

Clinical Laboratory Technology Advisory Committee  
Minutes of the March 4, 2005 Meeting  
Meeting held by videoconference from Kaiser Permanente Oakland and  
North Hollywood, and by telephone bridge.

CLTAC members participating: Michael Borok, Teresa Bryant, Greg Clark, Tim Hamill, Curtis Johnson; Donna Kirven, Carmen Maldonado; Salim Rafidi, Les Revier; Michael Terry, Peggy Tessier Otoole, Mary York.

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

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

Public Members: 35 persons signed in in Oakland, 20 persons, in North Hollywood, 25 lines called in on the telephone bridge and 18 persons reviewed the digital replay of the meeting.

Introduction 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, 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.

Department News: Paul Kimsey, Division Chief of Laboratory Science thanked everyone for attending. He gave an update on the move to the Richmond by LFS, scheduled for July 15. The dedication of the building was moved to June. The December CLTAC may be held there. The California Performance Review is on the Governor's web page. The process may take another year. There is discussion about reorganizing DHS into five departments with LFS going into a different section consolidating licensing. This does not mean, however, that the functions will be consolidated. The department is very interested in on-line licensing and LFS has been at the forefront of this effort. DHS is discussing LFS's continuing insolvency with Agency, hoping for resolution. The Department is meeting with constituency groups about this and either the DHS director or Dr. Kimsey can be contacted about this. A question was asked, where LFS can be found in the Performance Review. Dr. Kimsey said under the Licensing and Certification section.

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 there were a lot of positive things happening that were

encouraging. The phlebotomy program continues to grow, the MLT regulations were signed on January 13, 2005 and are in their comment period now. Medi-Cal contracting by labs has added about 3,000 new labs performing waived and PPMP testing. There are several interesting new bills that may impact labs that we are following, and we are encouraged by the higher pass rate on the past licensing examination.

Staff shortages in LFS continues to be a real problem despite the addition of 5 new staff positions. LFS has been able to hire retired annuitants to carry out vital functions. Dr. Nickel encouraged people to apply for Examiner I, II, and III position openings which would be advertised soon.

It was announced that a quorum was present. Chairperson Teresa Bryant asked for any corrections to the minutes of the December 3, 2004 meeting: There were several corrections. Dr. Hamill noted on page 5 that the process of validations at the new location, although set by the laboratory director, must still meet all basic CLIA requirements. Mention of the telephone bridge must be deleted several places. Michael Borok asked about CLIA 1994 mentioned on page 6. He asked if the regulation process could automatically accept the CLIA changes. Karen Nickel said that the Department would work with the legislature to adopt CLIA 2003 but might not adopt all parts. Bob Footlik responded that BPC Section 1208 said the Department should be in consultation with CLTAC about what changes to adopt. Jim Ottosen suggested that the CLTAC committee appointed to work on any revisions to CLIA be involved. Donna McCallum stated that if CA wants to go exempt, the state will have to be in compliance with CLIA. Dr. Nickel said there were no resources to work on CLIA 2003 with CLTAC right now. Someone asked to change the minutes to read that the September minutes were approved. Dr. Hamill made a motion and Dr. York seconded to approve minutes as corrected. The motion carried.

## **Legislation**

AB 433 (Nava) Sponsored by the California Medical Association. This bill would exempt Physician Office Laboratories (POLs) from state licensure and registration, adding them to BPC 1241 (a). Mary York asked why the state can't collect money from them now. Karen Nickel responded that emergency regs were passed in 1996, after the passage of SB 113, to delay collection of fees until the state received exemption from the CLIA regs. This applied to those previously exempt labs that were in existence prior to 1/1/96 and had no changes in certificate type. Paul Kimsey stated that Agency was looking at whether to repeal the regulations and license and register all labs. Morton Field asked about the accuracy and reliability of the complaints against POLs. Dr. Borok asked whether there were more complaints against POLs compared to larger labs. He also commented that the same inspector that does the CLIA inspection is the state inspector. Dr. Nickel responded that there are issues unique to state law that are different than CLIA. Peggy O'Toole asked whether the doctor is doing the testing. She commented that licensed labs are already paying two fees and the POLs are asking for special treatment. Bob Footlik commented that the emergency regs are unlawful because

they obstructed the intent of SB 113. Dr. Borok commented that maybe we should look at whether large labs should not pay two fees.

AB512 (Richman) allows for alternative sanctions and principal sanctions for the violation of the reportable disease requirements. The reporting requirements are found in regulation but the Department has been unable to enforce the reporting requirement.. Dr. York asked why the labs should be required to report and not the physician. Shiu Land Kwong said there was a separate requirement for the physician, covered under different law. Dr. Hamill asked whether this law would apply to future agents also. The answer was, yes. Dora Goto asked who was responsible for reporting: the ordering physician, the ordering lab, the site that collected the sample, or the lab who received and tested the specimen. The answer, the lab who tested the specimen and got the result. There were questions from the public members about reporting on the weekend, reporting when incomplete patient information was available, and why this bill was necessary. Answer-there is no authority currently to enforce.

AB 626 (Mathers) This bill would require the Department of Health Services to establish and appoint members to a Public/Private Anti-Fraud Task Force (PPAFTF) to review reports of fraud occurring in the delivery of clinical laboratory services to Medi-Cal beneficiaries and to recommend activities that would eliminate fraudulent practices to the legislature. Someone asked where this information would be obtained. Ms. O'Keefe said information could be obtained electronically by reviewing billing records.

AB 284 (Bermudez) This bill would require the Department and the state bargaining unit to survey annually the compensation for comparable service in other public and private employment and report those findings to the legislature.

Election of CLTAC Chair: Teresa Bryant opened the floor for nominations. Curtis Johnson nominated Teresa Bryant, seconded by Donna Kirven. Les Revier moved that the nominations be closed. Ms. Bryant was elected by unanimous vote.

Regulation update:

R-13-03E, MLT Licensing Regulations. Karen Nickel reviewed the status of regulations under development. The emergency regulations were signed on January 13, were noticed on February 4 and the comment period ends March 21, 2005. She encouraged everyone to review the draft regulations which were posted on the LFS website. There is much public interest in these regulations, and much work to be done. The MLT implementation plan was discussed in the last meeting. This spring and summer, without any additional staff, LFS management will work to approve MLT training programs and certifying exams. Also, forms and processes need to be set up and approved. LFS will not get any new staff for MLT licensing until possibly after July 2006, so that will delay implementation.

R-22-01E, Repeal of emergency regulations that postponed collection of laboratory fees. These regulations have been on hold since 2001. They would repeal the exemption from

fees given laboratory that were required to pay fees in the Maddy legislation in 1996. If AB 433 passes, these regulations would be unnecessary

Autoverification Standards: LFS is unable to work on changing the regulations at 17 CCR 1050 that prohibit autoverification. Perhaps legislation could be done to overrule the 30-year old regulations.

Other regulations needed: Amendments to 17 CCR 1032, CLS training standards, licensing standards for biochemical genetic scientists and lab directors, andrology scientists and lab directors, timeframes for lab licensing, criteria for denial of licensure, others?

Laboratory licensing-need time frames as to when a license application is abandoned and authority to deny license based on abandonment.

Personnel Licensing Issues: Robert Thomas, Section Chief, Personnel Licensing addressed several issues. He said that as of 2/27/05, 16, 449 persons had renewed their CLS licenses. There were some computer problems in that renewal notices were sent to some who had already renewed. The phlebotomy program is busy with renewals coming in now in addition to thousands of new applications. In the time period between 1/1/04 and 3/1/04, 3212 persons have been certified in phlebotomy. The MLT licensing program will probably start in 2006 when LFS gets some new staff. Regarding the November 2004 licensing exams, it. We are going to have the November exam for CLS. The plan is to switch to certifying exams over a 3-year period. LFS already accepts certain board exams for other license categories. On line processing of applications is being pursued. We will begin with the CLS license for first time applicants. The biggest problem is key data entry and on line applications will shift that responsibility to the applicant. Eventually we'll expand to renewals. Web site would allow applicant to track on line what is happening with their application.

Phlebotomy Certification-Applications are below what was expected. This is the third year of the three-year implementation. Persons drawing for forensic and insurance must be certified. Criminal background checks are being performed on those applicants with a felony conviction. A handout was supplied on the background checks.

MLT licensure-this allows a career ladder to CLS to Director. The program will be implemented by approving certifying exam services and then training schools. Salim asked if the department was going to publicize the end of the three-year phase in for phlebotomist. He suggested that LFS should send a letter to the labs. Also it was asked if the deadline is written in stone. The answer was, that a lab could be cited if they utilize phlebotomists that are not certified after the end date.

Sherrill questioned the exam statistics and said that she relies on it to give to college administration for funding.

**Presentation by Beatrice O'Keefe, Acting Section Chief for Facility Licensing,**

**Registration of Labs for Medi-Cal Provider and Contracting with Medi-Cal-SB 857** made changes to the Medi-Cal program to ensure the fiscal integrity of the program. It went into effect 1/1/2004. The bill allowed for enrollment, continue enrollment or enrollment at a new location and specified additional ground for Medi-Cal termination if the provider performs lab tests and does not meet CLIA and state law requirements, does not have a CLIA certificate and/ or does not have a clinical registration or license. To date, over 3000 labs have registered. In the process, we have educated physician offices that when they perform a laboratory test, they are considered a laboratory. We have also assisted many offices in fixing their billing problems by assisting them with the appropriate CPT codes to bill and certificate type.

Any lab that was billing medical under an LAB number or ZZZ provider # was sent an application package to contract for laboratory services with Medi-Cal. This is phase one. The second group of applications will be sent to physician and physician groups performing non-waived testing. The third group may be hospitals and clinics.

**Where Clinical Trials End and Diagnostic Testing Begins-** First the specimen must be a specimen that meets the state definition in regs, that is a biological specimen derived from the human body. In a totally random clinical trial, it is not known whether a patient is receiving a drug or a placebo, etc. Patients are not treated or diagnosed based on results. Statistics are compiled only. A CLIA certificate or state clinical license or registration is not required. The transition from a clinical trial occurs when patients are identified and results are known for individual patients. If a physiological state is determined based on the test results or treatment is initiated or altered, then a CLIA certificate and state license or registration is required.

**Concerns About Contract Labs-**LFS has recently become aware of arrangements between a physician office, clinic or hospital and a contract lab that performs laboratory testing for those groups at the physician, clinic or hospital location. The contract lab usually uses the CLIA certificate under the name of the above groups. The director is generally the MD in the physician office or clinic or the pathologist in the hospital. The contractual arrangements vary. We have seen several problems with these arrangements: 1. The contract lab may specify the use of licensed personnel but we have found situations where the testing person was unlicensed. 2. The contract lab may perform proficiency testing at one location and share the results with all of their clients. 3. The director may function as a nominal director, 4. There is a question of whether the contract lab needs to be disclosed on the disclosure of ownership and control interest statement, 6. There is the question of whether these arrangements violate federal laws. A Health and human Services advisory opinion on December 17<sup>th</sup>, 2004 served as a warning that contractual joint venture may violate federal law.

**Dates of the upcoming meetings: Fill in**

