Clinical Laboratory Personnel Committee March 23, 2019 – 10:30 AM Law Offices of Adams and Reese Baton Rouge LA

Members Present: Cheryl Caskey; Beverly Ogden, MD; George Roberts; Yolanda Bennett; Angela Foley; Ashley Ware; and Shannon Skena

Guests Present: Grant Guillot (Adams and Reese); Patsy Jarreau, AD, CLPC; Josie Roberts; Alexa Little (CLIA); Phyllis Toups; Johnny Koch (AAB attorney); Cary Koch (AAB attorney); Paula Pigford (LSBME); and Dr. Vincent Culotta (LSBME)

I. Call to Order

Meeting called to order at approximately 10:40 AM by Chair Caskey. A quorum was present.

II. Minutes of the Last Meeting

A motion to approve the minutes of the November 10, 2018 was accepted as printed.

Motion by Beverly Ogden
Seconded by Yolanda Bennett
Motion passed; approved unanimously

III. Introductions

Each committee member and visitor introduced himself/herself to the group and stated in what capacity they served the committee. Ms. Alexa Little was present as a consultant from CLIA. Mr. Cary Koch, Mr. John Koch, were present to represent AAB. Josie Roberts and Phyllis Toups were present as members of LSCLS. Dr. Vincent Culotta and Ms. Paula Pigford were present as representatives of LSBME.

IV. Appointments

The new educator position from the Louisiana Community and Technical College System representative, Ms. Shannon Skena was present and introduced. The Rural Family Practitioner has yet to be appointed. George Roberts reminded the groups that his position as educator on the CLPC was up in the fall and he needs to be replaced. Additionally, Chair Caskey's term will expire this December. We need nominees from the representative groups with authority to nominate for these positions.

V. Office Update

There is a new principal investigator from LSBME for the CLPC – Ms. Paula Pigford.

There was a request to waive requirement for high school graduation for the lab assistant position. LSBME denied the request per conflict with CLIA.

Ms. Jarreau pointed out that the LSBME Board minutes are posted on the LSBME website, and that committee members should review them to see what pertains to the CLPC prior to each meeting.

There was a motion that the CLPC recommend that the LSBME Board notify all members of all boards/committees of board meetings and provide board/committee members with a link that gives all members access to the minutes.

Motion by Angela Foley Second by Beverly Ogden Motion passed unanimously

VI. Lab Assistant – CLIA Requirement

Ms. Jarreau pointed out that changes to the CLPC Rules and Regulations states that a lab assistant can perform high complexity testing. CLIA states that this is unacceptable. Dr. Culotta advised that LSBME can override the rules based upon CLIA requirements.

Dr. Culotta also suggested that the CLPC needs to go through the rules and review line-by-line for all necessary changes so that changes will be global rather than making one change at a time since the process is so time consuming. It was suggested that the CLPC members who would be present at the LSCLS annual meeting in Monroe in early April meet to begin this process.

VII. Licensing for Grossing Tissue Specimens

From the 11-10-2018 meeting minutes: Histotechnologists and histotechnicians are not licensed under the Clinical Laboratory Licensure law and the qualifications for performance of tissue grossing from CLIA prevail.

As a point of information, the CLPC could inform the LSBME know that there is a void in licensure that allows histotechnologists and histotechnicians to perform grossing of specimens. Dr. Ogden will research this issue and report back to the CLPC at the next meeting.

There was considerable discussion related to this issue and the appropriate actions for the CLPC to take. CLIA states that grossing of tissues is high complexity testing and individuals performing such need a license, to meet continuing education requirements, and to demonstrate competency.

The question arises via Louisiana Revised Statutes Title 37 1312 (5) if the CLPC has the authority to license these individuals, to exempt these individuals, to not exempt these individuals, or to create a new licensure category for these individuals. Additionally, the question arises as to who would be licensed (histotechnologists and histotechnicians or only those who are unlicensed but qualify as high complexity testing personnel). The CLPC/LSBME will seek a legal opinion from Adams and Reese on how to approach this issue. CLPC/LSBME will also seek legal opinion as to whether this process can be affected through changes to the rules or if we have to back to the law to enact changes.

VIII. Skin Testing

Chair Caskey will send a recommendation to Dr. Culotta/LSBME Advisory Board regarding the CLPC position on skin testing as printed in the November 10, 2018 approved meeting minutes and reprinted below. Dr. Culotta needs this recommendation by next week to get it on the agenda of the LSBME Advisory Board meeting for April.

The CLPC recommends that skin testing is not within the scope of practice of medical laboratory personnel and that the following definition of skin testing be attached to the recommendation. If the LSBME concurs with this recommendation, all licensed laboratories and personnel must be notified of this change.

Skin Testing – A test carried out in allergic or immunologic conditions to identify the cause of immediate or delayed skin hypersensitivity. An allergic condition is one in which there is hypersensitivity to a certain agent identified as an allergen. The intradermal or Mantoux skin test is commonly used for tuberculosis and fungal infections and involves the injection of a premeasured amount of allergen intradermally. Allergen testing may also be performed by the patch (Vollmer), scratch, or tine methods to determine presence of immediate or delayed hypersensitivity.

IX. Act 655 Complaints

The Louisiana Legislature passed a law this past 2018 session stating that the following statement must be attached to all correspondence of LSBME and the groups that LSBME oversees. This statement can be used by all groups to meet this requirement.

CONFIDENTIAL

This email transmission, including any attachments, is intended for the named recipient(s) and may contain information that is privileged, confidential, and/or exempt from disclosure under applicable law. If you have received this transmission in error, or are not the named recipient(s), permanently delete this transmission, including any attachments.

In compliance with Act 2018-655, the Board gives notice to its licensees and applicants of their opportunity to file a complaint about board actions and board procedures. You may submit such complaints to one or more of the following organizations:

- (1) Louisiana State Board of Medical Examiners; 630 Camp Street, New Orleans, LA 70130; (504) 568-6820; lsbme@lsbme.la.gov
- (2) Committee on House & Governmental Affairs, La. House of Representatives, PO Box 94062, Baton Rouge LA 70804; (504) 342-2403; obriens@legis.la.gov
- (3) Committee on Senate & Governmental Affairs; La. Senate; PO Box 94183, Baton Rouge LA 70804; (225) 342-9845; sx&q@legis.la.gov

X. Continuing Education Audits

Ms. Jarreau stated that the continuing education audits for calendar year 2018 have been completed.

There was a motion to change the agenda and proceed to executive session.

Motion by Beverly Ogden Seconded by Shannon Skena Motion passed unanimously

XI. Executive Session

Upon completion of discussion of presented complaints, there was a motion and second to return to the regular meeting.

Motion by Beverly Ogden Seconded by Angela Foley Motion passed unanimously

Five individual complaints were referred to the CLPC for recommendations for action:

Alicia Danielle Joseph – CLPC recommends no action

XII. Other Business

Dr. Culotta and Ms. Jarreau discussed the possibility of employing C E Broker to handle continuing education audits for all licensees under the LSBME, to include CLPC.

CE Broker would affiliate with the national agencies recommended by the CLPC to the LSBME for approval of continuing education so that there would be a mechanism in place to transfer those credits directly to CE Broker, much like the process involved with ASCLS CE Organizer and ASCP BOR. For this service, there would be no charge to the individual licensee. There are two other levels of assistance that CE Broker could supply to individual licensees for a prescribed additional monthly charge when the individual licensee's continuing education is from one of the listed approved agencies. Documents would be submitted to CE Broker and they would ultimately approve the continuing education courses of those individuals and notify LSBME. This process would remove the burden of reviewing the 3% annual audit review and subsequent follow-up of deficient practitioners from the CLPC and assure the people of the state and the legislature that no licenses were renewed without proof of appropriate continuing education.

This audit process would begin 90 days prior to licensure renewal date and licensees would be notified how many approved hours they had completed and how many were lacking for continuing licensure. Those deficient at the end of the year would be allowed 60 days to complete the process before the license was suspended.

CE Broker will need a list of nationally approved continuing education providers for this process expected to begin in 2020.

A number of providers were mentioned by the CLPC members; however, this list is incomplete at the moment and needs to be refined (note question marks):

All PACE approved units

All ASCP approved units

All AMT/AMTIE approved units

All AAB approved units ???

All CDC approved units

All approved for cytotechnology – Dr. Ogden will verify

All AABB approved units ???

Other approved providers???

Individual college, instrument manufacturer units (if not PACE approved), and health care organization units will have to be approved by the CE Broker for the additional charges.

There was a motion and second from the CLPC to recommend that the LSBME proceed with the prospective evaluation of CE units prior to renewal and denial/removal of license if requirements not met.

Motion by Beverly Ogden Seconded by Ashley Ware Motion approved unanimously

There was an additional item submitted for discussion related to Louisiana Revised Statutes Title 37 (9) on page 8. Should this statement be modified to read "any felony arrests", not just related to contagious or infectious disease. CLPC/LSBME will seek legal opinion from Adams and Reese prior to next meeting.

XIII. Proposed Meeting Dates

July 20, 2019 November 2, 2019

XIV. Adjourn

Motion to adjourn by Beverly Ogden Seconded by Ashley Ware Motion approved unanimously Meeting adjourned at 1:10 PM

Draft minutes Submitted by George Roberts, Secretary CLPC 03-23-2019

Minutes approved 7-20-2019