

Tennessee Medical Laboratory Board Meeting

January 16, 2014

Minutes

Date: January 16, 2014

Time 09:00AM 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: Annie Washington, Medical Technologist, Chairman
Pamela Bullock, MD Non-educator Pathologist
Royce Joyner, MD, Pathologist Educator, Vice-Chairman
Cheryl Arnott, S.A.-Cytotechnologist
Stephanie Dolsen, Medical Technologist, Supervisor
Kathleen Kenwright, Medical Technologist, Educator
Patti J. Walton, Hospital/Lab Manager/Adm. Dir.

Members Absent: Jerry Lee Miller, MD Non-Pathologist Physician
VACANT: Citizen Representative
VACANT: Hospital Administrator
VACANT: Medical Technologist, Generalist
VACANT: Independent Lab Manager
VACANT: Pathologist, Non-Educator

Staff Present: Lynda S. England, Medical Technologist Consultant, Director, TMLB
Jerry A. Gowen, Medical Technologist Consultant
Diona Layden, Assistant General Counsel, Advisory Attorney
Mollie Gass, Advisory Attorney, Office of General Consel
Julia Daniels, Medical Technologist Consultant/ Surveyor, East Tennessee Regional Office
Taylor Carpenter, Medical Technologist Consultant/Surveyor, East Tennessee Regional Office
Onezean Otey, Jr., Medical Technologist Consultant/Surveyor, Middle Tennessee Regional Office
Richard Carroll, Medical Technologist Consultant/Surveyor, Middle Tennessee Regional Office
Mary Hamblen, Medical Technologist Consultant/Surveyor, West Tennessee Regional Office
Karon Hathcoat, Medical Technologist Consultant/ Surveyor, West Tennessee Regional Office

Staff Absent: None

CLIA Manager/Representative: Sandra Bogard, CLIA Manager

Presiding Officer: Annie Washington, Medical Technologist, Chairman, presided

Call To Order: The meeting was called to order at 9:02 AM CST by Annie Washington, Medical Technologist, Chairman, TMLB

Introductions of Board Members: The Board and staff made their introductions to the public in attendance.

Quorum: Seven members of the Board constitute a quorum. A sufficient number of Board members were present establishing a quorum of the Board.

Approve Minutes:

P & E Committee Meeting A motion to approve the October 16, 2013, Personnel & Education Committee minutes was made by: Ms. Kenwright
Second: Ms. Arnott
Motion approved

Full Board Meeting A motion to approve the October 17, 2013, Board meeting minutes was made by: Dr. Joyner
Second: Ms. Arnott
Motion 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 15, 2014.
Motion to ratify: Ms. Walton
Second: Ms. Dolsen
The actions of the Board’s P&E Committee were ratified as presented.

Contested Cases No Contested Cases were presented.

Consent, Agreed, Compliance Orders & Letters of Reprimand

Consent Orders No Consent Orders were presented

Agreed Orders An Agreed Citation regarding the practice as a Special Analyst-Cytotechnologist under an expired license was discussed.
Respondent: Elisha Leigh Hoskins, License #21206

Having met all requirements to reinstate expired license, having made application for reinstatement, having voluntarily signed and submitted the Agreed Citation along with a civil penalty in the amount of \$1200.00 and the Personnel and Education Committee having reviewed and approved application for reinstatement, the Board of Directors reviewed the signed Agreed Order.

Move to accept the Agreed Order issued and agreed to by Elisha Leigh Hoskins, License #21206: Ms. Arnott
Second: Dr. Bullock
Abstain: Dr. Joyner

Agreed Order Accepted.

Compliance Orders No Orders of Compliance were presented

Letters of Reprimand No Letters of Reprimand were presented

Presentations to the Board:

Tennessee Professional Peer Assistance Program (TNPAP):

Mr. Mike Harkreader, Executive Director of TnPAP presented the TNPap Report.

For the period July 1, 2013, through December 30, 2013, there was one (1) individual being monitored. There were three (3) referrals, one (1) from an employer, one referral from the TDOH and one (1) self referral. The reasons for these referrals were due to an arrest/conviction or from a workplace positive UDS. One individual declined services, One was evaluated and declined recommendations, One and was evaluated and monitoring was not recommended. Those declining services or recommendations were reported to the Tennessee Department of Health.

Move to accept the TnPAP report as presented: Ms. Kenwright
Second: Ms. Walton

Report accepted.

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
Lisa Tittle,
Vanessa Crutcher
Discussion/Fee Reduction**

Financial reports are not reported at each meeting.

Move to Table until April, 2014 Meeting: Ms. Dolsen
Second: Ms. Arnott

Motion to table 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
Tipton-Covington, TN
38019**

This is a request to modify the exemption granted October, 2013, to allow certified and registered respiratory therapists at Baptist Memorial Hospital – Tipton to perform and report pH, pCO₂, pO₂, HCO₃, tHbt, O₂HB, CoHb, MethHb, SO₂, TCO₂, BE and Anion Gap, Facility wide.

Move to approve modification of exemption: Dr. Bullock
Second: Dr. Joyner

Modification of exemption approved

**2: Methodist Hospital South
Memphis, TN 38116**

Request exemption for Respiratory Therapists with ABG endorsement be allowed to perform and report pH, pO₂, pCO₂, Sodium, Potassium, Chloride, Glucose, Lactate, Ionized Calcium, BUN, Creatinine, Hematocrit and Hemoglobin, facility wide utilizing the Abbott i-STAT 1 Meter.

Move to approve exemption: Ms. Walton
Second: Dr. Bullock
Abstain: Dr. Joyner

Exemption approved.

**3. Le-Bonheur Children's
Hospital
Memphis, TN 38103**

Request extension of a previous exemption (April, 2006) to allow EDT-P (Emergency Department Technician/Paramedic) to be added to testing personnel for performing and reporting blood gasses, sodium, potassium, ionized calcium, glucose, hematocrit, BUN, chloride and lactate utilizing the Abbott i-Stat, in the Emergency Department and Pediflite Team.

Move to approve extension to previous exemption: Dr. Bullock
Second: Ms. Kenwright
Abstain: Dr. Joyner

Extension to the previous exemption approved.

**4. St. Francis Hospital
Bartlett, TN 38133**

Request exemption to allow registered and certified, ABG endorsed, Respiratory Therapists to perform and report, pO₂, pCO₂, pH, base excess, HCO₃, O₂HB, MethB testing utilizing the Gem Premier 4000, facility wide.

Move to approve exemption: Dr. Bullock
Second: Dr. Joyner

Exemption approved.

Direct more than three (3) Laboratories

Dr. Sherri Flax was not present when agenda item called. This business will be delayed until later in the meeting.

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

T.C.A Statute Amendment §68-29-138

Ms. Gass referred to the amendment for statute §68-29-138 and stated the proposed rules were in internal review and there was nothing to discuss at this time.

Patient Access to Laboratory Reports (Meaningful Use)

Federal Rules preempt any State Statute regarding patient access to their laboratory reports. Discussion only. No action necessary.

ADDITIONS/DELETIONS TO THE BOARD'S WAIVED TEST LIST

No additions or Deletions to the Board's waived test list.

RECEIVE REPORTS AND /OR REQUESTS:

Board Director's Report

Ms. England gave a verbal report. The dates for the 2014 Board Meetings are listed with one important date change to place on calendar. The July meeting will be held on Thursday and Friday, rather than Wednesday and Thursday.

P&E	2014	Full Board
1/15/2014		1/16/2014
4/16/2014		4/17/2014
7/17/2014	DAY CHANGE	7/18/2014
10/15/2014		10/16/2014

Ms. England gave a brief statistical report

Motion to accept Director's Report: Dr. Joyner
Second: Ms. Kenwright

Report accepted.
(Copy of report is on file in the Administrative Office)

Reinstatement of License

Nothing to present and No action by the Board is required.

Office of General Counsel's Report:

Ms. Gass reported that there are three (3) open cases for review. October rule making hearing presently being reviewed in the Attorney General's Office. New rules discussed in the October meeting are in internal review.

No legislative updates

Motion to accept General Counsel's Report: Dr. Bullock
Second: Dr. Joyner

Report accepted.

Investigative Report

Medical Laboratory Board
Office of Investigations

Report is appended and mirrors the General Counsel's report.

Motion to accept the investigations report: Dr. Bullock
Second: Ms. Arnott

Report accepted.

(Copy of report is on file in the Administrative Office)

(The Chair called for a 15 minute break at 9:45AM. Meeting to reconvene at 10:00 AM)

Regional Surveyors Reports

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

**ETRO Report
Julia Daniels**

East TN Regional Office: Julia Daniels for the fourth quarter of 2013.

Unsatisfactory/ Unsuccessful Proficiency Testing: Zero (0)
Complaint Investigations: Zero (0)

**MTRO Report
Onezean Otey**

Middle TN Regional Office: Onezean Otey for the fourth quarter of 2013.

Unsatisfactory/Unsuccessful Proficiency Testing: Zero (0)
There were no second occurrences: Zero (0)
Complaint Investigations: Zero (0)

**WTRO Report
Karon Hathcoat**

West TN Regional Office: Karon Hathcoat for the third quarter of 2013.

First unsuccessful occurrence of PT: One (1)
There were no second occurrences: Zero (0)
Complaint Investigations: Zero (0)

Move to accept regional surveyor's reports as presented:
Dr. Bullock
Second: Dr. Joyner

Reports accepted

**Board Ratification of Laboratory
Initial License:**

**PathGroup Knoxville
1539 Agawela Avenue
Knoxville, TN 37313**

Medical Director: Quyn Rahman, M.D.
Dermatopathology

Specialties: Histopathology and Oral
Pathology

Surveyor: Julia Daniels
Consultant 2/Surveyor ETRO

**Move to approve license: Dr. Bullock
Second: Ms. Arnott**

Licenses Approved

**Diagnovus Esoteric Laboratory
336 Hill Avenue
Nashville, TN 37210**

Medical Director: Jeff McCormick, Ph.D
Director Histocompatibility

Specialties: Esoteric Testing Techniques

Surveyor: Onzean Otey
Consultant 2/Surveyor MTRO

DELAYED UNTIL REPRESENTATIVE ARRIVES (Explain Esoteric Lab):

Dr. James Stover, President of Diagnovus Esoteric Laboratory
Lab is involved in Clinical Genomics and outcomes determinations in specific
disease categories. High complexity, High Clinical Value and low volume.

**Move to approve license as an esoteric laboratory: Dr. Bullock
Second: Ms. Arnott**

Licenses Approved

**Easy Mobil Labs, Inc
149 Space Park South Drive
Nashville, TN 37221**

Medical Director: Howard DeHaven, MD
American Board of Pathology
Anatomic/Clinical Pathology

Specialties: Hematology,

Surveyor: Onzean Otey
Consultant 2/Surveyor MTRO

**Move to approve license: Dr. Joyner
Second: Ms. Kenwright**

Licenses Approved

PathGroup-Molecular Diagnostics
624 Grassmere Park, Suite 5
Nashville, TN 37211

Medical Director: Prnil Chandra, D.O.
Pathology-Molecular Genetics
Hematology

Specialties: Molecular Diagnostics

Surveyor: Onzean Otey
Consultant 2/Surveyor MTRO

Move to approve license: Ms. Kenwright

Second: Ms. Arnott

Licenses Approved

PathGroup-Cytology
624 Grassmere Park, Suite 25
Nashville, TN 37211

Medical Director: Wayne Lennington, MD
American Board of Pathology
Anatomic/Clinical Pathology

Specialties: Cytology

Surveyor: Onzean Otey
Consultant 2/Surveyor MTRO

Move to approve license: Ms. Kenwright

Second: Dr. Joyner

Abstain: Ms. Walton

Licenses Approved

**Tennessee Valley Regional
Laboratory**
930 Adell Ree Park Lane, Suite B
Knoxville, TN 37909

Medical Director: James Denham, MD
American Board of Pathology
Anatomic/Clinical Pathology

Specialties: Hematology, Clinical Chemistry,
Urinalysis and Endocrinology

Surveyor: Julia Daniels
Consultant 2/Surveyor ETRO

Move to approve license: Ms. Walton

Second: Ms. Arnott

Licenses Approved

Pinnacle Laboratories
9051 Executive Park Drive, Suite
103
Knoxville, TN 37923

Medical Director: Alan Galloway, MD.
American Board of Pathology
Anatomic/Clinical Pathology

Specialties: Clinical Chemistry, Toxicology

Surveyor: Taylor Carpenter
Consultant 1/Surveyor ETRO

Move to approve license: Ms. Kenwright

Second: Ms. Dolsen

Licenses Approved

Review and Approve Medical Laboratory Directors

Guangyu Gu, MD
Nashville, TN 37215

Application: Director – Cytogenetics. Previously licensed by this Board as a Special Analyst in Cytogenetics

Degree: Awarded the Bachelor of Medicine, July 1990, Fourth Military Medical University of the People’s Liberation Army, Xi’an, China

Equivalency: It is the judgment of the International Education Research Foundation, Inc. that this degree is considered comparable in level and purpose to the Doctor of Medicine degree, awarded by regionally accredited universities in the United States.

Training Program: University of Utah, Medical Genetics/Clinical Cytogenetics, July 1, 2010 to June 30, 2012.

Certification: Diplomate of the American Board of Medical Genetics (ABMG), September 1, 2013, expiring December 31, 2023.

File Status: All other qualifying documents are present in the file

Move to approve license: Dr. Bullock

Second: Ms. Walton

License approved

Mary Mayo, Ph.D
3200 Charleston Way
Mt. Juliet, TN 37122

Application: Director – Clinical Chemistry.

Degree: Awarded the BS in Chemistry, 1970-1974, Hope College, Holland Michigan, Master of Science, 1977, and the Doctor of Philosophy, 1979, in Biological Chemistry, from the University of Michigan at Ann Arbor.

Training Program: The American Board of Clinical Chemistry requires candidates to document at least five (5) years, full time/equivalent part time, diverse professional experience in clinical chemistry. Applicant may elaborate.

Certification: Diplomate of the American Board of Clinical Chemistry (ABCC) 7/18/2009 with an expiration date of December 31, 2013.

File Status: All other qualifying documents are present in the file

Motion to approve license once Board renewal documents received: Dr. Bullock

Second: Dr. Joyner

Motion approved.

NOTE: Dr. Mayo’s Board Renewal received in office and applicant was licensed as requested and approved: January 22, 2014.

Direct more than three (3) Laboratories

(Business delayed from earlier in the meeting)

Dr. Sherri Flax seeks to direct more than three (3) laboratories. Dr. Flax was present to elaborate upon her request and to describe her other commitments as a laboratory director.

Move to direct an additional laboratory (4): Ms. Dolsen
Second: Dr. Joyner
Abstain: Ms. Kenwright

Motion approved to direct four (4) laboratories.

OTHER BUSINESS: Guidance

Ms. England requested guidance from the Board regarding how esoteric laboratory initial licensing has been handled thus far and if it is the Board's guidance to continue in the same way.

Currently the surveyor goes on sight and conducts a survey of the laboratory operation; included in the survey is a detailed description of the testing being performed. The laboratory director, or their chosen representative is then requested to make an appearance at the next board meeting to answer any questions the Board might have regarding the esoteric operation.

The Board's response was to continue on the path of "Face to Face" meetings as it is needed for everyone's education and to assure that licensing of these facilities is being performed within the spirit of T.C.A. Statute Amendment §68-29-138.

No action needed or taken.

Question: Ms. Kenwright

Does all waived testing require a point of care exemption if performed outside the clinical laboratory? Ms. England answered if it is point of care testing and on Board approved waived test list then notification must be sent to the central office stating what waived testing is being performed and by whom; with this notification a copy of the medical director's license and CLIA certificate must be included. If the point of care testing is NOT on the waived test list, then a formal request to and appearance before the Board is required.

No action needed or taken.

Election of P&E and Board Officers for 2014.

Nomination for Board Chair: Ms. Cheryl Arnott. Name placed in nomination by Dr. Royce Joyner with a second from Dr. Pamela Bullock. There were no other names placed in nomination and Ms. Arnott agreed to serve in the capacity of Chairman. Election by acclamation.

Nomination for Board Vice-Chairman: Ms. Stephanie Dolsen. Name placed in nomination by Ms. Kathy Kenwright with a second from Ms. Cheryl Arnott. There were no other names placed in nomination and Ms. Dolsen agreed to serve in the capacity of Vice-Chairman. Election by acclamation.

Statement of Next Meeting

The next Board Meeting will be April 17, 2014, and will begin at 9AM CST/CDT in the Iris Conference Room, Ground Floor, Metrocenter Complex, 665 Mainstream Drive, Nashville, TN 37243

Record of Adjournment

With no further business to discuss, the meeting was adjourned at 11:00 AM CST on a motion properly presented by Ms. Walton and seconded by Dr. Joyner. The motion to adjourn was unanimously approved.