

## CLINICAL LABORATORY TECHNOLOGY ADVISORY COMMITTEE

Meeting Minutes

June 13, 2003

Convened: 9:30 AM at Harris State Building, Oakland, CA

Members participating: Vickie Bello, Greg Clark, Cherie Evans, Robert Footlik, Diane Hedler, Deanna Iverson, Lynn Kassouni, David Yong, Lou Dunka.

Past Members participating: Jim Ottosen, Fred Struve.

Department Staff participating: Linda Bryant, Ron Harkey, Paul Kimsey, Howard Manipis, Donna McCallum, Don Miyamoto, Karen Nickel, Jan Otey, Tom Tempske, Robert Thomas, Kathy Williams, Gwen Wong.

Topic/Agenda	Report/Discussion	Recommendation/ Action	Follow-up
1. Introduction	Chairman Robert Footlik opened the meeting, welcomed participants. He reiterated the purpose of the CLTAC is to advise the Department on matters related to rules and regulations for clinical laboratories. He thanked Peter Mackler for allowing the face-to-face meeting. Mr. Footlik asked attendees to introduce themselves and sign in.	Information only	
2. Approval of minutes 9/6/02.	The minutes of the March 14, 2003 were reviewed and no changes were made. However, since there was no quorum, the minutes could not be approved.	Approval of minutes of March 14, 2003 meeting held over until September 5, 2003 meeting.	
3. Department Update	Paul Kimsey said recent budget issues are difficult. The Governors Budget is due 6/15/03 but it won't happen. Some department has layoffs, but not DHS. There is still no decision on LFS' finances, as discussed last time. Currently LFS has expenditures over revenue and	Information only.	

<p>Department Update</p>	<p>we are awaiting a policy decision to repeal the emergency regulations that postponed collection of fees to correct this. LFS has not been able to fill any positions for 2 ½ years and there will probably be no resolution until after the recall is resolved.</p>	<p>Diane Hedler asked if all unfilled positions that were vacant for 6 months would be eliminated. Dr. Kimsey said that they would be. No freeze exemptions had been given to LFS.</p> <p>Martha Kunkel asked if the budget crisis had effected cancellation of the May exam. Dr. Kimsey said it had.</p>	
<p>4. LFS update</p>	<p>Karen Nickel said the current high vacancy rate in LFS makes it difficult to run the program. Nancy Stone has left LFS, leaving Gwen Wong the only examiner in phlebotomy certification. We are also in the process of licensing the new genetic scientist categories without additional help. We expect the MLT regulations to be enacted soon, also.</p> <p>There will be a major turnover of CLTAC members next year as 10 are leaving, ineligible for reappointment. Three persons have completed one term, are eligible for reappointment, and have said they want to continue.</p> <p>The next two meetings will be by teleconference, but Kaiser Permanente has offered videoconferencing facilities, in addition.</p> <p>LFS has been involved in a number of state-initiated complaint investigations. We continue our concern about accredited labs which are only inspected by LFS on complaints. The document, "Issues Unique to California Clinical Lab Law" was reviewed. Accredited organizations cannot address state issues in their surveys.</p>	<p>Information only</p> <p>The document, "Issues Unique to California Clinical Laboratory Law" is available at the LFS website at <a href="http://www.dhs.ca.gov/lfs">www.dhs.ca.gov/lfs</a></p>	

LFS Update	<p>Phlebotomy certification is having a big impact on LFS with lots of interest, 3 proposed bills in the legislature. We are reviewing national certifying exams in phlebotomy and have found it is imperative that actual exam review be conducted. Reliance on exam statistics may be misleading.</p> <p>LFS has developed a number of legislative proposals for DHS sponsorship. These were done with CLTAC input and your continued support and input on these is appreciated. These proposals include amendments to BPC 1208 (a) (Changes in CLIA), BPC 1244 (Health Fairs), BPC 1269 (Lab aides), BPC 1209.1 (Histocompatibility Lab Director) and HSC 1639.1 (AATB standards for tissue banks.)</p>	The CLTAC asked about the cost of phlebotomy examinations. The exams generally cost from \$60 – 100 and are sometimes included in training program costs.	
5. Legislation affecting clinical laboratories	<p>Karen Nickel reported on: <u>SB 165 (Machado)</u>, which were LFS' legislative proposals from last year. This bill would allow certification exams for bioanalyst licensure, temporary licensing of scientists and calendar continuing education.</p> <p>Gwen Wong reported on: <u>AB 371 (LaSuer)</u> which would allow CPTs to draw blood for forensic purposes.</p> <p>Bob Thomas reported on: <u>AB 685 (Leno)</u> which would allow HIV counselors to do skin puncture for rapid HIV tests. <u>AB 1087 (Frommer)</u> which would allow CPTs to draw blood for non-diagnostic purposes.</p> <p>Deanna Iverson reported on: <u>SB 1077 (Sen B&amp;P Comm)</u> which would change cytotech workload limits with new technology.</p>	Information only.	

	<p>Ron Harkey reported on: <u>SB 617 (Speier)</u> which would allow donors to opt out of donation for cause with penalties for non-compliance. <u>SB 112(Speier)</u> would create an organ donor registry funded by OPOs.</p>	Information only.	
Approval of minutes	Robert Footlik noted that there was still no quorum of CLTAC members and suggested CLTAC ByLaws be changed to amend how quorum was established.	No motion was made.	
6. Regulation update	<p>Karen Nickel reported on status of regulations underway:</p> <p><u>R-35-01E</u>: Genetic scientist licensure. It has taken almost 10 years to get this “emergency” package approved because of controversies, and there are still problems. About 10% of practicing cytogenetic scientists do not have baccalaureate and so are ineligible for licensure. No changes to regulations were possible in response to public comments.</p> <p><u>R-13-03E</u>: MLT licensure, The Machado bill last year (SB 1809) gave DHS new authority for MLT licensure, so package was re-numbered to “03E”. These regulations are well worked and include Section 1031.8, for emergency filing.</p> <p><u>R-22-01E</u>: Repeal of emergency regulations that postpone full collection of fees. These are still on hold pending decision.</p>	<p>CLTAC asked how these cytogenetic scientists had been allowed to work in CA without licensure and without degree. Dr. Nickel said labs were given standard-level deficiencies pending enactment of regulations. Now regulations are enacted, they would be condition-level deficiency.</p> <p>CLTAC said time to implement MLT licensure was too long, labs are waiting, colleges are geared up, out-of-state MLTs want to come to CA, MLT graduates are working as lab aides.</p> <p>Robert Footlik questioned the authority of DHS to enact the emergency regulations in 1996, countering legislation enacted the same year. He said, when are regulations allowed to displace the law? Why was this never challenged?</p>	

Regulation update		CLTAC asked about regulations to update CCR 1032, CLS training. Dr. Nickel said these have not been started yet. Also, Autoverification, CCR 1050 (h) have not been started.	
6. Implementation of phlebotomy certification	Gwen Wong reported on how the phlebotomy program was being set up with new databases, forms, cards, informative material on website. Staff shortages are problem. Applications from 9 Certifying exams have been received and 3 are approved. Of 71 training program applications, 28 have been approved	Donna Kirven asked about timing of certificate issuance and qualification of phlebotomy instructors	
7. Review of changes in CLIA effective 1/24/03  Review of state options for adopting changes in CLIA.	Donna McCallum summarized changes in CLIA regarding immunology, serology, microbiology, hematology and histocompatibility quality control. She also discussed changes in CLIA made to eliminate redundancy, add clarity and plain language. Some changes will result in reduction of QC frequency. Moderate and high complexity becomes "non-waived".  Kathy Williams discussed the options CA had for adopting or not adopting CLIA. The intent of SB 113 was that state law would be at least as stringent as CLIA. The more strict law holds, whether state or federal. A crosswalk needs to be done to truly compare state law with the new CLIA. Currently CLIA as of 1994 is incorporated into state law. Section 1208 (b)(c) gives method for accepting/denying changes.	CLTAC asked how this would be implemented in CA. Ms McCallum said it would be consultative for one cycle (two years) as labs made changes. In some situations it may take up to 4 years to change.	

<p>8. Appointment of CLIA Final Rule Subcommittee</p>	<p>Karen Nickel asked the CLTAC to assist DHS is reviewing the CLIA Final Rule to recommend which changes should be incorporated into state law pursuant to BPC 1208 (b)(c). A determination would need to be made whether new CLIA is more, less or equivalent to state law. The group would recommend to DHS to make the determination, case by case. If CLIA were less strict, it could be adopted or not with reasons given. If more strict, then it must be adopted.</p>	<p>Robert Footlik said he would chair the CLIA Final Rule Subcommittee, with Jim Ottosen, Les Revier, Deanna Iverson and Mary York. Kathy Williams would serve as DHS liaison.</p>	
<p>9. Licensing examination update</p>	<p>Robert Thomas reported on changes to the state licensing exams. He said having to cancel the May exam has put more pressure on the November exam. There are 1174 applications in process now for that exam, twice normal. LFS now administers 19 license categories and soon, 3 phlebo certificate categories. Of the 19 license categories, 11 take state exams and 8 take certifying exams. The trend is continuing to be a decrease in total number of licensees.</p>	<p>Diane Kelly asked about the May 2004 exam. Mr. Thomas said he did not know at this time whether we would be able to conduct those. Another person asked if only NCA exams were acceptable at this time. Mr. Thomas said no, others had been approved, as ASCP for cytotechs, ABMG for genetic directors, ASHI for histocompatibility scientists.</p> <p>Another person asked when DHS would switch to certifying exams. Mr. Thomas said when Section 1031.8 of R-13-03E was approved.</p>	
<p>10. Internet ordering of lab tests, health fairs</p>	<p>Karen Nickel said LFS was still being bombarded with internet ordering of lab tests by businesses outside the state, with illegal phlebotomy, inappropriate ordering of tests at health fairs, testing by unqualified persons, and ordering of tests by physicians on persons of whom they have no knowledge.</p>	<p>The CLTAC asked why these problems persisted, what could be done? Dr. Nickel said parts of CA law were unclear and prohibit clear enforcement. LFS is asking for amendments to the law to clarify. Until then, problems continue.</p>	

<p>11. Rapid HIV testing update</p>	<p>Shiu Land Kwong discussed the Rapid HIV test manufactured by OraQuick. Its complexity was reduced from Moderate to Waived, it uses whole blood and gives result in 20 minutes. Sales are restricted to labs with adequate QA program and testing personnel must follow instruction materials. The patient must have counseling and the kit cannot be used for blood or tissue donors. Introduction of this Rapid HIV test has been confusing for CA labs since state law requires separate approval for HIV testing, even Rapid, PT is required even though classified as waived, all POS need to be confirmed, fingerstick must be done by person certified in phlebotomy, there are limits at BPC 1206.5 (a) who can perform the test. Because of these conflicts, implementation of Rapid HIV in CA has been delayed.</p>	<p>Robert Footlik pointed out that all testing personnel need to be shown competent, even those doing waived testing as in the Rapid HIV test.</p> <p>A CLTAC person asked if an HIV counselor would be considered giving "direct patient care" as described in BPC 1206.5 (a). Ms. Kwong said no.</p> <p>Rhonda Becker asked how HIV counselors could do phlebotomy? Ms. Kwong said they must be certified in skin puncture like anyone else.</p>	
<p>12. New business</p>	<p>Robert Footlik asked if there was any new business. Karen Nickel said she wanted to thank Robert Footlik who was completing his term as Chair of CLTAC. She presented a plaque to him and thanked him for his service to the Department. Dr. Evans will start as Chair of CLTAC at the next meeting. Dr. Nickel also thanked the many members of the CLTAC who were completing the second full term of 8 years on the CLTAC. She presented certificates of appreciation to those present. Dr. Nickel also recognized the work of Sam Chafin, Fred Struve and Jim Ottosen who continued to actively participate in CLTAC beyond their appointments.</p>	<p>Information only.</p>	
<p>Next meeting.</p>	<p>The next meeting of the CLTAC will be Friday, September 5, 2003, by teleconference.</p>	<p>Information only.</p>	