

Tennessee Medical Laboratory Board Meeting
January 27, 2017
Minutes

Date: January 27, 2017

Time 09:00 AM CST

Location: Tennessee Department of Health
Division of Health Licensure and Regulation
Metro Center Complex, Iris Room, Ground Floor
665 Mainstream Drive
Nashville, TN 37243

Members Present: Patti J. Walton, MT-Hospital/Lab Manager/Adm. Dir, Chair
Stephanie Dolsen, MT- Medical Technologist Supervisor Vice-Chair
Kathleen Kenwright, MT- Medical Technologist, Educator
Cheryl Arnott, S.A.-Cytotechnologist
Tereyo M. Cox, MT-Medical-Technologist, General
Mark A. Calarco, DO, Independent Lab Manager/Administrator
Michael Johnson, MT-Medical Technologist Generalist
Royce Joyner, MD-Pathologist Educator

Members Absent: Carla M. Davis, MD-Pathologist
Gaye G. Jolly, MT-Hospital Administrator
Jason S. Nolan, MD-Pathologist, Non-Educator
Michael J. Wright-Citizen Representative

Vacant Position: Non-Pathologist Physician

Staff Present: Lynda S. England, Medical Technologist Consultant, Director
Nina V. Smith, Medical Technologist Consultant
Kyonzte Hughes-Toombs, Deputy General, Office of General Counsel
Julia Daniels, Medical Technologist Consultant/ Surveyor, East Tennessee Regional Office
Taylor Carpenter, Medical Technologist Consultant/Surveyor, East Tennessee Regional Office
Richard Carroll, Medical Technologist Consultant/Surveyor, Middle Tennessee Regional Office
Karon Hathcoat, Medical Technologist Consultant/ Surveyor, West Tennessee Regional Office
Debbie Haggard, Medical Technologist Consultant/Surveyor, West Tennessee

Staff Absent: All staff present for the meeting.

CLIA Manager/Representative: Sandra Bogard, MT CLIA Manager

Presiding Officer: Patti Walton, MT, Chair

Call To Order: The meeting was called to order at 9:00am CST by Board Chair Patti J. Walton.

Introductions of Board Members: Board members and staff made their introductions to the record.

Introductions of Staff:
Quorum: Eight (8) board members were present which constituted a quorum.

Approve Minutes:

P & E Committee Meeting A motion to approve the October 19, 2016 Personnel & Education Committee minutes was made by: Ms. Arnott
Second: Dr. Calarco
Committee Minutes Approved.

Full Board Meeting A motion to approve the October 20, 2016 board meeting minutes was made by: Ms. Arnott
Second: Mr. Johnson
Board Minutes: Approved.

Board Reports:
Ratification of Initial Determinations of the P&E Committee Meeting: Ms. Kenwright reported the actions of the Board's Personnel & Education Committee meeting, January 26, 2017.
Motion to ratify Committee actions: Ms. Arnott
Second: Dr. Joyner
Report: Ratified as presented.

Contested Case State Representative: Kyontzé Hughes-Toombs, Deputy Gen Counsel
Petitioner Counsel: Dan Dalrymple, Esq.

**Margrette Youssef
Nashville, TN 37211** Ms. Youssef appeared before the board to request reconsideration of her original application for a Tennessee license as a medical laboratory professional in the category of medical technologist.

**Administrative Law Judge:
Honorable Jerome Cochran** The original application was review by the Personnel & Education Committee of the Board during their July 15, 2015 meeting and subsequently ratified by the Board on July 15, 2015.

Docket: 17.08-139702A Ms. Youssef received her education in Egypt, obtaining a Bachelor Degree of Medicine and Surgery at Alexandria University, with those documents reviewed by board members during the July 2015 meeting. Board/committee members review all foreign-trained applicants before a license is granted. After subsequent review of the documents presented at that time, members determined inadequate training, and completion of science and mathematics coursework for the categorical specialty of medical laboratory technology. Board members denied her technologist application.

Ms. Youssef appealed the denial of her license per the contested case presented today.

Additional documentation was presented to board members to include transcripts that were not part of the July 2015 meeting. After witness testimony plus the additional documents, and subsequent review, board members reversed their earlier decision based on experience in a laboratory setting and in a physician's office relating to laboratory experience, and granted Ms. Youssef a license in the category of Medical Laboratory Technologist.

TENN. CODE ANN. §68-29-118(b), TENN COMP. R. & REGS 1200-06-01.22(1) and TENN. COMP R. & REGS. 1200-06-01.22h) (4), (5).

Motion: Dr. Calarco

Second: Ms. Dolsen

Roll Call Vote:

Aye: Dr. Calarco, Ms. Dolsen, Mr. Johnson, Ms. Arnott

Opposed: Dr. Joyner, Ms. Cox, Ms. Kenwright,

Abstain: Ms. Walton

Consent, Agreed, Compliance Orders & Letters of Reprimand

Consent Orders No consent orders were presented.

Agreed Orders No Agreed Orders were presented

Compliance Orders No Compliance Orders were presented

Letters of Reprimand No Letters of Reprimand were presented

Presentations to the Board:

Tennessee Professional Peer Assistance Program (TnPAP):

Mr. Mike Harkreader*
TnPAP Director

The statistical report for July 1, 2016-December 31, 2016 was presented with one (1) individual being monitored during this period.

One referral was made by an employer for impairment and positive urine drug screen in the workplace.

One TnPAP evaluation was performed with one individual consenting to treatment.

Another individual declined the TnPAP Service and has been reported to the Department for further review.

Motion to accept the TnPAP report: Mr. Johnson

Second: Ms. Arnott

*Ms. England gave report.

Note: Review of TnPAP materials via internet counts as clock hours toward continuing education credits. A certificate of completion documenting review Of these materials can be completed at the end of the internet session. Internet site: www.TNPAP.org

**Financial Report
Noranda M. French
Presentation/Discussion**

Ms. French discussed in depth the Board's financial status for the FY2016 Year End Report. Board finances continue to be in the black with revenue from licensures of personnel, facilities and training programs. The cumulative carryover for that time period was \$1,620,479.87.

Motion to accept report: Ms. Kenwright
Second: Ms. Arnott
Report accepted as presented with no changes.
(Copy of report on file in administrative office)

**Investigations Report
Nichelle Dorroh*
Presentation/Discussion**

January 01- December 31, 2016

Personnel: BIV* received a total of eight (8) complaints with seven (7) complaints closed to include three (3) complaints closed with a letter of warning. One (1) complaint related to unqualified personnel; two (2) complaints concerned the use of drugs; while five (5) complaints related to unprofessional conduct by licensees. (December 2015-December 2016)

Facilities: One (1) complaint was reported in October concerning possible malpractice/negligence.

A summary of currently monitored practitioners was presented for board review.

*Bureau of Investigations for DHLR Med Lab Board

Motion To Accept Report: Ms. Kenwright
Second: Ms. Arnott
*Report given by Ms. England

Compliance Orders

There was no compliance orders from the Bureau of Investigations submitted for discussion during the meeting.

Discuss, review, take action, if needed, regarding but not limited to:

Ratifications: The following items were presented to board members for ratification per staff, state surveyor or facility request:

**Wesley Neuromuscular
Laboratory
20 South Dudley Room 450
Memphis, TN 38103**

**Tulio E. Bertorini, M.D.
Laboratory Director**

Dr. Bertorini made a presentation to board members concerning the possibility of having an individual acting in a supervisory role and pertaining to compliance with state licensure personnel requirements.

Dr. Bertorini is the current supervisor of record and because of LOW testing volume he is not on site every single day.

This physician operates the neuromuscular laboratory with a very limited staff, and because of the extreme technicality of this testing process

Dr. Bertorini asked members to entertain the possibility of a Tennessee-licensed medical laboratory technician (with an associate's degree) and also certified as a histotechnologist (category not licensed in Tennessee) could assume the leadership role of laboratory operations during those days Dr. Bertorini would not be in the laboratory.

This individual was highly trained in this specialized muscle biopsy technique. After discussion, it was determined the sectioning and staining of tissue, according to federal oversight (CLIA,) is not considered a laboratory test and this individual's experience would satisfy the 24-hour supervisor review for federal guidelines.

After board member discussion, members decided to adopt CLIA regulations (CFR 493.1489b (7) pertaining to this very specialized muscle and nerve-biopsy laboratory.

Motion: Dr. Joyner

Second: Ms. Kenwright

**Legislative Report
DOH Commissioner's Office
Legislative Liaison**

No report was given during this meeting.

**American Society for Clinical
Pathology International Version
Review (ASCP_i)**

Board members reviewed a "revised" version of the board policy for acceptance of applicants successfully completing the international ASCP_i examination and licensure in Tennessee.

The policy reads:

"The Tennessee Medical Laboratory Board recognizes the examinations given by the American Society for Clinical Pathology (ASCP) for medical laboratory professionals as one of the pathways for licensure.

This policy recognizes the addition of the international version of the American Society for Clinical Pathology (ASCP_i) examination as a second ASCP alternate pathway for licensure in Tennessee and equivalent to the ASCP examination if successfully completed after the following dates:

October 01, 2014-Medical Laboratory Technicians.

October 01, 2014-Medical Laboratory Technologists-Mol. Biology .

January 01, 2015-Medical Laboratory Technologists.

The ASCP_i examination may be taken in the United States and/or territories and any other physical location where this agency (ASCP) sponsors the exam.

This policy does not affect any other board approved examination agency.

Motion: Mr. Johnson

Second: Ms. Arnott

Policy Approved.

**Tennessee Pharmacists
Association
Kenneth Hohmeier, Pharm D
James Wheeler, Pharm D
UTCHS College of Pharmacy
Memphis, TN**

Doctors Hohmeier and Wheeler made a presentation before board members concerning pharmacies evolving participation in point of care techniques relating to operations within the pharmacy associated with the physician/pharmacy/patient arena. They were particularly concerned with the limited menu of board-approved testing events for point of care testing events.

Another question pertained to the physician requirement on the state's notification form and perhaps to broaden that requirement.

Pharmacists are seeking to perform all CLIA waived tests in their pharmacies.

Board members expressed concerns about the physical atmosphere in which these clinical tests would be performed.

Doctors Hohmeier and Wheeler requested board-direction in having tests added to the board menu.

Board member response indicated that to add a specific CLIA-waived test to the board's test menu, presentation must be made during a quarterly meeting with appropriate documentation. Implementation within the state law is of primary importance. Patient safety, instrument quality control in the pharmacy is a concern.

No action was taken at this time.

Board Approval of Surveyor Supplies

Board members approved the purchase of six (6) portable printers + cases + cartridges for state consultants/surveyors to assist with the surveys performed for all state facilities. The printers go to each surveyor in the three (3) regions of Tennessee, East, West, and Middle.

Monies will be taken from the board's financial fund.

Motion: Ms. Kenwright

Second: Dr. Joyner

Motion: Expenditure for printers, approved.

Ratifications: The following items were presented to board members for ratification per staff, state surveyor or facility request:

Exemptions for point of care testing procedures (POCT) in a licensed Facility

**1: Baptist Memorial Hospital
Huntington
Huntingdon, TN 38344**

This exemption request permits Respiratory Therapists (ABG-endorsed) to perform and report blood gas to include pO₂, CO₂, pH, sO₂, carboxyhemoglobin and derived calculations for TCO₂, BE and HCO₃. These tests are performed in respiratory therapy utilizing the GEM Premier 4000 analyzer and methodology.

- Brent Oatsvall, MT**
Administrative Lab
Director
- Motion: Mr. Johnson
Second: Ms. Arnott
Exemption Request: Approved
- 2: Saint Francis Hospital**
Bartlett, TN 38133
Doretha Franklin, MT
Administrative Lab Dir.
- The request permits Registered Nurses (RN's), Registered Cardiovascular Invasive Specialists, Cardiovascular Technicians, Radiology Technicians and Registered or Certified Respiratory Therapists (ABG-endorsed), to perform and report oxygen-hemoglobin saturation results utilizing the AVOXimeter 1000 (E) in the Cardiac Cath Laboratory.
Motion to approve exemption: Ms. Kenwright
Second: Ms. Arnott
Request Approved
- Request for operating room technicians removed from presentation and exemption.
- 3. Parkwest Medical Center**
Knoxville, TN 37923
Tessa Shaw, MT(ASCP)
Point of Care Coordinator
- This request was presented and approved for Registered Nurses (RN's) to perform and report lactate testing in the Emergency Room utilizing the i-STAT CG4+ cartridge.
- Motion: Mr. Johnson
Second: Ms. Arnott
Request Approved.
- 4. Tenna Healthcare**
Turkey Creek Med Center
Knoxville, TN 37934
Diane Justice,
MT(ASCP),SC,DLM
Administrative Laboratory
Director
- Several requests were presented for board review with different instruments and locations:
- Request #1 AVOX4000 POCT Analyzer**
Permits Licensed Perfusionists to perform and report reduced hemoglobin(HHB) in the CVOR-Surgery Department.
Motion: Ms. Dolsen
Second: Dr. Joyner
Request: Approved.
- Request #2 AVOX4000 POCT Analyzer**
Permits Respiratory Therapists (ABG-endorsed) to perform and report oxyhemoglobin (O₂HB), carboxyhemoglobin (COHB), and methemoglobin (MetHb) with associated calculated parameters house-wide.
Motion: Mr. Johnson
Second: Ms. Arnott
Request: Approved.
- Request #1 Epop POCT Analyzer**
Permits Licensed Perfusionists to perform and report blood gas (pH, pCO₂, PO₂, and associated calculated parameters), electrolytes, hematocrit, lactate, and glucose in the CVOR-Surgery Department..
Motion: Mr. Johnson
Second: Ms. Dolsen
Request: Approved.

Request #2 Epoc POCT Analyzer

Permits Respiratory Therapists (ABG-endorsed) to perform and report blood gas (pH, pCO₂, pO₂) and associated calculated parameters, house-wide.

Motion: Ms. Dolsen

Second: Ms. Arnott

Request: Approved.

5. **Tennova Healthcare
Physicians Reg. Med
Center
Knoxville, TN 37917
Barry Noe, MT
POCT Coordinator
Mary Jones
ABG Coordinator**

Several requests were presented for board review:

Request #1 Epoc POCT Analyzer

Permits Registered Nurses (RN's), and Licensed Perfusionists to perform and report blood gas with calculated parameters, electrolytes, hematocrit and glucose in the Surgery Department

Motion: Mr. Johnson

Second: Ms. Arnott

Approved.

Request #2 Epoc POCT Analyzer

Permits Respiratory Therapists (ABG-endorsed) to perform blood gas (pH, pO₂, pCO₂) and calculated parameters, house-wide.

Motion: Dr. Joyner

Second: Ms. Arnott

Approved.

Request #3 AVOX4000 POCT Analyzer

Permits Registered and/or Certified Respiratory Therapists (ABG-endorsed) to perform and report whole blood tHb, %O₂, %COHB, and %MetHb along with associated parameters in the Respiratory Department Laboratory.

Motion: Ms. Dolsen.

Second: Dr. Joyner.

Board members asked this request for Perfusionists performing same tests in CVOR. during the April meeting because was not part of the original request.

6. **Methodist LeBonheur
Germantown Hospital
7691 Poplar Avenue
Germantown, TN 38138**

Permits Licensed Registered Nurses (RN's), Licensed Practical Nurses (LPN's), Registered Respiratory Therapists (ABG-endorsed), Radiology Technicians, Perfusionists and Cardiovascular Technologists to perform and report co-oximetry in the Surgical Services Operating Room. The instrument and methodology utilized in the performance of these tests is the AVOXimeter.

Request withdrawn before meeting date. (04/20/17)

**Direct more than three (3)
Laboratories**

No requests for this meeting

**RECEIVE REPORTS AND /OR
REQUESTS:**

Board Director's Report

Ms. England gave the board director's report for the quarter October 01, 2016 thru December 31, 2016.
The report included a statistical report of activities of licensure for personnel and laboratory facilities.

Motion to accept Director's report: Ms. Arnott
Second: Mr. Johnson

Motion: Ms. Arnott
Second: Mr. Johnson
Report accepted as given.
(Copy of report is on file in the Administrative Office)

Board Attorney Report Kyontzé Hughes-Toombs Deputy General Counsel

Counsel Hughes-Toombs gave her report for the past quarter:
2-open cases
2-remaining cases
Personnel Rules are still in internal review with questionable revision before advancing to next state before approval by Department.

Motion: Ms. Arnott
Second: Dr. Calarco
Report approved as given.
No licenses to reinstate this quarter.

REINSTATEMENT OF LICENSES

ADDITIONS/DELETIONS TO THE BOARD'S WAIVED TEST LIST

No requests were made to add to the waived test list.

Review/Discuss Approval Licensure of Medical Laboratory Director

Xiaorong Qian, Ph.D
Nashville, TN 37221
Director: Molecular Diagnostics

Dr. Qian appeared before members during this meeting to request licensure in the specialty of molecular diagnostics.
She was trained in Central South University, China (1994) and spent five (5) years in medicine studies and holds a Ph.D. in Pathology and Pathophysiology in the University.

Dr. Qian currently holds licensure in Tennessee in the following categories:

Special Analyst: Cytogenetics, Cytogenetics Supervisor (2010,2012)
Special Analyst: Molecular Diagnostics, Molecular Diagnostics, Supervisor (2010, 2012)

Training: Integrated Oncology Brentwood, TN (2010-2016)

Certification: American Board of Bioanalysis (ABB)
Molecular Diagnostics (Exp. 12.31.17)

Motion: Dr. Calarco
Second: Ms. Arnott
License Approved.

Joseph J. Saady, Ph.D.
Richmond, VA 23229
Director: Toxicology

Dr. Saady appeared before the board to request licensure in the specialty of toxicology. He obtained a BS-Chemistry from the University of Richmond; MS in Pharmacology & Toxicology from Virginia Commonwealth University and PhD from Virginia Commonwealth University in Pathology in 1997. His training was at the Medical College of Virginia, Hospital, attending the Toxicology Training Program from 1973-1987. Dr. Saady is currently boarded by the American Board of Forensic Toxicology as a Fellow in Forensic Toxicology with an expiration date of December 31, 2020.

Motion: Dr. Calarco
Second: Ms. Arnott
License: Approved.

Regional Surveyors Reports

Complaint Investigations and proficiency testing (East, West and Middle TN)

ETRO Report
Taylor Carpenter
MT-Consultant

East TN Regional Office: October 01-December 31, 2016
Unsuccessful Proficiency Testing: One (1) first unsuccessful event for pO₂ and pCO₂ with acceptable plan of correction.

No complaint investigations.

MTRO Report
Richard Carroll
MT-Consultant

Middle TN Regional Office: October 01, 2016-December 31, 2016
Unsuccessful Proficiency Testing: One (1) facility unsuccessful event with review pending.

Two (2) complaint investigations during this quarter; one substantiated; one not substantiated.

WTRO Report
Karon Hathcoat
MT-Consultant

West TN Regional Office: October 01-December 31, 2016
Zero (0) unsuccessful Proficiency Testing events during this period.

Zero (0) complaint investigations during this period.

Motion to accept regional reports: Ms. Arnott
Second: Dr. Joyner
Reports accepted as presented

**Board Ratification of Laboratory
Initial License:**

Vision Laboratory Solutions-R*
325 Seaboard Lane Suite #10
Franklin, TN 37067

Medical Laboratory Director:

Tara W. Chang, MD
Anatomic/Clinical Pathology

Specialties:

General Immunology, Clinical
Chemistry, Urinalysis,
Endocrinology, and Hematology

*R=regular clinical license

Surveyor:

Richard Carroll, MT
Consultant II/MTRO

Motion: Ms. Arnott
Second: Ms. Cox
License Approved.

Crestar Labs, LLC-R*
2001 Campbell Station Parkway
Ste C-2
Spring Hill, TN 37174

Medical Laboratory Director:

Marc J. Rumpler, Ph.D.

*R-regular clinical license

Specialty:

Hematology, Toxicology,
Molecular Diagnostics

Surveyor:

Richard Carroll, MT
Consultant II/MTRO

Application Withdrawn

*First time review in October 2016, application tabled pending
medical laboratory director qualifications to direct non-esoteric
laboratory.*

**NOTE: THE DESIGNATION –R* IS
UTILIZED ONLY WHEN A
LABORATORY HAS PREVIOUSLY
BEEN GRANTED A FACILITY LAB
LICENSE AS AN ESOTERIC
LABORATORY AND THE FACILITY
DESIRES TO OBTAIN A SECOND
FACILITY LAB LICENSE OPERATING
AS A REGULAR/NONESOTERIC
LABORATORY IN THE SAME
PHYSICAL LOCATION.
THESE DESIGNATIONS ARE
UTILIZED FOR ADMINISTRATIVE
USE ONLY.**

Vision Laboratories
6130 Shallowford Road Suite 100
Chattanooga, TN 37421

Medical Laboratory Director:

Adel Shaker, M.D.
Director: Anatomic Pathology
Forensic Pathology

Specialty:

Clinical Chemistry, Toxicology

Surveyor:

Taylor Carpenter, MT
Consultant I/EMTRO

Motion: Ms. Arnott
Second: Mr. Johnson
License Approved.

Tennessee Fertility Lab., LLC
9160 Carothers Parkway #201
Franklin, TN 37067

Medical Laboratory Director

Greg Christensen, PhD, HCLD
Director:
Andrology & Embryology

Specialties:

Andrology

Surveyor:

Richard Carroll, MT
Consultant II/MTRO

Motion: Ms. Arnott
Second: Ms. Kenwright
License Approved.

BHG Reference Lab, LLC
173 Madison Avenue #B
Memphis, TN 38104

Medical Laboratory Director

Rex Burrow, MD
Anatomic/Clinical Pathology

Specialty:

Clinical Chemistry
Toxicology

Surveyor:

Karon Hathcoat, MT
Consultant II/WTRO

Motion: Mr. Johnson
Second: Ms. Arnott
License Approved.

OTHER BUSINESS:

Item 1

Board clarification of items relating to operation of administrative office technicalities:

Nothing to present.

Item 2 **Review of
Reimbursement
for Board
Members
Lodging Fee**

Ms. England reviewed a document previously sent to board members during the quarter.

The document states all Department of Health Licensure and Regulation board members are paid on with a travel and stay reimbursement fee established by the Department.

The lodging fees are also set by the Department and applicable to all board members.

Nashville has exploded with new occupants (travel & moving) and we recognize a shortage in available lodging.

There are only a certain number of rooms that are available for "state rates" and while few might be available closer in downtown Nashville, there might be lodging in the suburbs.

Board meetings are booked at least two (2) years in advance and it is strongly recommended reservations for meetings are completed whenever meeting dates are available to members.

It is noted that travel to conventions and association events might be paid if the appropriate guidelines are followed.

No other action taken on this subject.

**Item 3 On-line
 Applications**

On-line applications will be a reality before much longer and we are looking forward to the event. Staff has been advised to approach the revision with a steady daily work effort. These applications will be for personnel licensure, and facility licensure. Training program on-line events are a future event.

No action taken.

Statement of Next Meeting

The next Board Meeting will be April 20, 2017 and will begin at 9AM CDT in the Iris Conference Room, Ground Floor, MetroCenter Complex, 665 Mainstream Drive, Nashville, TN 37243

Record of Adjournment

With no further business, with a motion properly filed, the meeting adjourned at 2:33 pm CST.

Motion: Dr. Calarco
Second: Ms. Arnott
Meeting Adjourned.