

CLINICAL LABORATORY TECHNOLOGY ADVISORY COMMITTEE

Meeting Minutes
September 5, 2003

Convened: 9:05 AM by videoconference and telephone bridge

Members participating: Ellen Jo Baron, Vickie Bello, Terry Bryant, Greg Clark, Cherie Evans, Morton Field, Robert Footlik, Paul Fu, Diane Hedler, Deanna Iverson, Curtis Johnson, Lynn Kassouni, Arthur Lurvey, Les Revier, Tony Van Kessel, and David Yong.

Past Members participating: Sam Chafin

Department Staff participating: Frank Barnes, Linda Bryant, Pam Farrell, Ron Harkey, Paul Kimsey, Kevin Reilly, Shiu Land Kwong, Howard Manipis, Donna McCallum, Karen Nickel, Lilia Shumaker, Tom Tempske, Robert Thomas.

Topic/Agenda	Report/Discussion	Recommendation/ Action	Follow-up
1. Introduction	Chairperson Cherie Evans opened the meeting, welcomed participants at two Kaiser Permanente sites and on the telephone bridge. She said Robert Footlik and Donna McCallum would lead North Hollywood site, Cherie Evans and Karen Nickel, the Oakland site. Dr. Evans asked attendees to introduce themselves. She noted there was a quorum.	Information only	
2. Approval of minutes 9/6/02.	The minutes of the March 14, 2003 were reviewed and approved. The minutes of the June 13 meeting were not yet prepared, but would be ready by next meeting.	Minutes of March 14, 2003 meeting approved	LFS to prepare minutes of 6/13 and 9/5/2003 meetings before 12/5 CLTAC meeting.

<p>3. Department Update</p>	<p>Paul Kimsey said he would discuss two things, the State budget and how that affects staffing and repeal of state lab law. (1) Recent budget drills have eliminated 15-18% of General Funded positions and 12% of Special Funded positions. There has been a sweep of vacant positions, and LFS has lost 15 more positions. There may be more cuts in 04/05 before things improve. (2) Regarding repeal of lab law, Dr. Kimsey read the notice "State to Withdraw from State Oversight of Clinical Laboratories". Dr. Kevin Reilly, Deputy Director of Health, came on the telephone bridge to answer questions.</p> <p>Dr. Reilly discussed the solvency of the fund for LFS, explained why CLIA exemption was not possible, insolvency of LFS required General Fund bail out to avoid duplicate fees for labs. This cannot continue so two options considered, increase revenue paid by licensed labs or reduce services and expenditures. Decision was made to eliminate state lab program to reduce costs.</p> <p>Dr. Kimsey said the administration made the decision and it has been discussed with CMS. The Department is unsure how the law will be changed.</p> <p>Dr. Kimsey said DHS wanted CLTAC input and the legislative process is open to public.</p>	<p>Diane Hedler asked if all current lab law would be removed? Dr. Reilly said DHS legal staff was working on this.</p> <p>Les Revier said this was an incredible decision, affecting healthcare consumers, gives regulatory relief to CMA and POLs.</p> <p>Cherie Evans said that fees not paid by labs now could pay for the program. How would complaints be handled? Why not charge fees? Dr. Reilly said there was lots of politics, need for guidance.</p> <p>Terry Bryant asked what would happen if legislature did not support repeal. Dr. Reilly said there were still financial issues to address. Ms. Bryant said DHS ought to charge fees to labs needing oversight. All labs need level playing field. Dr. Reilly said there were two options, CLIA exemptions or no state program.</p> <p>Robert Footlik questioned the effect on MediCal fraud if oversight removed. He said this is terrible public policy and labs will lose accountability.</p> <p>David Yong said this was more than financial, CLIA would take over, drop services or increase fees.</p> <p>Greg Clark said paying fees is cost of doing business. Labs should pay.</p>	
-----------------------------	---	--	--

	<p>Dr. Nickel said, when asked, that lab fee revenue is currently about \$1.5 million each year. If all labs paid their fees as required by law, revenue from CA labs would be about \$4.0 million.</p> <p>Dr. Reilly said the fees for waived and PPMP labs are low, about \$55 and \$85 per year.</p> <p>Dr. Nickel recommended the CLTAC wait until after her presentation on impact of law repeal to make a motion.</p> <p>Dr. Reilly said DHS has made the decision, there have been no recent talks with the CMA, DHS legal staff is writing the law repeal, no author has been found, and further pursuit of CLIA exemption is unlikely unless relief of high overhead fees is gotten.</p> <p>Dr. Reilly said the action must go forward. CLTAC will have opportunity for input after Jan 04. Department of Finance has reduced LFS' budget and services.</p> <p>Dr. Reilly said the decision was to reduce the program, not increase revenue.</p>	<p>EllenJo Baron asked why all 17,000 labs don't pay and asked if they had been asked?</p> <p>Cherie Evans asked how the CLTAC could have input.</p> <p>Robert Footlik asked that a motion to be to oppose current decision.</p> <p>Kathy Rees asked (1) who made the decision to repeal lab law, (2) has DHS spoken with the CMA, (3) who will write the legislation, (4) has author been found, (5) will there be further pursuit of CLIA exemption.</p> <p>Morton Field said POLs are inspected by COLA and that is enough.</p> <p>Ann Kroll said healthcare is not jeopardized in the CLIA exempt states.</p> <p>Tom Tempske said there were state issues, like phlebotomy, not covered by CLIA, but public wants oversight.</p> <p>Deanna Iverson said she has mixed feelings, CA law is good but slow to change.</p> <p>Joseph Musallam asked if there was a chance of reversal.</p> <p>Diane Hedler said already LFS cannot do their work.</p>	
--	---	---	--

		<p>Robert Footlik said no program oversight will hurt lots of programs like HIV no-name reporting.</p> <p>Rochelle Leimhus asked what POLs would get for their fees.</p> <p>Kathy Martin said why not raise fees? NY lab fees are very high and no one complains.</p>	
4. LFS update	<p>Karen Nickel thanked Kaiser Permanente for the use of their videoconferencing centers, and recognized the loss of Lyle Rosser of KP and Rod Hamlin, former chief of LFS.</p> <p>Dr. Nickel told good news first. Already 1150 people have been approved to take the Nov 2003 licensing exams. The genetic scientist licensing regulations were enacted in March 2003 and over 400 persons licensed already. LFS submitted 5 legislative proposals to DHS and so far, 4 have been accepted for consideration (1) Health Fairs BPC 1244, (2) Unlicensed Lab Aides (BPC 1269), (3) AATB standards for tissue banks (HSC 1639.1) and (4) Histocompatibility lab director (BPC 1209.1). Also, all organizations have been contacted for CLTAC nominations for 2004. The CLTAC has been approved for a face-to-face meeting in December 2003. A recent audit of our CLIA program shows high marks.</p>	Information only	

LFS Update	<p>Dr. Nickel said there was some bad news, too. The notice of the repeal of state law probably came as a shock to the CLTAC. Although we have been discussing this issue for a number of years with you, this decision was still a shock. Staff shortages in LFS continue to cripple our program. We lost two more key staff persons. We have an estimated 37 vacancies now, and they have been taken away. We have problems with staff to answer phone, do filing, etc. In addition, we will not be able to offer May 2004 licensing exams again. Dr. Nickel said Section 1031.8 would allow certifying exams in lieu of state exams, these were part of MLT regulations, and would be expedited</p>	<p>Several CLTAC members expressed concern about cancellation of the May 2004 exams, saying what are the alternatives? When will Section 1031.8 regulations be approved? Dr. Nickel said there were no alternatives until the regulations are enacted, hopefully in 2004.</p>	
5. Legislation affecting clinical laboratories	<p>Robert Thomas reported on: <u>SB 165 (Machado)</u>, which were LFS' legislative proposals from last year. Cytology billing was added to bioanalyst, temporary scientist licensing, and dating of continuing education. This is ready for enrollment. <u>AB 685 (Leno)</u> would allow HIV counselors to do skin puncture for rapid HIV tests. <u>AB 1087 (Frommer)</u> would allow CPTs to draw blood for forensic purposes. Ron Harkey reported on: <u>AB 777 (Dutton)</u> would allow OPOs and coroners to take tissue. <u>SB 112(Speier)</u> would create an organ donor registry funded by OPOs. <u>SB 617 (Speier)</u> would allow donors to opt out of donation for cause with penalties for non compliance.</p>	Information only.	

<p>6. Regulation update</p>	<p>Karen Nickel reported on status of regulations underway: <u>R-13-03E</u>: MLT licensure, includes Section 1031.8, key importance right now. Still being reviewed by DHS legal staff. <u>R-35-01E</u>: Genetic scientist licensure, enacted March 2003, finalized in August 2003. Over 400 persons licensed already. Problem with non-BS persons certified by NCA. <u>R-54-00</u>: Autoverification. No further work on this. <u>R-22-01E</u>: Full collection of lab fees. On hold. Will discuss later.</p>	<p>Several CLTACers asked about how Section 1031.8 would be implemented. Dr. Nickel said probably over 3 years, high volume categories first, with CLTAC involvement.</p>	
<p>7. Decision to repeal state lab law: implementation and impact.</p>	<p>Karen Nickel said she was going to review the history of lab law that led to the decision to repeal it, the implementation orders, the transition and impact. <u>History</u>. CA state lab law started in 1926 with public health labs. In 1951 all labs (hospital and commercial) needed to be inspected, licensed and pay fees. CLIA 88 came into CA in Sept 1992 and SB 113 in 1996 added CLIA to state law and prepared way for CLIA exemption. At that time emergency regulations postponed collection of fees from CLIA labs, mostly POLs. In 1999 CA got approval for CLIA exemption and in 2000, turned it down because of overhead fees. Since then there has been no decision to allow full collection of fees, until July 2003. The decision was made to repeal state law to prevent duplicate fees. <u>Implementation orders</u>. Need to repeal state law, Department sponsored bill, need an author. How to repeal the law is an issue. <u>Transition</u>. Partial fee collection, enforcement continues. Need public input, evaluation of program input, communication with regulated public.</p>	<p>Information only.</p> <p>David Yong asked how this action would impact non-doctorate PHMs in CLIA. Dr. Nickel thought it would not impact this.</p> <p>Dora Goto asked how enforcement would be impacted. Dr. Nickel said the standards would still be in place.</p> <p>Jim Ottosen said the CLTAC should strongly oppose this action.</p> <p>Robert Footlik said the same authority used for the emergency regulations in 1996 could be used to repeal them.</p> <p>Cherie Evans says if state law is repealed, there is no enforcement, laws become a “suggestion”.</p>	

<p>Decision to repeal state lab law: implementation and impact.</p>	<p><u>Impact on LFS.</u> Reduction in staff, deferral to CLIA program, no state services, enforcement, fraud investigations by LFS.</p> <p><u>Impact on labs.</u> Single fees and inspection. No state license fee. No consultation by LFS, complaints, database maintenance.</p> <p><u>Impact on public.</u> No local control, only federal. No enforcement of state issues.</p> <p><u>Impact on public health.</u> Time will tell. CLIA standards enforced.</p> <p>Dr. Nickel said the sliding scale was under consideration after CLIA exemption.</p>	<p>Linda Bryant said when state eliminated Cal OSHA to depend on Federal OSHA, the state had to bring Cal OSHA back.</p> <p>Diane Hedler asked is LFS was the only program affected. Dr. Kimsey said he thought so, yes.</p> <p>Robert Footlik made a motion that the CLTAC oppose repeal clinical laboratory law, Seconded by Curtis Johnson. Discussion followed.</p> <p>David Yong, all fees collected into special fund, should be given to LFS.</p> <p>Morton Field, all volume-based (CLIA) fees would remain.</p> <p>Diane Hedler, said CLTAC needs to meet with decision makers, discuss options.</p> <p>Robert Footlik, said CLTAC should meet with Director, Governor, Agency.</p> <p>Ellen Jo Baron, why not adopt sliding fee schedule?</p> <p>Robert Footlik's motion to oppose repeal of state law passed with one declining vote. Morton Field asked to be identified as the one opposing the motion.</p>	
---	--	--	--

<p>Decision to repeal state lab law: implementation and impact.</p>		<p>Diane Hedler made second motion that the CLTAC meet with Dr. Bonta and senior staff to discuss issue of repealing state lab law and recommend other options. Ellen Jo Baron seconded. The motion was passed unanimously.</p> <p>Cherie Evans said she would write a letter to Dr. Bonta on behalf of the CLTAC, requesting a meeting. She also urged interested persons to write to Dr. Bonta.</p>	
<p>8. Implementation of phlebotomy certification</p>	<p>Robert Thomas reported on progress in certification of phlebotomists. He said the program initiated six months ago and 43 of 83 training school applications have been approved, 4 of 8 certifying examinations. We expect 5000 CPT applications this year, have 50 in already.</p>	<p>CLTAC asked if staff shortages were delaying implementation. Mr. Thomas said the program had only half the staff it was supposed to have and the two people there were working hard to get the program up.</p>	
<p>9. MediCal contracting update</p>	<p>Linda Bryant reported that the new MediCal RFA will be mailed in a few weeks, requiring labs to re-enroll for Medical payment.</p>	<p>Information only.</p>	
<p>10. Personnel licensing update</p>	<p>Robert Thomas told how licensure of genetic scientists had been expedited because of lab demand for licensed persons. Of 405 licensed persons, 330 are cytogenetic scientists. For the November exam, staff has reviewed 1569 applications, a record. The exam site in southern CA will be Buena Park. Mr. Thomas said LFS regrets having to cancel May 2004 exam.</p>	<p>Information only.</p>	

<p>11. New business and open discussion.</p>	<p>Denise Salazar had asked that licensure of biochemical geneticists be put on the agenda. Dr. Salazar explained that this category of license is different than the two recently implemented by LFS. It has separate board requirements and exam by ABMG, There are 203 certified in US, 33 in CA and they need license opportunity.</p> <p>Dr. Evans asked if there was any other new business and there was none.</p>	<p>Karen Nickel said LFS was not aware of this category in 2000 when the doctoral-level genetic license categories were implemented. It could have been added at that time, but now, would be difficult.</p> <p>EllenJo Baron asked what the 33 people were doing in CA without licensure. Dr. Salazar said they were consulting.</p> <p>Robert Footlik said the andrology scientist regulation should go first as that is a fast expanding field.</p>	
<p>12. Next meeting dates.</p>	<p>Dr. Evans reminded the CLTAC that the December 5, 2003 meeting would be in Oakland, at the Harris State Building. This may be the only face-to-face meeting in the 2003-04 state fiscal year, so everyone should attend. The other meetings will be: March 5, 2004, June 11, 2004, September 10, 2004 and December 3, 2004.</p> <p>The meeting was adjourned at 12:20 PM</p>		

Motion by Robert Footlik: I move that the Clinical Laboratory Technology Advisory Committee oppose the proposed repeal clinical laboratory licensure law in California and that the CLTAC recommend to DHS that license and registration fees be imposed on those clinical laboratories that currently do not pay California laboratory license and registration fees.

Second by Curtis Johnson

Vote of the CLTAC: All in favor except one dissenting vote by Morton Field.

Motion by Diane Hedler: I move that the Clinical Laboratory Technology Advisory Committee request a meeting with Dr. Bonta and senior staff in the Department of Health Services to discuss the issue of repealing state clinical laboratory law and recommend other options. In discussion the motion was amended to read, "as soon as possible or before October 2."

Second by Ellen Jo Baron

Vote of the CLTAC; Unanimously in favor.