

Clinical Laboratory Technology Advisory Committee
Minutes of the June 11, 2004 Meeting
Held by Videoconference from Oakland and North Hollywood, CA

CLTAC members participating: Michael Borok, Teresa Bryant, Greg Clark, Carolyn Days, Tim Hamill, Curtis Johnson, Lyn Kassouni, Donna Kirven, Arthur Lurvey, Salim Rafidi, Les Revier, Michael Terry, Peggy Tessier, David Yong, and Mary York.

Former CLTAC members participating: Ellen Jo Baron, Sam Chafin, Morton Field, Imre Fischer, Robert Freedman, Deanna Iverson, Jim Ottosen.

Department of Health staff participating: Paul Kimsey, Shiu Land Kwong, Howard Manipis, Don Miyamoto, Donna McCallum, Karen Nickel, Bea O'Keefe, Robert Thomas, Gwen Wong.

Public members participating: Carol Bostwick, Ardzz Ticsay, Cheryl Harris, Pat Fournier, Bill Gardner, Fred Ung, Lori Dean Yoakum, Merle Son, Diane Thomas, Linda Santos, Anita Dolce, Tom Noone, Rebecca Rosser, Kathleen Doty, Betty Lindgren, Matt Rapp, Sarina Rodriguez, Linda Vincent, Dena Bates, Howard Koo, Karla Kleman, Karen McRae, Debbie Wagner, Faye Stauffer, Mila Braganza, Maxi Edora, Leticia Acosta, Carola Howe, Shirley Wong-Jose, Barbara Brunell, Mel Solis, Jerry Hurst, Rod Maquinana, Michele So, Joseph Musallam, Milt and Diana Kelly, Dora Goto, Robert Dawson, Judy Wilbur, Paul Lovato, Pat Doyle.

In the absence of Chair Cherie Evans, Karen Nickel had asked Teresa Bryant to preside at the CLTAC meeting. Ms. Bryant is senior member of the CLTAC, and agreed to participate in Dr. Evans' absence. Ms. Bryant opened the meeting, welcomed the participants and noted that there was a voting quorum. She reminded the audience that CLTAC members would be heard first, and telephone participants must be on "mute".

Update of Department of Health Service: Paul Kimsey gave Department news related to clinical laboratories. He said the Department had a new director, Sandra Shewry and a new state health officer, Dr. Richard Jackson. Dr. Jackson was formerly epidemiologist at the CDC in Atlanta and was head of the communicable disease division for the Department of Health 10 years ago. Dr. Kimsey said there had been talk about creating a Department of Public Health, and this may be recommended in the California Performance Review that is expected to be released the end of June. There may be reorganization of state government. In meetings with Ms. Shewry and Dr. Jackson, Dr. Kimsey had been impressed with their knowledge and interest in laboratory matters, funding issues impacting LFS; documents have been prepared to revisit the repeal of lab law. He encouraged the CLTAC to try to meet with Mr. Shewry and Dr. Jackson. He said there was some optimism with the new fiscal year that things would get

better. Dr. Kimsey said he was going to ask the CLTAC to form a subcommittee on public health laboratory issues. Mary York asked for a copy of the Health and Safety Code law relating to public health labs.

CLTAC appointments. Dr. Nickel reviewed how the CLTAC was established in law in 1972 at BPC 1228. The multi-disciplinary committee had grown to 21 members in recent years, was much lauded and much assailed. The CLTAC meets quarterly, operates under bylaws, appointees are nominated and are appointed at pleasure of the Director of Health Services for 4-year terms. Dr. Nickel reviewed the members of the CLTAC, who they represented, and welcomed the new members.

LFS update. Karen Nickel thanked Kaiser Permanente for their kind hospitality in hosting the videoconferences and the telephone bridge. She reminded the group that the December 3, 2004 meeting would be in Oakland, and CLTAC members would be getting travel information. Dr. Nickel said it was extremely difficult operating a program which was critically short of staff. LFS is in a survival mode, setting priorities to get key activities done and leaving others undone. She said she hoped there would be some relief with the new fiscal year which starts on July 1. Gwen Wong will be leaving as program manager of phlebotomy certification and she will be greatly missed. The backlog of work is increasing in all areas, and the number of persons complaining is escalating. We are encouraged by the interest in molecular diagnostics, genetics, phlebotomy, and MLT licensure, however, and that alone is encouraging. Dr. Nickel added that there has been no further word on repeal of lab law, but that Ms. Shewry is being sent briefing documents on the subject.

Legislative updates.

Gwen Wong reported on the three phlebotomy bills, AB 371 (forensic phlebotomy), AB 1087 (insurance company phlebotomy) and AB 685 (HIV counselors doing finger sticks). All three bills authorized persons to do phlebotomy in new situations, and would lead to enforcement concerns. Joseph Musallam asked what the HIV counselors could do. (Finger stick only, for rapid HIV) and how long it would take to be certified in phlebotomy (3-6 months, or longer). Bob Thomas said current phlebotomists have 3 years to be certified, so the push is mostly for new applicants. Carolyn Days asked if CLTAC had supported these bills and how had they been changed? Gwen Wong said the bills started last year and had been changed quite a bit, were carried over and enacted in February 2004. Cheryl Harris about CLS' training in phlebotomy. Ms. Wong said CLS can do phlebotomy as part of scope of practice, don't need to be certified except if they want to teach phlebotomy in a training program.

Robert Thomas reviewed AB 2138 and AB 2409, personnel licensure bills. AB 2138 would require the Department to accept equivalence for licensure purposes for national certification or licensure in other states, and would require a

background check for applicants. Mr. Thomas felt this was unnecessary since LFS had approval of certification exams already underway by regulations (Section 1031.8 in the MLT regulations). AB 2409 would allow cytogenetic scientists who were board certified prior to 1997 to be licensed even if they did not have a baccalaureate degree.

Karen Nickel reported on AB 2436, the health fair bill. This bill would clarify what health fairs could do in California and would limit what non-diagnostic general health assessment program could do. The latter programs are under control of county health programs and have limited oversight.

Ron Harkey reported on SB 1355, the cytotech workload bill. This bill would increase the number of Pap smears a cytotechnologist could screen in a day from 80, to 100 using liquid-based preparation and 160 using liquid-based with automated screening. The technical supervisor could set limits lower than this, but not higher. There were concerns that the imaging technology was new and based on a limited population of patients done by a few cytotechs. There were a number of questions and comments on this bill. Someone felt this bill did not allow proper oversight of workload, and should require input from cytotechs and the unions. Someone asked why the Department had not made its concerns known. Deanna Iverson said the bill had been amended yesterday to make the workload negotiated in labor contract. She said CMS had deferred to the FDA for workload limitations. Others criticized the FDA as exceeding their authority, and said the state should intervene. Bob Achermann said the CSP had had extensive interaction on this bill, that they did not want to diminish quality by keeping manual at 80, but increasing for automated.

Ron Harkey reported on SB 1913, Pap smear reporting, which would change BPC Section 1274 to only require letters to physicians for high grade dysplasia found in Pap smears.

Update on the MLT regulations, R-13-03E. Karen Nickel said the regulations had to be modified somewhat in response to legal concerns. She said she was still hoping for a September emergency filing. Some of the changes in the regulations included, removing extraneous sections and only including MLT licensing and Section 1031.8 (certification exams for licensure purposes). LFS had to explain why an exam for MLT licensure was required when it was not mentioned in the Machado legislation. LFS had to strengthen the request for emergency filing and explain why Section 1031.8 had to be included. LFS had to explain why an organization needed to have at least 5 years experience administering an exam before it would be considered, to expand security and confidentiality requirements for the exam, to un-involve the CLTAC from the exam approval process, to explain grandfathering of persons passing the exam and taking MLT training before the regulations are enacted, to justify the fee (same as CLS'), to justify 12 hours of continuing education and to explain how MLTs would be trained in phlebotomy. The CLTAC members encouraged 12

hours of continuing education for MLTs, urged implementation of certification exams, asked a timeframe for implementation, asked about the grandfather provisions, asked if MLTs could release their own results (yes).

Other regulations. Dr. Nickel said the R-22-01 CLIA “non”-exemption regulation repeal was still on hold, as were the autoverification regulations. Those regulations on the back burner were licensure of biochemical geneticists, licensure of clinical andrologists, and CLS training requirements.

Public health laboratory standards. Dr. Nickel reminded the CLTAC that Dr. Kimsey had asked for their help in developing a position paper on public health laboratory standards. The current regulations are 30 years old and are deficient in many areas. Alice Brydon and Kathy Williams had worked on these with the public health lab directors in 1996, but this has not been finished. Dr. Nickel asked David Yong to chair the subcommittee and Tim Hamill, Ellen Jo Baron and Mary York volunteered to help. Dr. Nickel said they would be receiving an official charge and would be looking forward to their recommendations.

Who can order lab tests in California? Dr. Nickel said she agreed to discuss this with the CLTAC because of recent problems with test requisitions used by laboratories that led to sanctions and a hearing. There are 3 laws that cover test requisitions. The first is BPC 1288 which says a lab may accept a test (requisition) from and make reports only to persons licensed in the healing arts or their representative. The primary referring entity is the one who is supposed to get the results. “Licensed in the healing arts”, means within their scope of practice as a licensed person to order lab tests. “Or their representative” means persons to whom test ordering may be delegated legally. The second law is the Medical Practice Act at BPC 2052 which is not clear, authorizes a physician to diagnose a person, but does not explain. The third law is CLIA at 42 CFR 492.1241 that says a test requisition must come from an authorized person (Interpretive Guidelines explain this is a person authorized under state law to order tests or receive test results). CLIA requires the test requisition to include the name and address or suitable identifier of the authorized person requesting the test and a contact person for panic or alert values. (Interpretive Guidelines say, if appropriate, a telephone number should be included and if any information is missing, the lab must determine whether to test the specimen.

Who can receive lab tests in California? Test results should only be released to authorized persons, the individual responsible for using the test results and/or the lab initially requesting the test. The lab must set up security measures to assure confidentiality of test results.

What about drawing blood at a PSC from an unidentified ordering physician? BPC 1282.2 says it is illegal to draw blood unless authorized to do so. A lab must make sure that its PSC does not perform phlebotomy based on an illegal test requisition.

What must a lab do to comply with the law?

- (1) Accept test requisitions only when they clearly identify the name and address, or identifier, of the authorized person ordering the test.
- (2) Person ordering the test and receiving results must be licensed or authorized to practice under CA law and authorized to order and receive test reports.
- (3) A suitable identifier cannot be a business name or a non-specified list of physicians. The person receiving the requisition must be able to identify and verify the authenticity of the person ordering the test, and should be able to make immediate contact with this person.
- (4) A test requisition from a physician outside CA, as when a non-resident comes to CA or when a CA resident has a pre-existing relationship with a physician in another state, shall be dealt with in a case-by-case manner. This shall be the exception, not standard practice.
- (5) Labs should check their requisition slips to make sure they comply with these requirements.

Implementation of phlebotomy certification. Gwen Wong said phlebotomy certification had started on April 2003 and so far LFS has received about 1,500 applications, about 75-80 phlebotomy training programs had been approved with 30 waiting, 4 certifying exams had been approved with 4 waiting and about 650 certificates will soon be printed. Questions from the CLTAC followed. Terry Bryant: can phlebotomy trainees continue beyond the required time if necessary? (Yes). Someone: why doesn't LFS process new applications first because they cannot work without the certificate, others can. Salim Rafidi: will everyone be certified in 3 years? (We hope so). Gwen Wong said only the CPTs had job mobility, others must work onsite.

Status of MediCal contracting. Bea O'Keefe spoke on the new MediCal contracting for lab services. She said the contract bid had been put on hold since the labs said it was too difficult. It will be shortened and simplified, and ready in near future. Ms. O'Keefe also said that over 6000 physician office labs are billing for MediCal without CLIA and/or state licensure or registration. In order to continue, they must get both. LFS has processed 400 lab registrations from MediCal POLs and is receiving lots of calls.

Personnel licensing update. Robert Thomas gave an update on personnel licensing issues. He said a number of complaints and new lab inspections have shown some labs are employing unlicensed persons to perform testing, in violation of state law. He said that some hospitals have several labs operating under the same ownership with different directors. The main lab must be directed by a pathologist, other labs require licensed technical supervisor. Mr. Thomas said that his section is currently processing 1,012 CLS, 1,500 phlebotomist, 47 cytogenetic scientist, 200+ CLS trainees, and 35 director applications, and the backlog was increasing each week. Questions of Mr.

Thomas, Mara Williams, when will national certification exams be used? (after Section 1031.8 is implemented and exams are approved). What about a look back for certification exams? (A 4-5 year look back is proposed). What about the exam scheduled for November 2004? (The ban on contracts has been lifted and we are working to get the new contract in place). Joseph Musallam, why not move the deadline back to August or September before the November exam? (This puts too much of a time crunch on processing) and will there be only one exam given in 2005, November? (Probably although some certification exams may be approved by 2005.) Mr. Thomas said we want to have online applications and electronic review and approvals. This will same time. Dr. Kimsey was very encouraging.

New business.

- (1) Terry Bryant said the new CLIA hematology and microbiology QC should be adopted in California. She encouraged CLTAC to send a letter to LFS requesting this. Dr. Nickel commented that CA QC requirements were still set on CLIA as published in 1994.
- (2) Tim Hamill said hospital labs moving to a new location, leaving stat testing are required to get separate CLIA and state license. They should not have to re-validate all their tests at the new location. Bea O'Keefe said moving offsite, getting new equipment, persons, methods being modified, all require re-validation. LFS needs letter of intent for the move. Milt Kelly said this changed after 1992 when you could move without change. Ms. O'Keefe said CLIA requires re-validation at new lab. Jerry Hurst said "home-brew" versus FDA-approved had different requirements. Tim Hamill said the lab needs to keep testing during the move and that is a problem.

The meeting was adjourned at 12:15 by Chair Teresa Bryant. The next meeting will be held at Oakland and North Hollywood Kaiser Permanente facilities, by videoconference and telephone bridge, on September 10, 2004, 9:00 to 12:30 PM.