

Clinical Laboratory Technology Advisory Committee
Minutes of the December 3, 2004 Meeting
Held at the Harris State Building, Oakland, CA

CLTAC members participating: Terry Bryant, Carolyn Days, Lou Dunka, Tim Hamill, Curtis Johnson, Lin Kassouni, Donna Kirven, Carmen Maldonado, Salim Rafidi, Les Revier, Michael Terry, Peggy Tessier, David Yong, Mary York, David Zingmond.

Former CLTAC members: Vickie Bello, Sam Chafin, Clark Chow, Robert Footlik, Robert Freeman, Deanna Iverson, Jim Ottosen, Fred Struve

DHS staff present: Frank Barnes, Wenn Chen, Maria deSousa, Ron Harkey, Jim Howard, Shiu Land Kwong, Howard Manipis, Don Miyamoto, Karen Nickel, Jan Otey, Shahrzad Radahd, Pat Toomer, Robert Thomas, Clint Venable, Kathy Williams,

Public members: About 70 other persons participated by phone or in person at the videoconference sites.

Introductions and general announcements. Teresa Bryant opened the CLTAC meeting, welcomed the participants and noted that there was not yet a voting quorum. She 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, then the others. She also noted that the telephone bridge participants were all on "mute" and could only access the meeting thru the operator. This was done to eliminate background noise of phones left on.

Approval of the minutes of the September 10, 2004 meeting. The reading of the minutes was postponed until a quorum of the CLTAC was present.

Department news. Mr. Jim Howard, Assistant Division Chief spoke for Dr. Paul Kimsey who was out of town. He said Governor Schwarzenegger's California Performance Review (CPR) looked at statewide licensing and certification, at government organizations and boards to look for consolidation of efforts. Lab Field Services was one of the programs studied. Changes may be done by the governor's office, by legislation or by the Little Hoover Commission. Mr. Howard discussed the new state budget and said the state was broke financially. Fee-supported programs as Lab Field Services would continue to have restrictions in hiring, travel and training. Regarding repeal of the emergency regulations that have postponed collection of laboratory fees, this is being considered at high levels right now. Mr. Howard thanked the staff of Lab Field Services for their work with the backlogs, on the exam and with license renewals.

Les Revier asked if there were changes in state organization, would the public have an opportunity for input. Mr. Howard said that if they were substantial, they would. Mr. Revier asked about repeal of lab law, and Mr. Howard said that would likely not happen. Robert Footlik said the CLIF fund was fee-supported and Lab Field Services should be able to draw on those funds. Mr. Howard said costs were going up and the state needed to subsidize the CLIA program. Mr. Footlik asked about CLIA exemption and renegotiation of the overhead fees. Mr. Howard said this probably would not change. Jim Ottosen said when the emergency regulations are repealed, will Lab Field Services get more money? Mr. Howard said, yes, but the program costs would also go up.

LFS update. Dr. Karen Nickel welcomed the CLTAC and public members, and thanked Kaiser Permanente for providing both the videoconference sites in North Hollywood and Oakland, and the new and improved telephone bridge. Dr. Nickel said that LFS was continuing to struggle with severe staff shortages, lots of backlogs, people calling to complain about poor services. She said there are especially problems with phlebotomy certification and MediCal application backlogs. She said there were a few bright spots. The personnel licensing section had given the licensing exams in November 2004, and that went well. Bob Thomas will give a preliminary report on that later. Dr. Nickel said Lab Field Services has two new hires, the first new examiners in 3-4 years, and they are Maria deSousa and Wenn Chen. Maria will work in phlebotomy certification and Wenn in licensing and examinations. Also, Jan Otey has transferred from the CLIA section to tissue bank licensing. The third bit of good news is that Lab Field services has been allowed to update the examiner certification list, so if anyone is interested in working for Lab Field Services, please apply. The fourth good note is MediCal contracting has positively impacted our program with about 2200 new labs getting registered and about 200, licensed. The MLT regulations are close to being signed, we hope and there is lots of public support for that. Lab Field Services is being deluged with phlebotomy applications and we currently have a 10-week backlog (not good news). We are pleasantly surprised on the impact of MediCal contracting on the number of new registrations of labs, and also, as Mr. Howard said, that repeal of state lab law seems to be a dead issue now.

Approval of minutes of September 10, 2004 meeting. David Yong asked that the minutes be corrected at "Status of public health lab standards." The minutes state that these standards have been "put on hold pending support from the public health lab directors." He asked that the minutes say "the project has been reassigned to the CA Association of Public Health Lab Directors and CCLHO to develop draft regulations in coordination with Lab Field Services. When completed, the draft regulations shall be given to CLTAC for comment." The CLTAC did not approve this change since this action had been taken after the last meeting of the CLTAC and did not reflect the action of that meeting. There were no other changes to the minutes and they were approved as prepared.

Impact of 2004 Legislation Karen Nickel reviewed the new laws which were enacted from the 2004 legislature, as follows:

AB 371 (LaSuer), which allows CPTs to do forensic phlebotomy when directed by police officer (not necessarily MD) for DUI or drugs (not necessarily diagnostic purposes), at police state or jail, supervised within 30 minutes by MD, RN or CLS, and must be competency tested.

AB 1087 (Frommer) which allows CPTs to work for insurance companies under general supervision of an MD, RN or CLS, must be competency tested. Problem, persons working for insurance companies prior to this bill lack clinical experience and cannot be certified.

AB 685 (Leno) which allows HIV counselors to do fingerstick blood collection for rapid HIV testing, even without high school diploma. Impact, Office of AIDS and LFS shall develop training and certify these persons as LPTs.

AB 2409 (Yee), which allows board, certified genetic scientists to be licensed with BS if certified < 1991. Impact on LFS, we are getting such applications now.

AB 2436 (Bates) which clarifies what non-diagnostic programs can do (waived tests only, fingerstick, onsite testing by any person, under auspices of county health) versus what health fairs can do (any test if appropriately licensed or registered, and CLIA certified.)

SB 1355 (Aanestad) which increases the number of slides a cytotech can perform each day when using automated screening instruments. Impact, concern about how to tabulate daily workload when doing both manual and automated.

AB 1091 (Negrete McLeod), which gives more flexibility on infectious disease reporting requirement.

SB 1623 (Johnson), which removes the requirement that labs doing forensic alcohol testing be licensed for alcohol testing.

SB 142 (Alpert), which extends the date to initiate expansion of genetic screening of newborns.

Regulation update: Karen Nickel reviewed the status of regulations under development:

MLT regulations are still with HHS agency. There is lots of public pressure for release and implementation and concern about staffing and ability of Lab Field Services to start up. There will be no new staff for this program at least until after July 2005, concern about not being able to meet public expectations. Bob Footlik

asked why the Department could not provide resources to carry out the Machado bill which mandated MLT licensure. Jim Ottosen asked why July 2005? (Start of new state fiscal year). Mara Williams urged everyone to write a letter to the governor because of the lag time in getting MLT programs started in colleges.

Autoverification regulations. DHS is seeking a change in the law this coming year. This would avoid need to amend the current regulations.

Public health lab standards. These have been under development by PHL directors and they want to continue. They have no timeframe for completion.

Other regulations needed. Dr. Nickel said CLS training regulations needed to be updates and there have been requests for licensure of biochemical geneticist scientists and lab directors. Bob Footlik said andrologists needed to be licensed and Terri Bryant said if the phlebotomists did not get certified, there would be nobody to work.

MediCal contracting update: Paula Patterson and Donna Martinez gave an update on MediCal contracting. Ms Patterson said November 29, 2004 was the cutoff for Phase 1 applications for MediCal contracting and they had received multiple applications. They hoped to start with 500, but right now had 220 laboratories. They were concerned about consistency of the review process so more than 2 people would review each packet. What about labs that have not yet applied? The tentative cutoff date is March 2005 for MediCal. Labs can still bill Medicare. Phase 2 would start next and phase 3, hospitals and clinics, later.

November exam statistics: Robert Thomas handed out the preliminary results of the November 2004 licensing exam. He said of 1521 applications received as of July 15, 2004, 1223 were approved for the exam, 997 took the exam in November and 644 passed the exam. One question was disqualified. LFS is pleased with the higher pass rate and think that reflects on people being better prepared. Some participants expressed concern about the pass rate. Martha Kunkel asked how many questions had been replaced, and what about the other statistics. (Mr. Thomas said that would be available at the next CLTAC meeting.) Karen McRae heard the test was easier this time, Joseph Musallam said it had more recall questions. Mr. Thomas said the same type of questions had been used as before when the pass rate was much lower. Bob Footlik said 4 students from his lab took the CA exam and they thought it was good, ASCP more clinical, and harder. David Yong thought 70% pass rate is good if the applicant knows the material. Karen McRae wanted to know if the upcoming statistics would include those repeating the test. (Yes).

Personnel licensing update: Robert Thomas said the license renewals had been mailed out the last week in November (later than we had hoped). He said this year there would be an attestation of criminal conviction that must be answered.

He said LFS was working on online applications to improve efficiency and reduce labor-intensive processes.

What happens when a lab moves? Shiu Land Kwong handed out information on lab moves. Test method verification must be done at the new location and this is a problem. Sometime labs move completely, A to B, sometimes, labs split into two and sometimes, they move in phases. There were questions on what constitutes a “contiguous” location, at same address. What if two buildings have the same address? What constitutes a change in location? The law already allows a multiple site exception, but under certain conditions. A new lab must pass a state inspection before it opens. Ms Kwong said it is best to notify LFS in advance of a move so that inspection can be done in a timely manner, without down time.

Concerns about non-invasive testing. Dr Nickel said this issue came up recently about transcutaneous bilirubin testing. These instruments are classified as medical devices and not subject to CLIA or any requirements other than what the manufacturer requires. There is some question about how they should be quality controlled, how the user can assure that they are giving accurate results. Other examples are breath analyzers for alcohol, H. pylori, transcutaneous hemoglobin, hematocrit and pulse oximetry for blood gases. Bob Footlik questioned classifying these as in vitro diagnostic tests since there is no sample derived from the human body.

Phlebotomy update. Mr. Thomas said LFS had received 3861 phlebotomy applications and we anticipated 6000 by April 2005. Of the ones received, 1835 had been reviewed and 1868 approved. Those that were denied either had no exam or no high school verification.

New proficiency testing for Pap smears. Jan Otey gave a report on the new CMS requirement for proficiency testing of gynecological cytology. CMS approved a new provider called MIME on September 30, 2004. The new program starts January 1, 2005. The first year will be educational and all labs will follow the same protocol. There will be 3 dates for the exam and the cytotechs will get 10 slides to review. They must pass 90%. If they fail, they must retake the exam and do remedial training. All their slides must be rescreened. If they fail a second time, they must take a 20-slide test within 45 days. Tim Hammil asked if this was for Pap smears only. (Yes). Jim Ottosen asked if a lab fails to pass, what will happen? (They will lose their certification in cytology.) He asked how the lab is monitored (The results comes to LFS.) Karen McRae questioned having only one provider. All 2,400 labs doing cytology must use MIME. Bob Footlik said CAP was coming up to cytology PT. Deanna Iverson said the test slides all must have 100% agreement by 3 pathologists, so the slides must be good. Jan Otey pointed out that a freelance cytotech might have to go to Indiana to be tested as they are not associated with a lab. She

asked if a new hire came, would they have to be tested before hiring? She also asked what would happen if a pathologist did the screening, or the review, or both?

Election of a new CLTAC: Chair Terri Bryant noted that the meeting had lost its quorum of members, so no vote could be held for a new chair. That would be done at the next meeting. Terri Bryant would continue as Acting Chair.

Dates of the upcoming meetings: The CLTAC voted that the next quarterly meetings of the CLTAC would be March 4, June 10, September 9 and December 2, 2005. Only the December meeting would be face-to-face (in Oakland). The others will be by videoconference.

New business:

Martha Kunkel asked when two-year licensing would be implemented. Bob Thomas said that would be another year yet. The severe labor shortage in LFS had stopped progress on this effort.

Mary York said that state law was based on CLIA as of 1994 and when would it be changed to CLIA 2003. Dr. Nickel said work would start on this no sooner than summer 2005.

Being there was no more new business, Chairperson Bryant asked for a motion to adjourn. Peggy Tessier moved for adjournment, Michael Terry, seconded, all in favor. The meeting was adjourned