

**Clinical Laboratory Personnel Committee Meeting Minutes**  
**March 3, 2018 – 10:00 AM**  
**Law Offices of Adams and Reese**  
**Baton Rouge LA**

**Members Present:** Cheryl Caskey; Beverly Ogden, MD; George Roberts; Larry Broussard; Ashley Ware; Morteza Vaziri; Gaye Brunson;

**Guests Present:** Patrick McCune (Adams and Reese); Patsy Jarreau, AD, CLPC; Phyllis Toups, former CLPC member, Josie Roberts, Alexa Little (CLIA Program Manager), John Koch and Cary Koch (AAB attorneys)

**I. Call to Order**

Meeting called to order at approximately 10:10 AM by Chair Caskey. A quorum was present.

**II. Minutes of the Last Meeting**

A motion to approve the minutes of the September 16, 2017 meeting was accepted as amended.

Motion by Beverly Ogden  
Seconded by Gaye Brunson  
Motion passed; approved by all

**III. Introductions**

Each committee member and visitor introduced himself/herself to the group and stated in what capacity they served the committee. Alexa Little was introduced as the CLIA Program Manager who is not a member of the CLPC but is present to serve as a consultant to the committee and answer questions related to CLIA and licensure. Mr. John Koch and Mr. Cary Koch were present to represent AAB.

**IV. Appointments**

The CLPC needs nominees to fill the MLT position on the committee. Anyone with a possible name should submit to Chair Caskey so that we can follow through with the appropriate nominating organizations.

Dr. James Taylor's position as the rural family practitioner will expire following the conclusion of the 2018 legislative session. Dr. Taylor is actively seeking an individual to fill his position.

## **V. Office Update**

Director Jarreau stated that Executive Director Vincent A. Culotta, Jr., MD was unable to meet with the CLPC today due to a previous meeting with Physician Assistants in Alexandria but is still anxious to meet with the CLPC, either in Baton Rouge or New Orleans.

Director Jarreau reported that Licensure Analyst Nile Hull is leaving the LSBME in the near future due to family issues. LSBME will be seeking an individual to fill this position.

## **VI. Comments to CLIA on Rule Changes Related to RN Eligibility**

Committee members were provided with a summary of a conference call that involved some members of the CLPC on February 15, 2018. Each item on the CLIA proposed changes were discussed by those present on the call (George Roberts, Cheryl Caskey, Patsy Jarreau (CLPC Director), Ashley Ware, Morteza Vaziri, Gaye Brunson, and Phyllis Toups (visitor). No quorum was present, no votes were taken. The summary of this conference call is appended at the back of these minutes.

A discussion by members of the committee and guests followed related to the answers proposed by the conference call participants. Comments made by ASCLS and ASCP were also reviewed by the committee.

The following points were discussed:

1. The CLPC does not believe that nursing degrees are equivalent to educational requirements for technical consultants and moderate and high complexity testing personnel.

The CLPC believes that the minimum educational requirements for both moderate and high complexity testing personnel should be a mirror of the current CLIA educational requirements for high testing personnel:

493.1489

a. current state license

b. MD, DO, or doctoral, master's, or bachelor's degree in chemical, physical, biological, or clinical laboratory science/medical technology

2(i) or have an associate's degree in laboratory science or medical laboratory technology that includes 60 hours as follows:

(ii) 24 semester hours of medical laboratory technology courses; or 24 hours of science that include: 6 semester hours of chemistry; 6 semester hours of biology; and 12 semester hours of chemistry, biology, or clinical laboratory/medical technology courses; or any combination of each.

The CLPC does NOT believe that it would be appropriate to add nursing degrees as separate qualifying degree (as opposed to the equivalent of a biological sciences degree.).

2. The CLPC does **NOT** believe that a physical science degree is equivalent to biological sciences or clinical laboratory science degree.
3. The CLPC does **NOT** believe that CLIA regulations should be amended to allow general supervisors with associate degrees to perform competency testing for moderate complexity testing personnel in laboratories that perform both moderate and high complexity testing.
4. The CLPC believes that laboratory training and experience should be minimally equivalent to that required by the ASCP and AMT to qualify individuals to sit for the appropriate MT/MLT examination.
5. The CLPC does **NOT** believe that there are any nontraditional degrees that should be considered equivalent to chemical, biological, physical, clinical laboratory science, and/or medical technology degrees.
6. The CLPC does **NOT** believe that there are any circumstances under which discretion should be applied in situations where CMS determines that a laboratory has referred its PT samples to another laboratory and has reported the other laboratory's results as its own.
7. The CLPC does **NOT** believe that alternative sanctions instead of principal sanctions should be an option where CMS has determined that a laboratory has referred its PT samples to another laboratory and has reported the other laboratory's results as its own regardless of the certificate type held by the laboratory referring and reporting another laboratory's results.
8. THE CLPC does **NOT** believe that virtual crossmatching should be an acceptable alternative to physical crossmatching under any criteria and decision-making algorithms. Establish and implement reasonable fees
9. THE CLPC believes that CLIA should be able to establish, implement, and perpetuate fees necessary to cover continued operations.

The CLPC recommends that the above and attached comments from the conference call should be submitted to LSBME to submit as the LSBME's comments on the proposed changes to CLIA regulations. No motion and second was received.

#### **VII. Update on Certification Examination Eligibility Requirements (ASCP, AMT, AAB)**

The published requirements to sit for the ASCP, AMT, and AAB MT and MLT certification examinations as well as the information provided by each agency (ASCP, AMT, AAB) were received by the deadline. Chair Caskey verbally read the responses from each agency. There was significant discussion.

Motion (Larry Broussard) and second (Beverly Ogden) to accept the ASCP published guidelines as meeting the Louisiana licensure requirements to sit for the ASCP MT and MLT was passed unanimously.

Motion (Gaye Brunson) and second (Beverly Ogden) to accept the AMT published guidelines as meeting the Louisiana licensure requirements to sit for the ASCP MT and MLT was passed unanimously.

The AAB published requirements were discussed and opportunity for comments was afforded to Mr. John Koch, AAB attorney. Upon conclusion of the discussion, a motion (Gaye Brunson) and second (Beverly Ogden) was made to send a letter to AAB indicating the changes to the published AAB guidelines to sit for the MT and MLT exams that would have to be implemented in order for AAB to continue to be an accepted credentialing organization for licensure in Louisiana. Motion passed unanimously. The following draft letter was proposed to send to the LSBME for their action:

Dear Dr. Birenbaum:

Upon review of your updated brochure, it is noted that clinical laboratory experience/training is not included in your published qualifications for certification for MT(AAB) and MLT(AAB). The only mention of laboratory training/experience is listed in the section for Provisional Status. Provisional status does not concern us regarding Louisiana Licensure since provisional certification does not fulfill our certification requirements.

When AAB was approved as an acceptable certification agency, each of the certification categories included laboratory training/experience in each route. Prior to 2006 laboratory training was listed in your qualifications (see attached MT(AAB) and MLT(AAB) requirements downloaded from your website on 9/11/2006) but changes made to your website at some point after 2006 removed the necessary laboratory training/experience (see attached MT(AAB) and MLT(AAB) requirements downloaded from your website on 3/3/2018). To meet Louisiana clinical laboratory personnel licensure requirements (see Louisiana Revised Statutes Title 37 section 1323 – Qualifications of clinical laboratory scientist – generalist; clinical laboratory scientist – specialist; clinical laboratory scientist – technician; cytotechnologist; laboratory assistant; and phlebotomist {Source: <http://www.legis.state.la.us/>}).

Please reinstate necessary laboratory training/experience requirements to the AAB certification qualifications to meet Louisiana clinical laboratory personnel licensure requirements as indicated in the attached Changes to MT and MLT qualifications for certification as posted on the AAB website.

#### **VIII. Continuing Education Audits**

There were no audits to consider. These will probably be brought to the next scheduled CLPC meeting.

## **IX. Executive Session**

The CLPC entered into executive session following a motion (Beverly Ogden) and second (Ashley Ware) that was approved by all members and considered two issues brought to the committee by Director Jarreau. The CLPC came out of executive session following a motion (Larry Broussard) and second (Gaye Brunson) and was approved by all.

One issue dealt with an individual who has been licensed, but may not meet the educational requirement (more information will be requested by Director Jarreau). The second issue involves an individual with a lapsed license who would like to be licensed again. Director Jarreau will contact this individual and provide appropriate guidance.

Motion to suspend the individual's license was made (Beverly Ogden) and seconded (Ware). A vote on the motion failed.

There was a motion (Beverly Ogden) and second (George Roberts) to request additional information from the licensee to include undergraduate and master's level transcripts and documentation of the required clinical experience component if not already provided to LSBME. The committee would review this documentation at the next CLPC meeting. Motion passed unanimously.

Regarding the second issue, there was a motion (Larry Broussard) and second (Gaye Brunson) to contact the previous licensee and instruct that individual to reapply for reinstatement of license along with the appropriate fee and proof of continuing education. This application for reinstatement would be reviewed by the licensure analyst and Director Jarreau. If necessary, this information could be referred to the CLPC for determination. Motion passed unanimously.

## **X. Other Business**

Guest Toups asked if there was a possibility that the LSBME or CLPC could contact the individuals/groups who own the parking lots near the Adams and Reese offices and obtain permission for committee members to park in those lots at no charge for regularly scheduled Saturday meeting.

Director Jarreau provided the form that has to be signed by all committee members as a part of the LSBME/state requirements. Members present provided the required information.

Chair Caskey reminded members, that in order for them to be reimbursed by the LSBME for travel to the CLPC meeting, that each member must complete the State of Louisiana Defensive Driving on line course. Once complete, a copy of the

certificate should be provided to Director Jarreau who will see that the appropriate LSBME individual has the certificate. If this course is not completed, members will not be reimbursed for travel.

**XI. Proposed Meeting Dates**

The next meeting of the CLPC is tentatively scheduled for July 14, 2018 and an additional meeting on November 10, 2018. Chair Caskey expressed the importance of members attending the scheduled meetings since no business can be acted upon without a quorum being present.

**XII. Adjourn**

Motion to adjourn by Ashley Ware  
Seconded by Morteza Vaziri  
Meeting adjourned at 2:20 PM

Note: The agenda was misnumbered. These errors have been corrected in the minutes.

Minutes Approved by CLPC submitted by George Roberts, Secretary CLPC  
November 10, 2018

## **CLPC Conference Call**

### **Feb. 15, 2018 6:30 PM – Adjourned 7:45 PM**

No quorum present; therefore, no vote, only discussion. These comments will be reviewed by the CLPC and voted on as an advisory committee and recommended to LSBME as an aid in their response to these proposals.

Present:

George Roberts

Cheryl Caskey

Patsy Jarreau, CLPC Director

Ashley Ware

Morteza Vaziri

Gaye Brunson

Phyllis Toups – visitor

1. **Nursing Degrees** - A nursing degree is **NOT** equivalent to a MLS/CLS/MT/MLT degree except with regard to the general education and mathematics requirements. There are insufficient credit hours of basic science courses required for the degrees to provide individuals with adequate understanding of basic science let alone laboratory science. A baccalaureate degree in biology generally requires approximately 30-40 credit hours of biology courses including laboratories above the introductory level and in addition to general education requirements. MLS/CLS/MT/MLT degrees require many of the same basic science course along with specific medical laboratory courses, laboratories, and clinical training. Nursing degrees only require introductory level courses in anatomy and physiology, chemistry, and general microbiology with insufficient depth and breadth of the course to be accepted to even meet the general education requirements for a baccalaureate degree in biology of medical laboratory science. Nursing degrees do **NOT** require any specific medical laboratory courses, management, laboratory practice, or quality control and assurance in the major areas of laboratory practice (hematology, immunology/serology, clinical chemistry and body fluids, immunoematology, laboratory practice, or medical microbiology). Neither does the nursing degree require any clinical component related to laboratory practice.

The committee does **NOT** believe that it would be appropriate to add nursing degrees as a separate qualifying degree (as opposed to the equivalent of a biological science degree) to the current list of qualifying degrees for each of the reasons stated above.

2. **Physical Science Degrees** – Natural sciences can be broken down into two main branches: life sciences (for example biology) and, physical sciences (physics, astronomy, chemistry, geology, and earth science). The life sciences are sciences such as

anthropology, anatomy, biochemistry, biology, botany, microbiology, and zoology are concerned with the structure and behavior of living organisms and their life processes. Therefore, a physical science degree is **NOT** equivalent to an MLS/CLS/MT/MLT degree except with regard to general education requirements and mathematics and in fact do not include courses outside chemistry which could be considered equivalent to a biological sciences or MLS/CLS/MT/MLT degree.

3. **Competency Assessment** – CLIA regulations should NOT be amended to allow general supervisors with associate degrees to perform competency testing for moderate complexity testing personnel in laboratories that perform both moderate and high complexity testing. This leadership piece is what differentiates the associate- and baccalaureate-degree prepared individuals.
4. **Laboratory Training and Experience** – Nursing degrees do **NOT** contain courses which would provide appropriate laboratory training, experience, and skills when determining the qualifications necessary for all personnel to meet CLIA requirements for laboratory testing.

Acceptable appropriate laboratory training, experience, and skills requirements should be equal to those required by the ASCP and AMT to be eligible to sit for those national certification examinations at each level of practice.

The minimum acceptable degree would be an appropriate degree in the biological, physical, chemical sciences or MLS/CLS/MT/MLT that are currently in place in the CLIA regulations for High Complexity testing personnel:

The CLPC believes that the minimum educational requirements for both moderate and high complexity testing personnel should be a mirror of the current CLIA educational requirements for high testing personnel:

493.1489

a. current state license

b. MD, DO, or doctoral, master's, or bachelor's degree in chemical, physical, biological, or clinical laboratory science/medical technology

2(i) or have an associate's degree in laboratory science or medical laboratory technology that includes 60 hours as follows:

(ii) 24 semester hours of medical laboratory technology courses; or 24 hours of science that include: 6 semester hours of chemistry; 6 semester hours of biology; and 12 semester hours of chemistry, biology, or clinical laboratory/medical technology courses; or any combination of each.

This should also be the minimum for moderate complexity testing personnel.

If the degree is NOT in MLS/CLS/MT/MLT, laboratory training or experience should be equivalent to that required for the MLS/CLS/MT/MLT degrees and requirements established by ASCP and AMT to sit for the certification examinations.

Verification of the degree from the appropriate college or university would document the degree. Verification of certification by the appropriate nationally recognized certification agency would serve to document training. For institutions hiring individuals without an appropriate certification to perform laboratory testing, there should be a documented training period equivalent to that required by ASCP and AMT where the appropriately qualified laboratory completes an approved checklist of competencies that the individuals who do not hold a certification must compete during an appropriate training period minimally equal to that required by ASCP and AMT to sit for the certification examination. Uncertified individuals would only be qualified to perform specific testing as indicated by the competency checklist.

5. **Non-Traditional Degrees** – This committee does not believe that any other degrees should be considered to meet the requirements for a chemical, physical, biological, or clinical laboratory science/medical laboratory science/medical laboratory technology degree. All individuals who perform laboratory testing should complete the required general education requirements for the CLS/MLS/MLT degree, complete an applicable training program including clinical training, and successfully complete an approved national certification examination.
6. **PT Referral Discretion** – There are no circumstances under which discretion should be applied in situations where CMS determines that a laboratory has referred its PT samples to another laboratory and has reported the other laboratory's PT results as its own. There should be one set of standards or rules and those rules should be imposed across the board to all laboratories regardless of the type of certificate possessed by the laboratory. All testing personnel should be aware of the rules related to PT testing and should be expected to adhere to that set of rules with no exceptions. This action will create parity for all certificate types and does not leave room for interpretation. Laboratory should lose their license to practice if convicted and the lab shut down. Recommend no change.
7. **PT Referral CoW** – Alternative sanctions instead of principal sanctions should **NOT** be an option where CMS has determined that a laboratory has referred its PT samples to another laboratory and has reported the other laboratory's results as its own regardless of the certificate type held by the laboratory referring and reporting another laboratory's results. Recommend no change
8. **Histocompatibility** – A virtual crossmatch is a crossmatch that involves a determination of the presence or absence of donor HLA specific antibodies (DSA) in a patient by comparing the patients' HLA antibody specificity profile to the HLA type of the proposed

donor without carrying out a “wet” crossmatch such as the Complement Dependent Cytotoxic (CDC) or flowcytometric crossmatch. The committee does not believe that there should be acceptable criteria under which virtual crossmatching would be an acceptable substitute to physical or wet crossmatching. Virtual crossmatching should be used in addition to physical or wet crossmatching.

Knowledge of CLPC individuals related to histocompatibility is insufficient to make suggestions; however, the committee believes that it does seem appropriate that histocompatibility regulations should be updated to align with current practice. It further seems appropriate that regulations should be updated on a routine and regular basis based upon currently accepted practice.

9. **CLIA Fees** – No knowledge to speak to this. Other national organizations have established fees for revised certificates, post-survey follow-up visits, complaint investigations, and activities related to imposition of sanctions. It does not seem inappropriate for additional fees in these areas to be added as long as they are reasonable. CLIA should be able to establish and perpetuate fees necessary to cover continued operation.