

## **Clinical Laboratory Technology Advisory Committee**

Minutes of the September 7, 2007 Meeting

Meeting Held by Videoconference from CDPH Richmond Campus and North Hollywood Kaiser Permanente, and by Telephone Bridge.

CLTAC Members Participating: Michael Borok, Tony Butch, Elizabeth Dequinia Tim Hamill, Lin Kassouni, Donna Kirven, Carmen Maldonado, Peggy O'Toole, Salim Rafidi, Les Revier, Jan Schwarz, Fred Ung, Lorri Dean Yoakum, David Yong, Mary York, David Zingmond.

Former CLTAC Members Participating: Imre Fischer, Robert Footlik, Morton Field, Jim Ottosen.

DPH Staff Participating: Frank Barnes, Maria DeSousa, Robert Hunter, Dona Lynch, Howard Manipis, Donna McCallum; Don Miyamoto, Karen Nickel, Bea O'Keefe, Shahrzad Radahd, Tom Tempske, Robert Thomas, Pat Toomer, Clint Venable, Kathy Williams.

Welcome and General Announcements. The meeting was called to order at 9:10AM by Tim Hamill, Chair. He welcomed the participants and asked persons to identify themselves at both videoconference sites and on the telephone bridge. He noted that there was a quorum of CLTAC members present.

Approval of the June 8, 2007 Minutes. The CLTAC reviewed the minutes of the previous meeting and made a few amendments which were noted. Following these changes, the minutes were approved by the CLTAC.

Department News. Karen Nickel welcomed the participants and thanked Kaiser Permanente for hosting the videoconference in North Hollywood and the telephone bridge. She noted that Lab Field Services was now part of the Department of Public Health, Center for Healthcare Quality. Licensing and Certification is the other program in the Center and they are responsible to inspecting/licensing hospitals and nursing homes. Dr. Mark Horton is the new Director and Kathleen Billingsley, our Deputy Director. Ms Billingsley is unable to attend the meeting today. Dr. Nickel explained the organizational structure of the new DPH. She said the Governor's budget was finally passed on August 21, 51 days late, and LFS' budget was cut \$50,000 to accommodate changes with the new Department.

LFS Update. Karen Nickel introduced LFS' new Assistant Branch Chief, Ellen Yasumura. Ellen comes from Laboratory Science, so she is very familiar with LFS. She is going to work on administrative assignments, as contracts, budgeting, expense tracking, purchasing, IT, leaving the Section Chiefs (Ron Harkey, Bob Thomas, Donna McCallum and Bea Okeefe) more time to manage the technical aspect of their programs. Dr. Nickel said LFS is interviewing new Examiner staff and hopes to fill some of its vacancies.

Dr. Nickel said LFS was switching to all email CLTAC meeting notifications now, however, if anyone does not have access to email, we need to provide surface mail. As a public meeting, access to CLTAC meetings cannot be denied because of lack of notification. She urged anyone to contact her for other than email notices.

This fall LFS will initiate the second phase of the staggered license renewals as odd birth year people and those without birthdays in the licensing data base, get their renewal invoices. By the end of this renewal cycle, all licensed persons should either have their birthday or license issuance date as renewal date.

Approval of certification exams for licensure purposes has been at the top of Dr. Nickel's agenda this year. LFS has already approved 3 CLS exams (ASCP, International ASCP and AAB) and 2 MLT exams (ASCP and AAB). Applicants for MLT licensure can take either the California-Specific MLT exam and the full MLT exam from both providers. Either one would be acceptable for licensure purposes. LFS is now working to approve BS- and doctorate-level chemist and microbiology exams for licensure. Our goal is to approve at least 2 in each license category by spring 2008 so the state-administered exam in 2008 can be cancelled.

#### Legislation impacting clinical labs

AB 34, SB 962 (Umbilical cord blood). Ron Harkey said these bills would create a program to promote cord blood donations. They would produce an educational brochure about cord blood, with special emphasis to ethnic groups. Five facilities statewide would collect and store cord blood. Funding was a problem.

AB 1442 (HIV testing) Bea O'Keefe said this bill was pulled back at the last minute and it may be introduced next year. This bill would have repealed the current HIV regulations at 17CCR 1230. Primarily affected would have been the labs doing waived HIV screening tests. These labs would not have to get prior approval before testing, but labs doing moderate/high HIV screening tests would still have to. All other requirements would still be retained.

AB 1175 (autoverification) Bob Thomas said this bill authorized the lab director to appoint a technical supervisor to oversee autoverification. Nothing else was changed.

SB 661 (pathology billing) Karen Nickel said this bill requires labs performing AP (broadly defined) to bill for by "direct billing". This eliminates the middle man and potential markup of charges. This requirement has been in state law since 1990 for Pap test billing. If an originating lab provides any technical component to the AP, then that lab may indirect bill for that portion.

Report of the CLIA 2003 Subcommittee. Robert Footlik said this subcommittee last met on August 30 and is working on the Quality Control sections.

Petition to Repeal 17CCR 1050, DPH Response. DPH received a petition from the CA Clinical Lab Association to repeal CCR 1050. This section of the law dates back to the 1970s and has problematic sections that prevented autoverification and limits directors to 3 labs. Repeal of this entire section was recommended by the CLTAC in 1998, but LFS has not had time to do this. More recent legislation has superseded the prohibition against autoverification but the 3 lab limit for directors is still a problem. LFS is going to make a concerted effort to work on repealing this section this winter and is tempted to add amendments to other problem sections, as 17CCR 1032, at the same time. Dr. Nickel makes no promises that this will all be done soon, however.

Review of Lab Director Qualification in State Law. Bea O'Keefe said LFS is receiving lots of applications from labs where the lab director is not qualified to serve as director. She wanted to discuss this with the CLTAC in hopes the lab community would be better informed.

For Waived or PPMP Labs, the lab director must be a CA-licensed physician or osteopath, a licensed Bioanalyst, a board-certified, CA-licensed pathologist or a board-certified, licensed PhD. We receive lots of applications for waived labs that list an RN as director.

For Moderate Complexity Labs, the same persons listed above may direct the lab, BUT if the physician received his/her license after Feb 28, 1992, he/she must have one year experience directing or supervising moderate complexity testing OR he/she must obtain 20 hours of CE in laboratory practice before they can be director. LFS will not license the lab or do on initial onsite inspection until the director is qualified.

For High Complexity Labs, the lab director must be a board-certified, state-licensed pathologist. If a physician wants to direct a high complexity lab (experience after Feb 28, 1992), he/she must have 2 years experience directing/supervising high complexity testing. A board-certified, licensed PhD director must also have 2 years experience. There is no provision for obtaining CE to qualify. For brand new licensed physicians or PhDs who want to direct a high complexity lab, this may require having another qualified director direct the lab for 2 years while the new physician/PhD supervises. They would then have the required experience to serve as director.

Action Taken When a Physician License is Revoked. LFS is receiving on-time reports from the Medical Board of California when disciplinary action is taken against a physician license, including suspension or revocation. We are receiving about 15 such notices each week. If a physician license is suspended or revoked, he/she is no longer qualified to direct a laboratory, so the lab license is automatically revoked unless a new director is appointed. The lab must appoint an interim director within 5 days after suspension notice. This also impacts the CLIA certificate.

Update on 3 Lab Limit for Directors. Last time we talked about regulations (CCR 1050 (c)(8) that limit a qualified person from directing no more than 3 laboratories. Bea O'keefe said this differs from CLIA in that federal law limits persons to 5 non-waived laboratories. SB 1048 was introduced in March 2007 as part of the Senate Committee on Business, Professions and Economic Development as "clean up" language affecting many licensing programs. This bill would authorize persons to direct up to 5 licensed labs or unlimited registered labs. However, a person directing cytology labs would be limited to only 3 labs. One important difference, SB 1048 does not require the director of a cytology lab to be present daily in the laboratory. This bill implements on January 1, 2008.

MediCal Moratorium, New Edits and Denials. Bea O'keefe said the MediCal moratorium on new laboratory enrollment was extended again in August 2007. This moratorium has been in effect since March 1, 2001. This limits those labs that can enroll as a provider for lab services. Labs that can still enroll are those performing waived or PPMP testing, acute care hospitals, licensed clinics, pathology laboratories, or purchase of a lab that is already a MediCal provider. LFS continues to get many calls from labs that are being denied payment. Typical reasons include: (1) Labs are billing outside their certificate type, (2) Lab payments are cut off suddenly when MediCal finds out the lab lacks a current state license or registration, or a CLIA certificate; (3) A lab adds subspecialties after March 1, 2001 that were not included in the original approval; (4) A pathology lab wants to add specialties outside

pathology, as HPV, Chlamydia or GC; (5) An accredited lab, otherwise qualified to bill for MediCal, added subspecialties and their accrediting organization did not update their approval in the federal database. The lab must ask LFS to do this for MediCal purposes.

CLIA Issues. Donna McCallum reported to the CLTAC about the survey workload in 2006-07. LFS has inspected 718 labs including 176 waived labs and has done 32 validation inspections of accredited labs. We have also issued sanction notices to 83 labs failing proficiency testing. Time did not permit for her to discuss the 13 recommendations from the GAO on the CLIA program in the US. Some of that will be discussed at the next meeting.

Personnel Licensing. Bob Thomas welcomed the Loma Linda Med Center CLS class which has signed on the telephone bridge. Their participation is encouraging. He said that LFS is working hard to recruit Examiners so we can start the MLT program, hopefully before the end of the year. LFS is still working to streamline processes for licensure of persons taking certification exams, staggered renewals. Mr. Thomas said there were 847 applicants for the state-administered exam in November. Of these, 596 have already been approved for the exam

Online Quiz. Bob Thomas discussed operation of the online quiz on state lab law offered on the LFS website. All persons seeking licensure with certifying exams must take and pass this quiz before they can be licensed. The certifying organizations are unwilling/unable to prepare questions on California State Law. The online quiz seems to be working well. LFS gets the passing score as soon as the person passes. LFS is on its second roster now; the first has 250 candidates.

Temporary Licenses Bob Thomas said LFS would no longer be issuing temporary licenses as it is switching to certification exams which are offered continuously. His program cannot manage both systems in the transition if temporary licenses were issued.

Application Process with Certification Exams. Shahrzad Radahd explained how LFS is processing applications from persons now with the option for state exam or certification exam. Persons checking the state exam are issued an approval for admission to the state exam, once they are qualified. Those that check the certification exam option are given an approval letter that they give to the certifying organization, once they are qualified. They are also given a unique identifier number that allows them access to the online quiz. When they pass the certification exam and the online quiz, they satisfy the examination requirement for licensure.

Phlebotomy Certification. Maria DeSousa updated the CLTAC on phlebotomy. As of this date, LFS has received 25,938 applications, has approved 24,225, and has abandoned 651. There is extra work with these applications as 5.5% have criminal convictions which must be investigated. Ms. DeSousa is getting questions. How does a CPT-1 get CPT-2 certification? The CPT-1 needs to apply online for CPT-2, provide written proof of arterial draws within the past 5 years. No additional coursework is required. Does a person get phlebotomy credit for military experience? They need to document practical experience like anybody else. What about out-of-state experience? This needs to be properly documented. How does a CPT renew her certificate? The renewal invoice is mailed automatically from Sacramento. CPTs need to make sure LFS is notified within 30 days of address change.

Training of Genetic Scientists. Frank Barnes said training programs apply with a LAB156 form available on the LFS website. Genetic scientist applicants need a BS degree, one year

training (on or after March 14, 2003) in a program approved by LFS. Prior to this date, the training could be in a program acceptable for admission to the NCA exam. The problem is, labs are training genetic scientists without LFS approval, and this training cannot be accepted for licensure.

Cystic Fibrosis Testing on Pap Smears. There was no time for this discussion and it will be postponed to the next meeting.

More Thoughts on Validating Autoverification. Karen Nickel was asked to talk about how autoverification can be validated before use. There was no time for this discussion, but she briefly said autoverification was part of the whole "test system". It cannot operate separately as middleware, manipulating data and making decisions for the lab. Autoverification involves gathering information, establishing rules, setting limits, testing, re-setting limits, testing, and continued improvements. There is lots of good information on the internet, especially by the AACC.

New Business/Open Discussion. The CLTAC asked that there be further discussion on autoverification and the need for consistency in setting standards for phlebotomy training programs and their approval. This will be set for the next meeting.

There was a motion that the meeting be adjourned at 12:30, seconded and the meeting was then adjourned. The next meeting will be December 7, 2007.