

Minutes of the Clinical Laboratory Technology Advisory Committee Meeting
March 5, 2004

This meeting was held by videoconference from Kaiser Permanent Northern California in Oakland and from Kaiser Permanente Southern California in North Hollywood. In addition, a telephone bridge was available to those not able to attend at the videoconference sites.

The meeting was called to order by Robert Footlik, substituting for Cherie Evans, Chair, who was unable to attend the meeting. Mr. Footlik noted that the CLTAC members would be allowed to speak first on each issue and then the public would be allowed to speak. He asked that all persons on the bridge mute their phones to avoid audio interference.

A roll call was held called by Robert Footlik and the following CLTAC members were present: Ellen Jo Baron, Greg Clark, Lou Dunka, Cherie Evans, Morton Field, Robert Footlik, Paul Fu, Diane Hedler, David Jong, Curtis Johnson, Lin Kissouni, Arthur Lurvey, Patty Ovalle, and Les Revier. This constitutes a quorum.

CLTAC nominees awaiting appointment were present: Carolyn Days, Carmen Maldonado, Peggy Tessier, Mary York and Michael Borok.

Former CLTAC members participating were: Sam Chafin, Imre Fischer and Jim Ottosen.

Cherie Evans greeted the meeting of the CLTAC by telephone and thanked Robert Footlik for presiding in her absence. Mr. Footlik welcomed the attendees, thanked Kaiser Permanente and gave his best wishes to Dr. Evans.

The minutes of the December 5, 2003 meeting were approved.

Paul Kimsey, Assistant Deputy Director for Laboratory Science/DHS, gave Department news. He said Diana Bonta, former Director of DHS had resigned the end of January, 2004 and Kimberly Belshe was appointed Secretary of Health and Human Services and her appointment was pending. There are 2 Chief Deputy Directors of Health, Richard Bayquen and Tom McCaffery. Dr. Kimsey said the CLTAC appointments had not yet gone through so current CLTAC members were being held over. Regarding the pending repeal of laboratory law, this matter had been carried forward to the new administration which must make a similar decision. A new policy document on the subject is under review to go to agency and the governor, but this may be held up until we get a new director. Dr. Kimsey said funding for Lab Field Services is still a problem and there is a deficit still as a year ago.

Jim Ottosen asked Dr. Kimsey to predict the future of lab law repeal. Dr. Kimsey said all options are still on the table, and the program is still in the red. Robert Footlik said he wanted to visit Kim Belshe on behalf of the CLTAC, but was unable to get an appointment. He said the CLTAC should wait to meet the new director.

Karen Nickel gave the LFS update. She thanked Kaiser Permanente for their willingness to host the videoconference again. She said the legislature is cranking up and there will be some interesting bills again this year. This is the second year of this session, yet there are still some new bills being heard. Dr. Nickel said work in the Oakland headquarters office was greatly impacted by staff shortages. This has not impacted the CLIA staff in the Los Angeles office, however, just state staff positions, mostly in Oakland. Many activities mandated by law are not being done, and staff is being redirected to keep the program going. All incoming calls now have to be directed to a call router because we cannot handle the volume. Governor Schwarzenegger has had all state programs do a number of interesting drills to evaluate program efficiencies and backlog. Regarding backlog, a quick check showed the following in our office:

- 42 labs backlogged up to 6 months waiting for onsite inspections for initial licensing. Impact? Cannot start testing until licensed.
- 40 labs outside CA backlogged about 6 months. Impact? Cannot bill for MediCal.
- 450 laboratory license renewals are backlogged up to 4 months.
- 32 lab awaiting approval to do HIV testing, cannot perform HIV in meantime.
- 100 applications for PHM backlogged for >3 months.
- 40 MD/PhD lab director applicants awaiting oral exams.
- 650 phlebo applicants awaiting certification
- 75 persons awaiting genetic scientist licensing. Did 450 in July, none since.
- May 2004 exam cancelled. 255 persons now waiting for Nov 2004 exam when 1500 are expected again.
- Tissue bank licenses are being issued without inspection
- There is only 1 blood bank inspector when 3 are authorized. Currently blood banks are inspected only once in 3 to 3 ½ years.

Dr. Nickel said that both the LA and Oakland offices might have to move to save money, adding further disruption. LFS Oakland is losing 4 more staffers. Howard Manipis, Linda Bryant and Ricky Chang are retiring and Gwen Wong is taking another position in the private sector.

LFS is getting continued interest in health fairs especially from out of state, Internet ordering and reporting, phlebotomy and genetic testing.

CLTAC questions for Dr. Nickel. Can the CLIA staff help with state programs? NO. Robert Footlik said this was an intolerable situation. (Note, Dr. M. Borok asked that this statement be entered into the minutes, "The Los Angeles office

was in the black due to (federal) funding for the CLIA program.”) Dr. Kimsey said many programs were experiencing similar problems and have not been successful in getting relief. There is hope with the new administration. Another question asked for clarification on the number of labs awaiting onsite inspections for state licensure, 40 not 400.

LFS staff reviewed legislation affecting clinical labs. Ron Harkey discussed AB 1200, Longville, in which a motorcycle driver killed while not wearing a helmet would qualify for automatic tissue donation. SB 38, Denham, would make tissue donation to a prisoner optional and SB 1355, Aanstedt, would impact cytotech workload using semi-automated systems. SB 1081 from last session eliminated the Deferred Donor Registry which required blood banks to report rejected blood donors.

Bob Thomas reported on AB 371, LaSuer, Certified Phlebotomy Technicians doing phlebotomy for forensic purposes, AB 1087, Frommer, CPTs doing phlebotomy for non-diagnostic purposes, AB 2409, Yee, would exempt cytogenetic scientists from BS requirement and AB 2138, Mayes, would require acceptance of certification and out-of-state licensure for CA licensure purposes.

Linda Bryant reported on AB 685 which authorizes HIV counselors to do Rapid HIV testing and to do finger stick collection of the blood sample. AB 1460, Nation, which would have allowed pharmacists to be lab directors, died. AB 2769, Richman, would split DHS into a new DPH. AB 2436, Bates, clarifies testing done at health fairs.

Ms. Bryant discussed SB 857 which was enacted recently for MediCal contracting. She said a letter was sent to all labs billing for MediCal on March 3, 2004 that said they had to be CLIA certified and state licensed or registered in order to continue billing MediCal.

Karen Nickel reported on progress on regulations underway. R-22-01E, Clinical lab licensing and registration standards, CLIA “non”-exemption. These regulations would reverse action taken by emergency regulations enacted in 1996 that postponed collection of fees from all labs. About 15,800 labs in CA and about 400 outside CA are not paying fees to the state, while about 1,700 are. These regulations have been pulled out of the file, dusted off and reviewed, in anticipation of a positive decision on laboratory licensing by the new administration. No further action will be taken on these until this decision is made.

The CLTAC had many questions about this. Would there be a back collection of fees since 1996. NO. Why not pursue CLIA exemption again to avoid duplicate fees. MAYBE that decision would be made. Why inspect accredited labs, wouldn't that be duplicative. ANSWER, the state does not have regulations for accepting accreditation in lieu of state inspections. Would this mean double

inspection. NO. One CLTAC member stated, accredited labs are not really inspected, but peer reviewed. (Note, Dr. M. Field protested the inclusion of this statement into the minutes.) Donna McCallum said LFS does a few validations each year of accredited labs. CLTAC said labs should be subject to state inspections rather than CLIA.

R-13-01E, Medical Laboratory Technician licensing standards. These regulations have been awaiting legal review since June 2003. We have asked for emergency filing and are getting lots of public requests for information. There were a number of CLTAC comments on these regulations. What about out-of-state interest? ANSWER, there is a lot. What would be the impact of MLTs coming from out of state on job availability? ANSWER, we think there are lots of jobs for everyone. What about NAACLS programs for MLT training in other states? ANSWER, these would be acceptable for licensure. How long will it take LFS to implement the program once approved? ANSWER, LFS has already had to agree to no new staffing first year, so that will be spent approving training programs and examinations by redirected staff. We hope to get staff second year.

Gwen Wong discussed implementation of phlebotomy certification. This program is really beginning to take off since it was implemented in April 2003. Over 100 training programs have applied and 70 approved, 825 applications received for CPT1. The CLTAC was concerned how this program would continue with the departure of Gwen Wong as program manager.

Bea O'Keefe reported on MediCal contracting. SB 857 has been implemented which changes MediCal participation for laboratory tests. Provisional enrollment will be given, the signature of the person requesting the test and date is required, with monetary penalties and appeal. Ellen Jo Baron said the beneficiary should be required to sign the test requisition to cut down on fraud. Another person asked how a reference lab receiving a test from a POL without a signature would get the signature. Whose responsibility would that be?

Bob Thomas gave an update on personnel licensing. He apologized that his section could not handle the thousands of phone calls it is receiving each month and has had to rely on a call router. This has made lots of people unhappy. His section is processing applications and the good news is that the number of licensed personnel has increased this year, stopping a 10-year down trend. We badly need MLT licensure for persons unable to pass the CLS exam. Mr. Thomas' section is working hard on phlebotomy activity, data base conversion and CLS application review. Ellen Jo Baron said LFS badly needs online applications to save workload. Mr. Thomas agreed, saying the initial work on this had been done already.

Donna McCallum reported on CLIA 2003 implementation. The new CLIA was implemented on 4/24/03 and will have 2 years to be incorporated by labs. The

first year is educational with deficiency statements only for the “old” CLIA and a letter for deficiencies with the “new” CLIA. This adds workload, but CMS wants a user-friendly implementation. Question from the CLTAC, when will state law be changed to reference the new CLIA? ANSWER, there is discussion on how to do this, and we have 2 years. What deficiencies does a lab need to correct? ANSWER, old CLIA right away, new CLIA before next cycle.

The discussion on cytotech workload was deferred to a later time.

There was no new business or open discussion

The next meeting of the CLTAC will be on June 11, 2004, videoconference and telephone bridge.

Motion to adjourn was passed by the CLTAC.