTAC members participating, (4) David Zingmond said that his name should be included among those CLTAC members participating. Motion to accept the minutes as corrected was made and approved, except Dr. Field is listed as a public member not CLTAC member.

Department News: Paul Kimsey, Division Chief of Laboratory Science, thanked everyone for attending. He noted that Dr. Dick Jackson, State Health Officer, was resigning after 14 months. Dr. Jackson had come to DHS from the CDC and will be missed. His replacement has not been made yet. Dr Kimsey updated the CLTAC on the Governor's CA Performance Review (CPR). He said some of the CPR issues might be moved to the state legislature. LFS may be involved with the licensing and certification consolidation within DHS. Common interests include efficiency of

processing of license applications, standardized background checks, direct access to licensing information, and fraud control.

Dr. Kimsey read a letter from Sandra Shewry, Director of DHS, on laboratory licensing. This letter, dated June 6, 2005, announced a decision to require all laboratories in California to be either licensed or registered, to repeal regulations that postponed collection of fees and to again seek CLIA exemption. Dr. Kimsey opened the floor to questions.

Michael Borok asked if labs that had been in existence before 1996 and were unchanged would have to be registered or licensed. Dr. Kimsey said all labs would be subject once the emergency regulations were repealed. Until then, these labs may be exempted.

Morton Field asked if exempted POLs would not be inspected by the state. Dr. Kimsey said they would not until licensed. Would POLs be subject to personnel requirements and Dr. Kimsey said yes.

Lily Spitz asked why the state would consider CLIA exemption, as it was too expensive in 2000. What has changed? Dr. Kimsey said he hoped the CA lab community would help influence CMA regarding fees and they would be lowered. He said the labs in CA would be subject to both state and federal fees until DHS achieved CLIA exemption. Ms. Spitz said the duplicate fees would be a burden for clinics.

Robert Footlik said that the intent of SB 113 did not rule out or mention the need to avoid duplicate fees. He said it said that fees after exemption should be no higher than before.

Michael Borok said that he thought the intent of SB 113 was to take over oversight, not duplicate it. He said Governor Wilson was hesitant to sign SB 113 for fear of duplicate programs.

Robert Footlik said that labs in existence prior to 1996 were required to comply with state law but were exempted from payment of fees, so they should not complain now. He asked how DHS would handle labs outside CA receiving specimens from CA. Dr. Kimsey said that would be discussed later.

LFS Update: Karen Nickel welcomed the CLTAC and public members, and thanked Kaiser Permanente for the kind use of their videoconferencing centers and for providing the telephone bridge. She said there were a lot of positive things happening that were encouraging. Robert Thomas, Section Chief of Personnel Licensing, would be receiving DHS Sustained Superior Performance Award in Sacramento later this summer. LFS is scheduled to move to Richmond Marina on July 15. That is good and bad with phone, mail, forms, website changes needed. LFS has started online processing of license applications with a demonstration later this morning. CLS' will be first with phlebo applications next and then all license categories. LFS is really pleased to get the "go-

ahead” about full implementation of lab licensing and registrations, after 9 years. The phlebotomy program continues to grow, and the MLT regulations have completed their second comment period with not additional changes. We are interested in seeing how the criminal background checks will impact our license applications, and Bob will talk about that later. LFS wants to hire new examiners and the job notice will be going out soon. We look forward to reviewing applications from certifying organizations for approval of exams for licensure purposes. Someone asked what organizations would be applying. Dr. Nickel said ASCP, NCA and AMT had expressed interest already.

Legislation: Dr. Nickel said LFS has been closely following 5 bills and 3 have been withdrawn. This is a very unusual legislative year for laboratories.

AB 896 and AB 1360 would have authorized pharmacists to serve as directors of laboratories performing routine patient assessment procedures which are defined as any waived test that a patient could perform on him/herself. These bills were withdrawn because of opposition by CAMLT, CCLA, CMA and 14 individuals.

AB 512 would promote better compliance with disease reporting requirements by clinical labs. DHS could take enforcement action on laboratories for failure to report findings of certain diseases. These sanctions could include principal sanction (license revocation) or alternative sanctions (directed plan of correction, onsite monitoring or civil money penalties). Supporters of this bill include Blood Center of CA, County Health Executive Association of CA. Opponents, CCLA because of concerns about sanctions for inadvertent failure to report.

AB 626 would require DHS to establish and appoint members to a task force to help fight fraud by reviewing reports of fraud to MediCal beneficiaries and to recommend activities that would eliminate fraudulent practices. The sponsor of the bill is CCLA.

AB 433 would have exempted physician office laboratories from state licensure and registration requirements. They would only be subject to federal CLIA standards. Supporters of this bill are the CMA; opponents are CCLA, CAB and CAMLT. This bill has been withdrawn.

Regulation update:

MLT Licensing Regulations Update. Karen Nickel discussed the comments received during the first and second comment periods of the MLT regulations. First comment period: A total of 29 persons submitted comments on the initial version of the regulations. 15 persons fully supported the regulations as printed, 3 asked how MLTs could do microbiology testing when not allowed to do high complexity testing, 3 thought MLTs should not be allowed to report abnormal or critical values, 4 said MLTs should not be allowed to calibrate instruments, 1 said MLTs should not be allowed to do method validations, 2 said MLTs should be allowed to do microscopics, 2 persons wanted a 3 to1 ratio and 4 wanted a 2 to 1 ratio of MLT to CLS. LFS made some changes to the regulations based on these comments and the revised regulations were sent to the 29 persons again. Second comment period: Only 5 persons responded to

the amended version of the regulations. Three said they liked the regulations as written and 2 were from certifying organizations with concerns about Section 1031.8 (approval of certifying examinations). The certification organizations said they appreciated the changes made that included: DHS shall return examinations after they are reviewed and not keep them as originally stated in the regulations, the certification organizations are no longer required to give a list of persons failing their examinations, and appreciate distinction made that a person passing a certification exam for state licensure may not necessarily qualify for national certification.

A summary of the changes made to the initial posting of the MLT regulations, which are considered minor, are summarized as follows:

- (1) Certification exams will be returned by DHS after confidential review;
- (2) Four year look back of exams requires 4 year review of previous exams,
- (3) Self-administration of state law exam was clarified;
- (4) Coagulation was added as part of hematology;
- (5) Onsite supervision of MLTs only necessary when doing moderate testing, not waived;
- (6) DHS justified in supporting documents retention of 4 to 1 ratio;
- (7) Removed requirement that MLTs pass phlebotomy certification exam in order to supervise CPTs;
- (8) Explained that MLT can only validate moderate complexity tests;
- (9) Specified that MLT practical experience can only be gained in a CLIA certified lab.

MLT implementation: No new staff has been approved for this program yet, with an application under review now for July 2006. Between now and January 2006, Bob Thomas and Karen Nickel will develop forms and get them approved, set up accounting codes, approve training programs and certification exams. After January 2006, very limited licensure may begin as possible. July 2006, start program if new staffing is approved.

The CLTAC and public members had a number of comments about the MLT licensing standards. Joseph Musallam thought the qualifications of a MLT supervisor should be specified beyond "a person licensed under chapter 3 other than another MLT". He thought educational courses in clinical lab science should be required and temporary licenses issued. Bob Thomas said this would not be necessary as certification exams are offered frequently. Salim Rafidi asked if temporary certificates could be given to phlebotomists, no. Mary York thought it would be a hardship for the certifying organization to develop CA-specific exams deleting activities not allowed in CA. Someone asked how the exams would be reviewed and approved and why MLTs would have to train in CLIA certified labs. Faye Stauffer asked if an MLT could serve as "lead" MLT, and David Yong said he was unsure about the supervision requirements of MLTs.

Full implementation of lab licensing/registration: Dr. Kimsey and Dr. Nickel gave the background on the development of legislation in SB 113 to incorporate CLIA in order to achieve CLIA exemption, why the emergency regulations were enacted to prevent

duplicate fees, why CLIA exemption could not be gained, and how the decision to again seek CLIA exemption was made. Some of the issues considered were, the (short term) necessity for labs to pay fees to both state and federal governments until CLIA exemption was gained, the differences between state and federal laws, concerns about laboratory quality without inspection and licensure, CLIA exemption and the overhead fee charged in 1999, and opposition from POLs and CMA concerns. Emergency regulations enacted in 1996 exempted all CLIA labs in operation with a CLIA certificate as of 1/1/96 that did not have a state license or registration, from having to be licensed or registered until CLIA exemption.

The decision to again seek CLIA exemption requires DHS to update CA law where CLIA 2003 is now more stringent or specific. All labs in the state must comply with state law and be licensed or registered, and DHS needs to provide documentation to CMS that it is capable of conducting a CLIA exempt program.

Implementation will be done over 3 to 5 years. A notice to all laboratories was released on June 6, 2005 and was read earlier. This is being discussed with the CLTAC and the public today. LFS is developing informational material that will be given to the CLTAC at their next meeting. All new CLIA applications (~100 per month) must now be state licensed or registered. Registration of all labs not exempted by the emergency regulations in 1996 will begin in July 2005. Licensing of all labs not exempted by the regulations in 1996 will begin in January 2006. Complete licensing and registration will be completed when the emergency regulations are repealed.

There were a number of questions about this information. Tim Hamill asked about licensure of labs outside CA which do testing on specimens from CA. (They will have to be licensed eventually.) He asked why CLIA exemption is so desirable. Mary York said to avoid duplicate fees. Paul Kimsey added, "to avoid duplicate oversight, not just fees." Paul Kimsey said there may be no cap on the overhead fees. Tom Tempske asked which states were CLIA exempt (WA, full and NYS, partial exemption) Mary York asked why DHS expect the overhead fee assessment to change. (Dr. Kimsey suggested public pressure.) Tim Hamill said state standards were important and should be upheld. Mary York said state inspectors are currently CLIA funded and DHS would lose federal funding if CLIA exempt. Morton Field said there are errors in the federal database that DHS would have to deal with. Lily Spitz said NYS has CLIA exemption that does not include POLs. Why doesn't CA do that? (Dr. Kimsey said DHS cannot remove oversight of entities without legislation) Donna McCallum said NYS never had oversight of their POLs where DHS has always has, and that is the difference.

Personnel Licensing Update: Bob Thomas reported on new developments in personnel licensing.

Online license application and renewals: LFS has been looking for ways to streamline and speed up license applications with the help of our contractor, CPS. Since May 9, the LFS website has allowed the option of online applications for CLS'. This was demonstrated by Daryl Hill and Xioling Shiu of CPS. The application fee is paid by credit card, LFS reviews the application, as usual, and application status will be

available on line. Phlebotomy applications online will begin in July and, if successful, will be applied to all personnel license applications and renewals. Questions about the process included timing when lab license applications and renewals would be online (unknown at this point, probably several years), and when can status reports be queried (eventually).

Phlebotomy certification update: By the next meeting of the CLTAC, LFS expects phlebotomy applications to be online also. As of this date, LFS has received 6,120 phlebotomy applications and has reviewed 4,334. The number of applications is increasing each week as the April 2006 deadline approaches. Mr. Thomas encouraged phlebotomists currently working to not wait until after January 2006 to start the application process. One unexpected problem with CPT certification has arisen. Applicants are having difficulty in satisfying requirement to observe two arterial punctures, so LFS is attempting to procure training videos that can be used by training programs. LFS has developed a form to help applicants document training and experience, to ease the application process.

Criminal background checks: Criminal background checks (“CBCs”) are getting high-level attention in DHS, as we discussed at the last CLTAC meeting. Mr. Thomas said LFS is surprised by the high number of phlebotomy applications that require CBCs. A person is required to self attest to a criminal conviction, and as of today, about 166 phlebotomy applicants have had to submit CBCs. Of these, 78 have been approved for certification, 3 have been denied, 2 have appealed and will have ALJ hearings, 9 provisional approvals have been given requiring follow up CBCs later, and 76 are still in process.

2004 Exam statistics: Bob Thomas said he would issue final exam statistics at the next CLTAC. In the last exam, of the CA-trained persons, 87 of 92 passed and 76 or 80 first-time takers passed. Other US-trained persons, 68 or 84 persons passed. The remaining persons (758) taking the exam were foreign educated and trained. Statistics were not available on their various pass rates.

Disease and condition reporting requirements: Bea O’Keefe and ShiuLand Kwong reported on the infectious disease and condition reporting requirements. The first requirement to report diseases was legislated in 1962, with frequent updates by regulation since that time. Currently findings of 7 agents must be reported within 1 hour to the county health officer and 18 others, within one day. The lab must provide patient and physician information that may not be available within this timeframe and that is the CCLA concern. Terri Bryant asked if the county health officer would reject the report if the information were incomplete. Ms O’Keefe said DHS was working on alternative language to make partial reporting with follow up reporting, acceptable. Jim Ottosen said a lab could give what they can and get the rest from the physician. Bob Footlik said there should be dual reporting with the lab reporting the lab finding and the physician reporting the diagnostic finding.

CLIA program issues: Donna McCallum reported on CMS efforts to improve communication between accrediting organizations and state agencies on problems with accredited labs. Part of this concern arose from problems found at Maryland General Hospital which reported 500 erroneous HIV results. CAP and JCAHO had not

responded to concerns at that facility. A state agency validates 5% of accredited lab inspections. If conditions are found, CMS makes the accredited lab correct them and cites the accrediting organization. Ms. McCallum said the partners in oversight are the CDC, FDA, the accrediting organizations, the state agencies (as LFS), the two CLIA exempt states, and CMS regional and central offices. There have been 4 meetings to work to improve communications about lab issues in accredited labs. One key issue is an effort to share survey findings, PT failures and complaints.

Cytology proficiency testing: Ms. McCallum said the PT of Pap smears was required once each year in CLIA 1988 and was to include both cytotech and pathologist. The new program requires applications before July 1, 2005 and completion in 2006. CMS has approved Maryland and MIME. ASCP/CAP is awaiting approval. In 2005 this PT will be educational with fees set by the testing program. CMS hopes for less than 10% failure rate. Bob Footlik asked how results would be seen by the state. Ms McCallum said this would be checked when onsite and also LFS would ask for information sharing.

New business: Dr. Nickel reminded the CLTAC that LFS would be moving, changing their phone numbers and address. This information would be given out at the next CLTAC meeting. She asked that the CLTAC update their roster information. The December 2, 2005 meeting of the CLTAC will be held at the State Office Building on Clay Street and there will be no telephone bridge available. She urged all CLTAC members to make the effort to come to Oakland for the meeting. Dr. Borok asked if the CLTAC members were obligated to come to Oakland. Dr. Nickel said in past years, all 4 meetings of the CLTAC required members to travel alternatively to Oakland or Los Angeles. Now thanks to Kaiser Permanente's providing videoconferencing facilities, the CLTAC members only needed to travel to one meeting each year. CLTAC members should feel obligated to make this trip in December.

Hearing no further new business, Chairperson Teresa Bryant asked for a motion to adjourn. Mary York moved, Tim Hamill seconded, CLTAC voted unanimously, to adjourn the meeting.