Tennessee Medical Laboratory Board July 21, 2017 Minutes

Date:	July 21, 2017
Time:	9:00 AM CDT
Location:	Tennessee Department of Health Division of Health Licensure and Regulations 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
	Keisha Burnett, S.ACytotechnologist Mark A. Calarco, DO, Independent Lab Manager/Administrator Tereyo M. Cox, MT-Medical-Technologist, General Carla M. Davis, MD-Pathologist Stephanie Dolsen, MT Supervisor Vice-Chair Michael Johnson, MT-Medical Technologist Generalist Gaye G. Jolly, MT-Hospital Administrator Kathleen Kenwright, MT- Medical Technologist, Educator Jon Parham,
Members Absent:	Royce Joyner, MD-Pathologist Educator Jason S. Nolan, MD-Pathologist, Non-Educator Michael J. Wright-Citizen Representative
Vacant Position:	All board positions filled.
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 9:01 am CDT by Board Chair Patti J. Walton.
Introductions of Board Members:	Board members and staff made their introductions to the record.
Introductions of Staff:	Board members and staff made their introductions to the record.

Ten board members were present which constitute a quorum.

Quorum:

Approve Minutes

P & E Committee Meeting

A motion to approve the April 19, 2017 Personnel & Education Committee minutes was made by Ms. Kenwright.

Second: Mr. Johnson

Committee Minutes Approved

Full Board Meeting

A motion to approve the April 20, 2017 board meeting minutes was made by Ms. Jolly.

Second: Ms. Dolsen Board Minutes: Approved

Board Reports:

Ratification of Initial
Determinations of the P&E
Committee Meeting:

Ms. Kenwright reported the actions of the Personnel & Education Committee meeting, July 20, 2017.

Motion to ratify Committee actions: Dr. Parham

Second: Mr. Johnson

Report: Accepted as presented

Consent, Agreed, Compliance Orders & Letters of Reprimand

Consent Orders

Two consent orders were presented to board members for consideration.

Consent Order #1: Geoff A. Dykes Murfreesboro, TN

Medical Laboratory Technician

License #10623

Mr. Dykes agreed to the stipulations found in the Consent Order #2017003641 based on his failure to comply with Rules & Regulations 1200-06-01-.12 relative to the completion of 24 hours of continuing education hours required for medical laboratory professional per this

rule.

(The approved continuing education pertaining to laboratory technology medicine for the two (2) calendar years which proceeds the license renewal year.)

To avoid any further administrative action Mr. Dykes agreed to the following:

- 1) place his license as a medical laboratory technician in TN on probation for no less than one (1) year.
- 2) obtain twenty-four (24) hours of continuing education for the 2014-2015 cycle for which he was deficient, and submit to the Board's administrative office within one year of the effective date of this order.
- these hours are in addition to the continuing education hours required to maintain his license with the Board as a Medical Laboratory Professional in Tennessee.
- 4) to lift the probation, Mr. Dykes must petition the Board for an Order of Compliance.
- 5) pay twenty-four (24) Type C civil penalties in the amount of fifty dollars (\$50.00) for each hour of the deficient continuing education hours (24) for a total of one thousand two hundred dollars \$1200.00 with payment due within six (6) months of the entry of this order.
- 6) Mr. Dykes is also charged with the payment of the actual and reasonable costs of prosecuting this case with the maximum amount one thousand dollars, \$1000.00, due within six (6) months of the issuance of the Assessment of Costs.

Motion to approve the Consent Order: Ms. Jolly

Second: Mr. Johnson Consent Order: Approved

Consent Order #2: Kelia N. Jenkins Pikeville, TN Medical Laboratory Technician License #23266

Ms. Jenkins agreed to the stipulations found in the Consent Order #2016043401 based on her failure to comply with the Rules and Regulations 1200-06-01 pertaining to providing professional services while mentally incompetent, or under the influence of alcohol, a narcotic or other controlled, dangerous substance that is in excess of therapeutic amounts or without valid medical indication and violating or aiding and abetting the violation of any provisions of this chapter or the rules and regulations promulgated under this chapter.

Tennessee Code Annotated 63-29-101 & 68-29-127

To avoid any further administrative action Ms. Jenkins to the following:

- her license as a medical laboratory technician in TN. is placed on probation to run concurrent the TnPAP* monitoring agreement that was signed by Ms. Jenkins, October 20, 2016.
- 2) to have the probation lifted Ms. Jenkins must petition the Board for an Order of Compliance.
- before the probation can be lifted, proof of completion of the terms of the TnPAP monitoring agreement must be available to the board's administrative office.
- 4) 100% compliance with the TnPAP monitoring agreement must be maintained to include any amendments made to the monitoring contract.

Motion to approve Consent Order: Ms. Dolsen

Second: Ms. Jolly

Consent Order: Approved

Agreed Orders No Agreed Orders presented.

Compliance Orders No Compliance Orders presented.

Letters of Reprimand No Letters of Reprimand were presented.

Presentations to the Board:

Tennessee Professional Peer Assistance Program (TnPAP):

Mr. Mike Harkreader, MS,RN,CARN
TnPAP Director

The statistical report for July 1, 2016-June 30, 2017 was presented with two (2) individuals monitored during this time period.

Two referrals were made by the employer for impairment and positive urine drug screen in the workplace.

TnPAP evaluations were performed with both individuals consenting to treatment.

Two individuals declined TnPAP services and both have been reported to the Department for further review.

Mr. Harkreader gave board members a synopsis of Public Chapter #481 which concerns the possession of prescribed medications if found after a drug screen.

^{*}Tennessee Peer Assistance Program

Note: See legislative report for web site, Public Chapter Section.

Motion to accept the TnPAP report: Dr. Calarco Second: Dr. Davis

Report accepted as given.

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 session. Internet site: www.TNPAP.org

Financial Report Noranda M. French Presentation/Discussion

Ms. French gave the Mid-Year financial report during the meeting. Expenditures for the mid-2017 cycle were presented in detail broken down into each category.

The projected current year net is \$32,260.81 with a cumulative carryover projected to be \$1,627,252.27.

Motion to accept the report: Mr. Johnson Second: Ms. Jolly

Report accepted as given.

A copy of the report is on file in the administrative office.

Investigations Report
Dorsey Luther
Disciplinary Coordinator
December 2016-July 2017

Personnel: BIV received a total of five complaints concerning personnel issues, with two complaints remaining from December 2016.

One complaint was for unprofessional conduct, one complaint was for alleged use of drugs and three complaints for continuing education violations.

Facilities: One complaint remains from December 2016 with four complaints in January 2017: three complaints for unprofessional conduct and one complaint for care of services.

Motion To Accept Report: Mr. Johnson

Second: Ms. Cox

Investigations Report accepted as given

Legislative Report DOH Commissioner's Office Legislative Liaison Legislative Affairs James Layman

Mr. Layman gave a summary of the legislative update for the 2017 session relating to operations and new legislation which could affect the practice of laboratory medicine in Tennessee.

Several Public Chapters, (PC350,PC215,PC240, PC481, and PC230) all pertain to health providers, some which specifically pertain to medical laboratory testing for drugs of abuse.

A summary of these legislative actions can be found on the TNMLB's web page: http://tn.gov/article/media-about.

Motion to accept report: Dr. Calarco Second: Ms. Kenwright

Report accepted as given.

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:

APRN Policy
Point of Care Exemptions

Board members reviewed a policy pertaining to Advanced Practice Nurse Practitioner parameter of practices in the performance of previously granted exemptions.

This policy states that APRN's can perform and report any previously granted exemption for Registered Nurses associated with Point of Care 1200-06-03-.16, Alternate Site Testing, Rules and Regulations Governing Medical Laboratories 1200.06.13.

Board members reviewed the policy again after their approval in April 2017 for any possible changes to the policy wording.

No changes were made; no further action was taken on the matter.

American Red Cross Tennessee Valley

J. Scott Webber, Executive Director of Quality & Regulatory Affairs/Compliance for the ARC Centers, appeared before board members to request an exemption to the Rules and Regulations Governing Medical Laboratory Personnel, specifically 1200-06-01-.20(5)(c); and Rules and Regulations Governing Medical Laboratories 1200-06-03,14 relative to the minimum requirements of once a month on-site visits by the medical laboratory director to each licensed ARC location in Tennessee.

After discussion, board members agreed to a visit every six months to the ARC donor stations in Johnson City, TN (license # 2081) and Murfreesboro, TN (license #4137).

These facilities perform hemoglobin testing as their only clinical laboratory procedure at these locations as part of their donor suitability evaluations, any changes to this menu will require a re-visit or re-evaluation by board members.

Note: This exemption is not applicable to the American Red Cross Blood Services Nashville, TN location.

Motion: Ms. Kenwright Second: Ms. Dolsen

Abstain: Dr. Calarco

Ratifications:

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

Point of Care Exemptions 1200-06-03.16 (1)

 Tennova Healthcare Dyersburg Regional Medical Center Dyersburg, TN 38024

This exemption request was for Registered Nurses who work in the Cardiac Cath. Laboratory to perform and report

activated clotting times (ACT's) utilizing the Hemochron Signature Elite instrument and methodology.

Motion: Ms. Jolly Second: Ms. Dolsen

Exemption granted

2. TriStar Summit Medical Center Hermitage, TN 37076

This exemption request was to permit Registered Nurses to perform and report lactate testing procedures in the Emergency Department utilizing i-STAT.

Motion: Dr. Calarco Second: Ms. Kenwright

Exemption granted.

3. TriStar Summit Medical Center Hermitage, TN 37076 Respiratory Therapy

This exemption request was to permit Licensed Respiratory Therapists (ABD-endorsed) to perform and report arterial blood gases to include associated parameters, and lactate testing procedures throughout the facility to include the Emergency Department.

The instrument of choice is i-STAT.

Motion: Ms. Dolsen Second: Ms. Jolly

Exemption granted.

4. Region One Health Memphis, TN 38103

Two exemptions were presented for board approval.

Exemption #1:

Permits Advanced Practice Registered Nurses to perform and report vaginal wet preps in the Employee Clinic, Ground Floor of the Medical Outpatient Services area.

Motion: Ms. Jolly

Second: Ms. Kenwright

Exemption granted.

Exception #2:

Permits Registered Nurses to perform and report urine drug screens in the OB/GYN Clinic using the BluRapids multi-drug test kit.

Motion: Ms. Kenwright Second: Dr. Parham

Exemption granted.

5. Williamson County Medical Center Franklin, TN 37067

Permits Licensed Registered Nurses (RN's), and CRNA's to perform and report blood gases to include pH, pO2, TCO2, HCO3, SO2, Base Access, all with associated parameters with the addition of lactate, hemoglobin, hematocrit, sodium, Ca+, and potassium in the Operating Rooms of this facility utilizing i-STAT instrument utilizing Registered Nurses. This exemption is granted with submission of correlation on the instrument to the administrative office.

Motion: Ms. Jolly Second: Mr. Johnson

Exemption granted.

Note: Ms. Walton recused herself from the discussion and vote and presented this request to board members.

Vice-chair Dolsen conducted this portion of the meeting.

The gavel then returned to Chair Walton for the remainder of meeting events.

TriStar Horizon Medical Center Dickson, TN 37055

This facility made the following exemption requests: to permit Licensed Registered Nurses (RN's), Licensed Practical Nurses (LPN's), EMT-Paramedics, Respiratory Therapists (ABG-endorsed), and Radiology Technicians to perform and report the following clinical laboratory testing procedures throughout the facility.

These procedure include: lactate, troponin 1, CKMB, myoglobin, activated clotting times, Pt/INR, sodium,

potassium, chloride, CO2, glucose, BUN, creatinine, Ca+, hemoglobin, hematocrit, and blood gas analysis to include pH, pCO2, pO2, HCO3, TCO2, SO2, BE, with applicable calculated parameters.

Specific test location, tests and testing personnel to be determined by the medical laboratory director of record.

Motion: Dr. Calarco Second. Dr. Parham

Exemption granted.

7. TriStar Natchez ER Dickson, TN 37055

This request was to permit Licensed Registered Nurses (RN's), Licensed Practical Nurses (LPN's), EMT-Paramedics, Respiratory Therapists (ABG-Endorsed), and Radiology Technologists to perform and report the following clinical laboratory test throughout the facility utilizing i-STAT.

The tests are: lactate, troponin 1, sodium, potassium, chloride, CO2, glucose, BUN, creatinine, Ca+, hemoglobin, hematocrit and blood gas analyses to include pH, pCO2, pO2, HCO3, TCO2, SO2, and BE with applicable calculated parameters.

Motion: Mr. Johnson Second: Ms. Dolsen

Exemption granted.

Direct 3+ Labs 1200-06-03-.13(5)

Ryan Brock Neil, Ph.D. BCLD Collierville, TN 38017

Dr. Neil appeared before the board to the addition of a 4th laboratory in addition to three labs he currently directs which include:

Memphis Pathology/AEL Memphis Germantown Surgery Center Germantown, TN 38138

Memphis Pathology/AEL Humphreys Memphis, TN 38120

Total Diagnostics II, CQuentia Labs Memphis, TN 38125

Note:

The 4th laboratory will be a second division of CQuentia Laboratories and is projected to open in September of this year and is located at the same physical location as the Total Diagnostics laboratory.

After discussion board members agreed to the addition of a 4th laboratory under Dr. Neil's direction.

Motion: Ms. Kenwright Second: Dr. Davis

Abstain: Ms. Dolsen

Motion: Approved

Reports/Requests:

Board Director's Report Lynda S. England BS MT(ASCP)

Ms. England gave the board director's report for the quarter April 01, 2017 thru June 30, 2017.

The report included statistical data concerning the licensure of laboratory personnel, laboratory facilities, health fair/health screening events.

After discussion board members accepted the report given by Ms. England.

Motion: Mr. Johnson Second: Ms. Cox

Report accepted as read.

(A copy of the report is kept on file in the board's administrative office)

Board Attorney Report Kyonzté Hughes-Toombs Deputy General Counsel

Counsel Hughes-Toombs gave her report for the past quarter: There are four open cases in the Office of General Counsel. Two consent orders were presented today, leaving two open cases for review.

Personnel Rules (1200.06.01) revisions may be presented in the form of a Public Rulemaking Hearing hopefully to be held during the October 19, 2017 board meeting.

The proposed rules will be posted on the Secretary of

State's web page 45 days for public review, and comment.

A separate Open Meeting Notice will also be posted to the web site for this event.

Motion: Ms. Kenwright Second: Ms. Dolsen

Report approved as given.

REINSTATEMENT OF LICENSE

No licenses to reinstate this quarter.

ADDITIONS/DELETIONS TO THE BOARD'S WAIVED TEST LIST

No additions or deletions were made to this board-approved waived test list.

Review/Discuss:

Licensure of Medical Laboratory Director

Matthew Hardison, Ph.D. Brentwood, TN 37027

Dr. Hardison received his BS degree From Lipscomb University and his Ph.D. from the University of Alabama in Birmingham.

His training was at the National Centers for Pain Management & Research in Alabama.

He holds current certification in the National Registry of Certified Chemists as a Toxicological Chemist and is currently licensed as a Director-Molecular Diagnostics.

Dr. Hardison requests an addition to his license to include licensure as Director of Toxicology.

Motion: Dr. Calarco Second: Dr. Davis

License approved.

Regional Surveyors Reports, Complaint Investigations/PT Events Regional Offices: East, Middle, West Tennessee

ETRO Report Taylor Carpenter, MT Consultant/Surveyor

East TN Regional Office: April 01-June 30, 2017

Complaint Investigations: Zero

Unsuccessful Proficiency Testing: One first unsuccessful PT event for BUN with an acceptable plan of correction.(April)

One first unsuccessful PT event for bacteriology with an acceptable plan of correction. (May)

One first unsuccessful PT event for antibody Identification with an acceptable plan of correction. (May)

East TN Regional Office: April 01-June 30, 2017

Complaint Investigations: Zero

Unsuccessful Proficiency Testing: One first unsuccessful PT event for BUN with an acceptable plan of correction.(April)

One first unsuccessful PT event for bacteriology with an acceptable plan of correction. (May)

One first unsuccessful PT event for antibody Identification with an acceptable plan of correction. (May)

MTRO Report Richard Carroll, MT Consultant/Surveyor

Middle TN Regional Office: April 01-June 30, 2017

Complaint Investigations: One

Unsuccessful Proficiency Testing:

Two facilities were reported with a first unsuccessful PT event with acceptable plans of correction per on-site inspections in the facility.

WTRO Report Karon Hathcoat, MT

Consultant/Surveyor

West TN Regional Office: April 01-June 30, 2017

Complaint Investigations: Zero

Unsuccessful Proficiency Testing:

One laboratory with first unsuccessful occurrence for PT event.

One laboratory with second unsuccessful occurrence for PT event.

In both instances acceptable plans of correction were provided to the surveyor.

Motion to accept regional surveyor reports: Mr. Johnson Second: Ms. Jolly

All surveyor reports accepted as presented.

Board Ratifications
Facility Laboratory Applications

Sumner Station ER Lab Suite 100 225 Big Station Camp Blvd. Gallatin, TN 37066

Specialties:
Microbiology (limited)
Parasitology (limited)
Virology (limited)
Hematology
Immunohematology
(limited to emergency release)
Clinical Chemistry
Urinalysis
Endocrinology
Toxicology

Laboratory Director: Julie W. Lemmon, M.D. Anatomic/Clinical Pathology

Motion: Ms. Kenwright Second: Dr. Parham

Abstain: Mr. Johnson License Approved.

Associated Pathologists/ PathGroup 1755 Gunbarrel Road # 1 Chattanooga, TN 37421

> Specialties: Pathology Histopathology Oral Pathology

Laboratory Director: Thomas Mezzetti, M.D. Anatomic/Clinical Pathology

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

BioMat, USA 3748 Nolensville Pike Nashville, TN 37211

Specialties:

Plasmapheresis Center

Hematocrit

Total Serum Protein

Glucose

Laboratory Director: Gates J. Wayburn, M.D.

American Bd./Ophthalmology

Motion: Ms. Jolly Second: Ms. Dolsen

Licensed Approved.

Resolve Molecular Diagnostics Esoteric Laboratory 357 Riverside Drive Ste. 214 Franklin, TN 37064

Specialties:

Esoteric Molecular Diagnostics

Laboratory Director:

David L. Smalley, Ph.D. ABB-BCLD

Motion: Dr. Parham Second: Ms. Dolsen

License Approved.

Resolve Diagnostics Esoteric Laboratory 357 Riverside Drive Ste. 204 Franklin, TN 37064

Specialties:

Esoteric Toxicology

Laboratory Director: James W. Denham, M.D.

Anatomic and Clinical Pathology

Motion: Dr. Davis Second: Mr. Johnson

License Approved.

Statement of Next Meeting

The next Board Meeting will be October 19,2017 and is scheduled to begin at 9 AM CDT in the Iris Conference Room, Ground Floor, Metro Center Complex, 665 Mainstream Drive, Nashville, TN 37243

Record of Adjournment

With no further business to discuss and with a motion properly presented, the meeting adjourned at 12:04 pm CDT.

Motion to adjourn: Dr. Calarco

Second: Dr. Parham

Meeting Adjourned.