

Clinical Laboratory Technology Advisory Committee
Minutes of the September 9, 2005 Meeting
Meeting held by videoconference from Kaiser Permanente Oakland and
North Hollywood, and by telephone bridge.

CLTAC members participating: Michael Borok, Teresa Bryant, Carolyn Days, Tim Hamill, Curtis Johnson; Lin Kassouni, Carmen Maldonado; Salim Rafidi, Les Revier; Michael Terry; David Yong, Mary York, David Zingmond.

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

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

Public Members: 24 persons signed in in Oakland, 16 persons, in North Hollywood, 25 lines called in on the telephone bridge and 22 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 June 10, 2005 Meeting Minutes: Teresa Bryant asked for any corrections to the minutes of the June 10, 2005 meeting of the CLTAC. Dr. Field asked that he be listed as a CLTAC member and not a public member. Dr. Nickel said he had completed two terms on the CLTAC and was not eligible to continue as a member, but was welcome to attend as a public participant. Jim Ottosen said the CLTAC Bylaws restricted the length of time a person could serve on the CLTAC to 2 four-year terms. This change was not be made to the minutes. There were not other corrections, Mary York moved, David Yong seconded that the minutes be approved, and they were approved.

Department News: Paul Kimsey, Division Chief of Laboratory Science, thanked everyone for attending. He noted that Dr. Dick Jackson, State Health Officer, had resigned and would be replaced by Dr. Howard Bacher, Chief of the Immunization Branch and former ER Physician. Dr Kimsey updated the CLTAC on the Governor's CA Performance Review (CPR). He said some of the CPR issues, as the criminal background check requirement for licensure, might require a change in state law. Dr. Kimsey said the move of the other DHS programs to Richmond had been completed

and there were now 1100 employees at the Richmond site. He encouraged people to look at the DHS website, including LFS', and the FAQ on laboratory licensing.

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 LFS had moved to Richmond on August 12 and is getting settled in to the new space. Dr. Nickel said she hoped the CLTAC meeting could be held there in December. She said a key contact phone list was being distributed at both video sites so people would know the new phone numbers. The LFS website had also been updated with the new contact information thanks to Maria deSousa, Kathy Williams and Dona Lynch's hard work.

Dr. Nickel said the Bea O'Keefe had been promoted to Section Chief of Laboratory Licensing, taking on a massive job as we again seek CLIA exemption. LFS is also recruiting Examiners I and II to fill vacancies, and Dr. Nickel encouraged people attending the meeting to consider applying.

LFS has started online applications for phlebotomy and clinical laboratory scientists/specialists. Bob Thomas will talk about that later. LFS is working hard now to finish reviewing applications from about 1500 persons wanting to take the November 2 licensing examinations.

Legislation: Dr. Nickel said LFS has been quite light this year as some bills have been carried over to 2006.

AB 512 Enforcement of infectious disease reporting requirement. We had talked about this bill last time. It gives DHS authority to sanction labs that do not report infectious disease findings. This bill has now been enrolled. The last changes to this bill added exemption from sanctions for a lab that makes a good faith effort to get the required information from the physician but can't, but still reports on time. With that change, the CCLA removed its opposition.

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. This bill has been carried over to next year.

AB 1161 Unlicensed lab assistant bill. This bill was introduced late in the session, taking over a real estate bill that was "gutted". It was sponsored by CCLA and addresses many important issues discussed previously at CLTAC meetings, as

- (1) Autoverification defined.
- (2) Supervision of unlicensed lab assistants clarified.
- (3) Analytical phase of testing defined.
- (4) Licensure of histocompatibility lab directors clarified.
- (5) Definition of unlicensed lab assistants clarified.
- (6) Authority for DHS to issue trainee licenses for MLT students given.

- (7) Work scope of unlicensed persons explained.
- (8) Pre-analytical activities specified.
- (9) Analytical activities specified.
- (10) Activities prohibited for unlicensed persons specified.
- (11) Explained what activities medical assistants can perform.
- (12) Bill asked for urgency filing.

This bill was extensively reviewed in a short time. Robert Footlik said the short timeframe did not allow consensus on the bill and it would be re-introduced next session.

MLT Licensing Regulations Update. The Office of Administrative Law has until September 15, 2005 to either give concerns about these regulations or to approve them. We have not heard anything back, so consider this a good sign for them to be signed off next week.

The only other regulations under development at this time are the R-22 regulations that will reverse the emergency regulations that postponed collection of lab fees until CLIA exemption.

Clinical laboratories providing phlebotomists in nursing homes: This is an issue that has come up recently and we would like to discuss this with the CLTAC. The two facilities under consideration are nursing homes (long term healthcare facilities) and non-profit community health centers (AKA federally qualified health centers). Both potentially would need phlebotomy services for their patients. The Physician Ownership and Referral Act (PORA) and BPC 650 restrict inducements for laboratory service and referral of testing to labs in which physicians have a financial interest. In 1996 this act led to concerns about labs providing phlebotomists in physician offices who would in turn send their referrals to the lab. This was deemed at the time to violate the PORA, so labs took phlebotomists out of physician offices, and set up patient service centers in the proximity of physician offices. A similar situation occurs in the two above facilities in which bedridden patients cannot come to remote patient service centers to get their blood drawn, and providing a phlebotomist would seem to be an inducement for lab services. Legislation in 2004, AB 2821, changed the law to accommodate this concern. It is now lawful for a lab to provide phlebotomists to a nursing home provided the services are appropriate, the facility assumes responsibility for timeliness, and the services are ordered by an attending physician. However, this service cannot be provided to the other type of facility, a non-profit community health center unless the services are compensated.

Dr. Borok said the key is the ordering physician. He/she should be able to order a test and not have a lab worry about inducements.

Clinical laboratory issues: Bea O'Keefe addressed a number of laboratory issues, as follows.

- (1) Implementation of lab registration. Registration of laboratories was actually started in March 2004 for labs that wanted to participate in MediCal testing.

LFS has now registered about 3,500 laboratories and licensed about 120 new laboratories for MediCal. This process is going quite smoothly and the labs are renewing now. However, LFS has started to register non-Medi-Cal laboratories which are not exempt from registration pursuant to the emergency regulations enacted in 1996. This is going more slowly because each lab must be evaluated whether it falls under the exemption of these regulations, i.e., no changes in CLIA certificate since 12/31/95. We need to improve the state database for tracking lab information. We would like to have online search potential for both labs and personnel. Licensing of labs not currently licensed and not exempted by the emergency regulations will begin on 1/1/06. Out-of-state (OOS) lab licensing for over 400 facilities will take several years because of staff shortages.

- Dr. Hamill asked what if OOS labs don't get licensed? Will that hurt access to testing? Ms. O'Keefe said she hoped not as more and more OOS labs get licensed.
- Dr. Borok asked what would make a lab exempt in the emergency regulations. Ms O'Keefe said changes of location, owner or director would not require a change in CLIA certificate, but a change from waiver to compliance would.
- Joseph Musallam asked if OOS labs would be inspected and would there be exception for labs doing unique tests? Ms O'Keefe said yes and no.
- Dr. Field said OOS labs do not use college grads to do testing, and DHS would have to assure equal standards. Ms O'Keefe said CA specimens need same quality testing.
- Robert Footlik said NYS had required labs outside NY to be licensed for years. Ms O'Keefe said LFS cooperates with NYS on inspections.
- Would out-of-country labs need to be licensed? Yes.
- Would LFS make a list of OOS licensed labs? Possibly online later. Currently 158 licensed OOS.
- OOS labs must be CA licensed to be reimbursed for MediCal? Yes
- What about POLs that refer tests OOS? Test report must identify OOS lab.

(2) MediCal moratorium. Bea O'Keefe said the moratorium on approval of new labs for MediCal reimbursement had been extended until next year. Access to testing appears to not be an issue. Some of the facilities exempt from the moratorium are hospitals, clinics, public health labs, physician groups, changes in location of enrolled lab and any lab that provides test offered no where else.

(3) Physician office lab FAQ. Ms O'Keefe read a list of FAQ regarding POLs and answered questions.

- Dr. Borok asked what is meant by PT oversight? Ms O'Keefe said CLIA only reviews non-accredited labs PT. The state reviews all labs PT. All POLs must comply with PT requirements whether accredited or not.
- Dr. Field asked why PT participation was not enough and inspections were not needed. Ms. O'Keefe said an inspection could find things that

would not be found with PT alone. Donna McCallum said some physician office labs were not aware of what PT they should enroll in and PT is only one of the issues of compliance.

- Dr. Borok asked about tests without PT? Ms O'Keefe said CLIA and state law requires quality assurance procedures at least twice a year for these.

- (3) Accreditation of labs in California. Ms. O'Keefe said labs may voluntarily decide to be accredited for CLIA but still need to be licensed or registered with the state. This will not change until after CLIA exemption.

Personnel licensing issues: Robert Thomas discussed several personnel licensing issues, as follows:

- (1) Use of SSN for licensure purposes. Robert Thomas said the law requiring social security numbers (SSN) for licensure were not strictly enforced, but new law (Family Code) and regulations require a SSN. The SSA used to issue non-working SSNs but does not do that any more. About 150 non-resident aliens were admitted to the exam and came to the US but could not get SSNs. These people were denied admittance to the exam and were very unhappy. LFS will make an effort to communicate this new information to foreign applicants.
- (2) Phlebotomy certification update. Gwen Wong left in June 2004 and now Maria deSousa is lead person for phlebotomy. Online applications for phlebotomists started on July 11, 2005 but only 160 have used this option as of this date. Most are still applying with paper applications. This has created a backlog of about 3 months now. A total of 7,500 phlebotomy applications have been received, 4,700 have been approved and 1,078 are pending missing documents. Mr. Thomas encouraged labs to get their phlebotomists to apply as soon as possible, and to use online applications as possible.
- (3) License renewals. Mr. Thomas said he hoped the license renewals would be mailed in mid October and would be received by the first of November. There would be no fee increase, but he encouraged people to keep their addresses current.
- (4) Preparation for November 2005 exam. Mr. Thomas said his section was working hard to review about 1,355 applications for licensure before the exam. So far, 711 have been approved, 200 have missing documents, 150 are missing SSNs and 55 are applying using certification exams (as genetic scientists, cytotechs).
- (5) Criminal background checks. All LFS license applications and renewals must self-attest to arrests and convictions. This is being considered for all other licenses in the state, too. Since the majority of LFS license applicants are from outside the US, it is difficult to get background checks done before licensure and CA residency. This requirement has added to LFS' workload.
- (6) Exam statistics from 2004. In 2004, 98% of the CA trained passed the licensing exam, 81% of US trained, passed and 64% of foreign trained, passed. This is considerably higher than before. Mr. Thomas discussed how the exams were developed using SMEs, and how the exam questions were weighted and changed. Mr. Thomas said LFS would be transitioning to certification exams

over the next 3 years. Already LFS accepts certification exams for histocompatibility techs, cytotech, cytogenetic techs, genetic molecular biology techs, phlebotomists and will for MLTs. LFS wants to have 2 exams approved for MLTs and for CLSs in 2006, with others to follow.

- (7) Online applications. Online applications will save time of key data entry which is laborious and should eliminate mistakes in information. Mr. Thomas said LFS hopes to get all applications and renewals, for personnel and labs, online.
- (8) Phlebotomy backlog. LFS staff is currently reviewing applications received the end of May, so there is a 3-month backlog and the volume of applications is increasing each month.

Robert Thomas answered questions about personnel licensing as follows.

- For online applications, how are the documents handled? All applications need an original signature, an attestation page, and documentation of education (transcripts) and training. These are mailed separately to LFS and they are matched up in a file.
- How does ACCROA work for foreign transcripts? Original transcripts from foreign countries must be sent to this organization for evaluation. Sometimes the transcripts need to be translated if not in English. LFS relies on ACCROA evaluation of coursework.
- What is an applicant can't get his/her high school transcript? Will a diploma work? A diploma cannot be accepted. If an applicant has gone to college in the US, those transcripts can be used. If nothing else, the applicant must pass an approved GED.
- The phlebotomy has an April 2006 deadline. What happens if a person applies late and does not make the deadline? The grandfather extension goes until April 2006 and after that time, there is not more grandfather provision unless the law is amended. This does not affect new phlebotomy applicants who must be certified before they can work.
- The SSN requirement is not fair to foreign applicants.
- Fingerprints and criminal background checks are done by the INS already. Why does LFS have to do it again? The law requires it.

New business. Bea O'Keefe discussed quality control of allergy testing, describing the major types of testing done, their complexities and the hundreds of allergens now available. Some antigens are FDA approved and some are ASRs (non-FDA approved). The question has arisen; must each allergen be subject to QC? Ms O'Keefe said this is under review by LFS and DHS legal staff. It appears that if the FDA has approved an allergy kit for group allergen QC rather than specific allergen QC, then group allergen is acceptable for state and federal purposes. If a lab chooses to use ASR allergens that are not included in an FDA-approved group, then that allergen must be subject to verification of test performance and individual QC. LFS has checked with Judy Yost of CMS on this, and CMS is unclear on how this should be handled. This matter will be discussed further at the next meeting.

Mary York was unhappy that LFS had not informed the CLTAC about AB 1161 so they could have input on the bill. She said this bill imposed very important changes in the law and the CLTAC needed to be involved. Robert Footlik said the bill was already very complicated, and Dr. Nickel said the bill came and went too fast to discuss with the CLTAC. She said she anticipated an opportunity next session. Salim Rafidi said the CLTAC should take a strong position. Mary York asked what was DHS position on autoverification. Jim Ottosen asked if LFS had the CLTAC position paper on autoverification. Dr. Nickel said the CLTAC position had been mostly incorporated into AB 1161 and she anticipated DHS support of autoverification. Robert Footlik asked why DHS had not sponsored the changes proposed in AB 1161. Dr. Nickel said it was better coming from the regulated community rather than DHS anyway. Terri Bryant said the CCLA and Robert Footlik had worked hard on developing the language of the bill.

The meeting dates for 2006 were set as March 3, June 9, September 8 and December 1, 2006.

Chair Terri Bryant reminded the CLTAC that nominations and election of the CLTAC chair would be held at the December meeting.

The meeting was adjourned at 12:25 PM.

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.