

Clinical Laboratory Technology Advisory Committee
Minutes of the June 9, 2006 Meeting
Meeting held by videoconference from CDHS Richmond Campus and
North Hollywood Kaiser Permanente, and by telephone bridge

CLTAC members participating: Michael Borok, Carolyn Days, Curtis Johnson, Tim Hamill, Lin Kassouni, Donna Kirven, Carmen Maldonado, Salim Rafidi, Les Revier, Michael Terry, Peggy O'Toole, David Yong, David Zingmond.

Former CLTAC members participating: Vickie Bello, Sam Chafin, Morton Field, Jim Ottosen, Imre Fischer.

CDHS staff participating: Alan Ankerstar, Frank Barnes, Linda Bryant, Maria Desousa, Jim Howard, Robert Hunter, ShiuLand Kwong, Howard Manipis, Don Miyamoto, Karen Nickel, Bea OKeefe, Jan Otey, Shahrzad Radahd, Steve Rubin, Joanne Sparhawk, Tom Tempske, Clint Venable, Kathy Williams.

Public members participating: 39 persons signed in in Richmond, 18 persons signed in in North Hollywood and 36 persons called in on the telephone bridge.

Introduction and general announcements: Chairman Tim Hamill opened the meeting at 9:05AM, called the meeting to order, welcomed the participants and asked persons to identify themselves at both videoconference sites and on the telephone bridge. He reminded the audience that CLTAC members would be heard first, then the others. He asked all participants on the telephone bridge to mute their phones to eliminate background noise.

Approval of the December 2, 2005 meeting minutes: Several corrections were made to the minutes. Morton Field asked that his name be listed as CLTAC member. David Zingmond said that he was not listed as a participant. The reference to "BD" in the section of Quality control of allergy testing, should be changed to "Pharmacia". The statement under the section HIV testing update that "This is called no-name reporting and only applies to reports to public health labs" was incorrect, and this will be deleted from the official minutes. The reference to "all with ownership interest in lab" will be deleted from the section on how physicians are counted for licensing. A physician does not need to have ownership interest in a physician office lab to be counted as part of five or fewer requirement, if they are seeing patients, ordering and performing tests onsite, they must be included in the count. Clarification was made that phlebotomists may only perform the phlebotomy part of a glucose tolerance test, not testing. Kathy Williams asked that correction be made that public health labs were exempt from B&P Code but not state law. They are subject to Health and Safety Code standards. A misspelling of CLTAC was corrected. With these corrections, the minutes were approved.

Approval of the March 3, 2006 meeting minutes: Michael Terry asked that his name be included among the CLTAC participants. ShiuLand Kwong asked that "confidential" HIV

testing be changed to “anonymous” for testing available persons at county health laboratories. She also said that SB 699 required clinical labs to report positive HIV results to county health officers, but not the Department of Health Services, as stated in the minutes. Bob Thomas asked that “42 different license categories” be changed to “22”. He also said that CLIA allows persons who were qualified prior to 1992 (not “certified” as recorded in the minutes) to work as pathologists’ assistants. With these corrections, the minutes were approved.

Department news: Dr. Paul Kimsey, Division of Laboratory Science, gave the report for the department. He said the work of Governor Schwarzenegger’s California Performance Review is ongoing. LFS is trying to implement staggered license renewals and web-based verification of licenses in response to this document. Dr. Kimsey discussed the effort to create a Department of Public Health in SB 162 (Ortiz). If this passes, it would take effect on July 1, 2007. He said the CDC Bioterrorism Grant to California may have some impact on clinical labs, and good news, LFS would be authorized 14 new positions starting July 1, 2006 as stated in the Governor’s Budget Bill. He also said that SB 169 which extended the deadline for grandfathering phlebotomists had put pressure on LFS to clear the backlog before January 1, 2007. A number of actions have been taken in LFS to make sure this gets done including redirection of staff doing phlebotomy training program approvals, public health microbiologist approvals, cytology lab inspections, out-of-state licensing, and enforcement of proficiency testing failures. Dr. Kimsey said next time he would like to talk about preparation for a possible pandemic influenza epidemic.

LFS update: Dr. Karen Nickel noted that Terri Bryant, outgoing chair of CLTAC, could not be recognized today since she was unable to attend the meeting. She thanked Kaiser Permanente for providing the videoconference site in North Hollywood and the telephone bridge. Dr. Nickel said that LFS is completing a very difficult year, one that has tried the patience of staff and our public. Hopefully things will get better as LFS has been authorized to hire new staff for phlebotomy, MLT licensing, complaints, and lab inspectors. She urged qualified persons to apply for Examiner positions in LFS.

Dr. Nickel reported on CLS certification exam review which is just starting. LFS has already received two applications. She also said that phlebotomy certification had had a profound impact on LFS in both positive and negative ways. The positive impact is an improved level of training now required for certification and the public acceptance. The negative impact has been the backlog and people’s unhappiness with the delay. LFS is working on a number of improvements for 2007-08 including a new licensing mainframe, efficiencies of operations and more staff. All of this is necessary to prepare for CLIA exemption.

Karen Nickel said that LFS would be subjected to an audit by the Bureau of State Audits in 2007-08 to evaluate its ability to enforce state laws and regulations regarding licensing, certification and registration of clinical laboratories, to investigate cases of non-compliance and to impose sanctions. The results of this audit will be made available to

both houses of the CA legislature. This audit is a result of concern whether LFS has staff to adequately enforce state law.

Legislative update:

SB 169 (Migden) phlebotomy deadline pushback: Robert Thomas reported on this bill which extended the time for grandfathered phlebotomists to be certified until January 1, 2007. The original legislation set the deadline to 3 years after the certification regulations had been implemented or April 9, 2006. There was a backlog of applications in LFS and these persons would have to stop working without certification. Mr. Thomas explained that all applications must be received from grandfathered phlebotomists on or before July 1, 2006 in order for them to continue working until January 1, 2007 at which time they must have the new certification.

AB 2156 (Niello) autoverification and licensure of histocompatibility lab directors: Mr. Thomas said this bill covers these two issues, defining autoverification, explaining how it can be used and how supervised, and standardizes the licensing requirements for histocompatibility lab directors.

AB 2452 (Richman) laboratory accreditation for licensure: Bea OKeefe said this bill would have exempted physician office labs from paying license fees until CLIA exemption, and then their fees to the state would be no higher than their CLIA fees. This bill failed and a similar bill failed last year.

AB 2757 (Evans) billing by primary care clinics: Ms OKeefe said this bill would authorize primary care clinics to send lab tests to a central lab under common ownership, and would allow billing by the lab that sent the lab tests.

SB 699, 945 (Soto) HIV reporting: ShiuLand Kwong discussed the new requirements for HIV reporting. This bill requires name-based reporting of confirmed positive HIV results by laboratories within 7 days, even if the confirmation is done at another location. This replaces the Soundex coding which was implemented in 2002.

SB 1785 (Figueroa) regulation of mother's milk storage: Discussion on this bill was tabled until next time.

SB 1369 (Maldonado) pathology billing: Dr. Nickel said this bill would require the lab that performs anatomical pathology reading and reporting to do the billing for the testing. This has been required of labs doing Pap smears since 1990. Current law requires the site and charge for referred pathology testing to be disclosed to the patient, but newspaper reports indicate that this is not being done. Direct billing for pathology would eliminate the incentive for a physician to mark up the cost of lab services that lead to over utilization.

Personnel licensing issues: Robert Thomas discussed the shortage of CLS' in California and efforts underway to increase the number of qualified workers. The

number of training programs in the state is increasing somewhat and this is shown in the number of California-trained persons taking the state licensing exam. The new MLT program will be starting in January 2007 and LFS is working to approve national certification exams for licensure purposes. Mr. Thomas gave statistics for persons taking the licensing exam that indicated a turnaround of qualified applicants and pass rate. Mr. Thomas described plans to implement staggered renewals of licenses in 2007. This would be done over two years and would lead to two-year licenses due during a person's birth month.

Laboratory licensing issues: Bea OKeefe said that her section was expecting to get 5 new Examiner positions when the Governor's Budget Bill passes. She encouraged interested CLS' to apply for Examiner positions. Ms OKeefe said there had been a problem this year with the lab license renewals. The mailroom in Sacramento lost the renewals and they were a month late being sent out. Many labs got warning letters needlessly, causing much concern. LFS is currently registering POLs, as well as clinic labs, home health agency labs, mobile labs and hospitals that have separate certificates for performing waived or PPMP testing. LFS is also registering labs that started testing after January 1, 1996 which are not exempted by the emergency regulations. For those labs refusing to be registered by the state, LFS is recommending that CMS terminate their CLIA certificates. This will cut off their Medicare and insurance payments, so it will get their attention. Regarding the MediCal moratorium, this has been continued but there are a few exceptions, as waived, PPMP labs and pathology labs. LFS is getting calls from pathology labs which have MediCal provider status and want to add other subspecialties. MediCal is not allowing this if they obtained their provider status after March 1, 2001 when the moratorium went into effect. On another topic, MediCal completed an error rate study which was mandated by the legislature. Of 1100 claims analyzed, 7.43% had problems which would equate to an error of about \$1.25 billion in the Medical program. When they re-looked at the claims, they decided that about 3.23% were at risk for error, of \$542 million per year. The largest dollar amount for errors was found in pharmacies, not labs.

Are labs double reporting infectious diseases? Bea OKeefe was asked to address the infectious disease reporting requirements in CCR 2505. These regulations require the laboratory to report findings of infectious diseases to the local health officer of the jurisdiction where the healthcare provider resides. The referral lab must also report their findings. The physician must report these findings to the health officer where the patient resides. Why all the reporting? Ms OKeefe was told that the system relies on redundancy to make sure no diseases are missed.

Can a parent do heel sticks on their own children? Robert Thomas said that if the collection is to be sent to a laboratory for testing, a parent cannot draw the blood. If the parent is going to use an over-the-counter kit to test the child's blood, then they can do it.

New training products: Marguerite Oates reported that the NLTN, part of the CDC and located in Richmond, had DVDs on verification of infectious disease assay and

molecular diagnoses available with 1.5 CEU credit. She can be contacted at 510-412-1410.

With no further business, Chairman Tim Hamill adjourned the meeting at 12:30 PM. The next meeting will be on September 8, 2006 in Richmond and North Hollywood.