

Tennessee Medical Laboratory Board
April 19, 2018
Minutes

Meeting Date: April 19, 2018

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.,
Board Chair
Keisha Burnett, S.A.-Cytotechnologist
Mark A. Calarco, DO, Independent Lab
Manager/Administrator
Tereyo M. Cox, MT-Medical-Technologist, General
Carla M. Davis, MD-Pathologist
Kathleen Kenwright, Ed.D MT- Medical Technologist,
Educator
Jon Parham, DO Non-Pathologist Physician
Michael Johnson, MT-Medical Technologist Generalist
Board Vice-chair
Gaye G. Jolly, MT-Hospital Administrator

Members Absent:

Stephanie Dolsen, MT Supervisor
Jason S. Nolan, MD-Pathologist, Non-Educator

Vacant Position:

Pathologist Educator
Citizen Representative

Staff Present:

Lynda S. England, MT Board Director
Nina V. Smith, MT Consultant Administrative Office
Kyonzte Hughes-Toombs, Deputy General OCG
Taylor Carpenter, MT Consultant/Surveyor ETRO
Richard Carroll, MT Consultant/Surveyor MTRO
Susan Wilson, MT Consultant/Surveyor MTRO
Karon Hathcoat, MT Consultant/Surveyor WTRO
Debbie Haggard, MT Consultant/Surveyor WTRO

Staff Absent:

Julia Daniels, MT Consultant/Surveyor ETRO
Mary Hamblen, MT Consultant/Surveyor

CLIA Manager/Representative: Sandra Bogard, MT CLIA Manager

Presiding Officer:	Patti Walton, MT, Chair
Call To Order:	The meeting was called to order at 9:12 am CDT by Board Chair Patti J. Walton.
Introduction of Board Members/ Staff:	Board members and staff made their introductions to the audience and for the record.
Quorum:	Nine board members were present which constitute a quorum.
Election of Vice-Chair	<p>Nominations were entertained for the position of board vice-chair.</p> <p>Dr. Calarco presented a motion to nominate Mr. Michael Johnson to serve as board vice-chair. A second to that motion was made by Ms. Kenwright.</p> <p>No other nominations were presented.</p> <p>Mr. Johnson was approved by acclamation.*</p> <p>*Ms. Dolsen was unable to accept the vice-chair appointment (January 2018) because of previous commitments during the year.</p>
Approve Minutes	
P & E Committee Meeting	<p>A motion to approve the January 17, 2018 Personnel & Education Committee minutes was made by Mr. Johnson.</p> <p>Second: Dr. Calarco.</p> <p>January 2018 Committee Minutes: Approved.</p>
Full Board Meeting	<p>A motion to approve the January 18, 2018 board minutes was made by Dr. Calarco.</p> <p>Second: Dr. Parham.</p> <p>January 2018 Board Minutes: Approved</p>
Board Reports:	
Ratification of Initial Determinations P&E Committee Meeting:	<p>Ms. Kenwright reported the actions of the Personnel & Education Committee meeting, April 18, 2018.</p> <p>Motion to ratify Committee actions: Mr. Johnson.</p> <p>Second: Ms. Cox.</p> <p>Report: Accepted as presented by Ms. Kenwright.</p>

Consent, Agreed
Compliance Orders
Letters of Reprimand

Consent Orders

No consent orders presented.

Agreed Orders

No Agreed Orders presented.

Compliance Orders

No Compliance Orders presented.

Letters of Reprimand

No Letters of Reprimand presented.

Presentations to the Board:

Tennessee Professional Peer Assistance
(TnPAP):

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

Mr. Harkreader asked Ms. England to present report because of a meeting conflict that morning.

The statistical report for July 1, 2017-March 31, 2018 was presented by Mr. Harkreader with two individuals monitored during this time period.

One individual was referred for a substance abuse disorder while the other individual was referred from a treatment facility and declined services; no practice act violations here.

Motion to accept the TnPAP report: Ms. Kenwright.
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 2018 Fiscal report during the April meeting to include expenditures and projections for the fiscal year. Those expenditures are comparable with those of 2017 year end data. No board action taken on this matter.

A motion to accept the report as given: Mr. Johnson.
Second: Ms. Kenwright.
Report Approved.

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

Investigations Report
Lori L. Leonard
Disciplinary Coordinator
October 2017-December 2017

Ms. Leonard's investigative report included the following:

Monitored Practitioners:
Four suspensions, one probation, two currently under board order, one TSAC suspension.

Investigative: Two new complaints; one drug allegation; one for unprofessional conduct.

Two complaints closed one sent on to OGC for CE violation another closed with letter of concern.

Motion To Accept Report: Ms. Jolly.
Second: Ms. Cox
The investigations report was accepted as given.

Legislative Report
DOH Commissioner's Office
Legislative Liaison
Legislative Affairs

Current legislative actions concerning the practice of laboratory medicine will be presented during the report given by Ms. Hughes-Toombs, consulting attorney for the board.

Discuss, review, take action,
if needed:

Advisgroup
Mokena, IL 60448
Susan Maupin
Representative

Board members discussed the parameters concerning the question of operations in a physician office laboratory which is exempt under the TN Code Annotated 68-21-109; Regulation 1200-06-03-.16 (2) and the activities under which a physician office laboratory (POL) becomes a reference laboratory. Staff and surveyors were unable to reach a consensus on the matter for operations of this particular agency in the transition-management of the physician's group.

The biggest determining factor is that the physician office laboratory work must be on the physician's OWN patients and not those of different clients.

After discussion, members wanted their advisory attorney, Ms. Hughes-Toombs, to research the matter and return with additional information after review of the operational structure of this practice group per the necessity of licensure by this board.

The key word seems to be the word "operate" and the association of the physician mechanism in the performance of day to day services.

Ms. Hughes-Toombs will make a report during the board meeting July, 2018. in July.

Motion for further research on matter: Dr. Davis
Second: Dr. Calarco.

Ratifications:
Point of Care Exemptions
1200-06-03-.16(1)

1. Baptist Memorial Hospital Memphis
Department of Pathology
6019 Walnut Grove Road
Memphis, TN 38120
Karen S. Clark, BSMT(ASCP)
Point of Care Supervisor

This exemption request permits licensed Perfusionists to perform and report blood gas analyses to include: pH, pCO₂, pO₂, (calculation of O₂ saturation), sodium, potassium, Ca⁺, glucose, hematocrit and lactate in the CVOR utilizing i-STAT.

Motion: Ms. Kenwright.
Second: Dr. Calarco.
Exemption granted.

2-Marsh Regional Blood Center
111 West Stone Drive #300
Kingsport, TN 37660
Jean E. Reece, MPH MT(ASCP) SC
Marsh Quality Specialist

Request for non-licensed personnel to inoculate specimens for bacterial contamination in leuko-platelet and platelet apheresis products relating to change in test methodology.

Note: Facility request be tabled until July meeting.

3. Baptist Memorial Hospital
1201 Bishop Street
Union City, TN 38261
Falena Bivins, MPH, CLS(ASCP)
Administrative Director

This point of care exemption request was approved to permit licensed Radiology Techs and licensed Registered Nurses to perform and report creatinine analyses in the Radiology Department utilizing the Nova StatSensor.

Motion: Mr. Johnson.
Second: Ms. Jolly.
Exemption granted.

4. Region One Health
877 Jefferson Avenue
Memphis, TN 38103
Elaine Pickens
Point of Care Coordinator

Board members granted this point of care exemption to permit licensed Registered Nurses, licensed Practical Nurses, licensed CRNA's, and MCTII (licensed EMT's) to perform and report PT/INR, and APTT testing procedures in the Trauma Intensive Care Unit. Instrumentation utilized in the performance of these tests is the Hemochron Signature Elite.

Motion: Ms. Kenwright.
Second: Dr. Parham.
Exemption granted.

5. LeBonheur Children's Hospital
50 North Dunlap
Memphis, TN 38103
Kelley Benson, BS MT(ASCP)
Point of Care Coordinator

This exemption request was granted to include the addition of personnel to previously granted exemptions.

~~1-The exemption request was granted to permit licensed Paramedics, licensed Cardiovascular Technologists and licensed Emergency Department Technicians to perform and report activated clotting times (ACT's) throughout the facility utilizing the Hemochron Elite analyzer.~~

Motion: Mr. Johnson.
Second: Ms. Jolly.
Exemption granted.

2-Permits licensed Emergency Department Technicians, licensed Registered Respiratory Therapists, licensed Certified Respiratory Therapists and licensed Cardiovascular Technologists to perform and report co-oximetry measures on the Co-Oximetry AVOX instrument throughout the hospital.

Motion: Dr. Davis.
Second: Mr. Johnson.
Exemption granted.

6. Johnson City Medical Center
400 N. State of Franklin Road
Johnson City, TN 37064

Facility requested delay in presentation.

7. Parkridge Medical Center
2333 McCallie Avenue
Chattanooga, TN 37404
Helen Richardson
Laboratory Manager

Two requests were granted by board members:

1-to permit licensed Registered Nurses to perform and report lactate testing procedures in the Emergency Center utilizing the EPOC instrument.

Motion: Ms. Jolly.
Second: Dr. Calarco.
Approved.

2-to permit licensed Registered Nurses to perform and report creatinine testing procedures in the Emergency Center utilizing the EPOC.

Motion: Ms. Jolly.
Second: Dr. Calarco.
Request approved.

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

Brian R. Carlson, M.D.
Pathologists' Laboratory P.C.
Andrew Jackson Complex
4733 Andrew Jackson Parkway
Hermitage, TN 37076

Dr. Carlson is currently the medical laboratory director of the following hospital laboratories:

- 1-Summit Medical Center-Hermitage, TN 37076*
- 2-Hendersonville Med. Cntr-Hendersonville, TN 37075*
- 3-Tennova of Lebanon-Lebanon, TN 37087

Dr. Carlson appeared before the board and requested an exemption to Rules Governing Medical Laboratories 1200-06-03-.13(5) to direct a fourth laboratory:

Portland Medical Center-Portland, TN 37148*

Tristar*

After discussion members agreed to grant the exemption to direct a 4th laboratory following a motion by Dr. Calarco.

Second to the motion: Dr. Davis

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

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

Motion to approve report as given: Mr. Johnson.
Second: Ms. Cox.

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

Board Attorney Report
Kyonzte Hughes-Toombs
Deputy General Counsel

Counsel Hughes-Toombs gave her report for the past quarter:
One open case in Office of General Counsel. The re-write of the Rules Governing Medical Laboratory Personnel 1200-06-01 are still under internal review.

Ms. Hughes-Toombs reported on the legislative passage of Senate Bill -2245 concerning the exemption of state operated laboratories and laboratory personnel working within state labs from the TN Medical Laboratory Act.

Board members expressed interest in the written language within the bill. The board's legislative liaison will be present during the July 20th meeting to give a complete report on the statute revision.

Board members agreed to seek inquiry concerning any/or ramifications in the application of this new legislation to the practice of laboratory medicine in Tennessee. Documentation will be presented along with and after discussion with the legislative liaison during the July 20, 2018 quarterly meeting. One board member will be working with council on this document.

Motion: Mr. Johnson.

Second: Dr. Calarco.

Report approved as given.

Reinstatement of License

No licenses were presented for reinstatement this quarter.

Additions/Deletions Board's Waived Test List

No requests for additions or deletions presented during this meeting.

Licensure of Medical Laboratory Director

Zahra S. Yi, Ph.D.
Brentwood, TN 37027

Dr. Yi received her BS degree in chemistry from the University of British Columbia, Vancouver, BC. She received her M.S. and Ph.D. in chemistry from the University of Washington, Seattle in 2003 and 2010 respectively.

Dr. Yi's fellowship was in clinical chemistry and obtained at the Dartmouth-Hitchcock Medical Center, Department of Pathology & Laboratory Medicine, Lebanon, New Hampshire.

The applicant is currently certified by the National Registry of Clinical Chemists as a Clinical Chemist.

Motion: Dr. Calarco.

Second: Mr. Johnson.

Approved: Director Clinical Chemistry.

Regional Surveyors Reports:
Complaint Investigations
Proficiency Testing Events
Regional Offices:

East, Middle, West Tennessee

ETRO Report
Taylor Carpenter, MT
Consultant/Surveyor

East TN Regional Office: January 01-March 31, 2018

Complaint Investigations: Zero
Unsuccessful Proficiency Testing: Zero

MTRO Report
Richard Carroll, MT
Consultant/Surveyor

Middle TN Regional Office: January 01-March 31, 2018

Complaint Investigations: One
Unsuccessful Proficiency Testing: One
(Acceptable Plan of Correction Submitted to Surveyor)

WTRO Report
Debbie Haggard, MT
Consultant/Surveyor

West TN Regional Office: January 01-March 31, 2018

Complaint Investigations: Zero
Unsuccessful Proficiency Testing : Zero

Motion to accept regional surveyor reports:
Ms. Kenwright.
Second: Dr. Parham.

All surveyor reports accepted as presented.

Board Ratifications
Initial Facility Applications

Innovative Pathology Services
7565 Dannaher Way
Rooms G103 & G158
Powell, TN 37849

Specialties: Cytopathology and Histopathology

Laboratory Director: Lauren Chiles, M.D.
Anatomic/Clinical Pathology
Cytopathology
Surveyor: Julia Daniels, MT Consultant II/ETRO*

Motion: Mr. Johnson.
Second: Dr. Davis
License Approved.

*Ms. England gave report to board members;
Ms. Daniels on leave during this meeting.

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

Specialties: Toxicology

Laboratory Director: Marc J. Rumpler, Ph.D.
NRCC Toxicological Chemist

Surveyor: Richard Carroll, MT Consultant II/MTRO
Susan Wilson, MT Consultant I/MTRO

Motion: Dr. Calarco.
Second: Ms. Jolly.

License approved.

Tennova ER-Sango
1325 Hwy 76
Clarksville, TN 37404

Specialties: Bacteriology (limited), Parasitology
(limited), Virology (limited), Hematology,
General Immunology (limited), Clinical
Chemistry, Urinalysis, Endocrinology,
Toxicology, pH and Blood Gas Analysis.

Laboratory Director: Randall Haase, D.O.
Anatomic/Clinical Pathology

Surveyor: Karon Hathcoat, MT Consultant II/WTRO

Motion: Ms. Kenwright.
Second: Dr. Parham.

Licensed Approved.

Statement of Next Meeting:

The next meeting will be July 20, 2018.

The beginning time is scheduled for 9 AM CDT in the
Iris Conference Room, Ground Floor, Metro Center
Complex 665 Mainstream Drive Nashville, TN.

Adjournment:

With no further business to discuss, the meeting
adjourned at 11:45 am CDT.

Motion to adjourn: Dr. Calarco.
Second: Ms. Cox.