

Tennessee Medical Laboratory Board Meeting

July 16, 2015

Minutes

Date: July 16, 2015

Time 09:00 AM CDT

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: Cheryl Arnott, S.A.-Cytotechnologist, Chairman
Stephanie Dolsen, Medical Technologist, Supervisor, Vice Chair
Kathleen Kenwright, Medical Technologist, Educator
Carla M. Davis, MD, Pathologist
Tereyo M. Cox, Medical Technologist, General
Mark A. Calarco, DO Independent Lab Manager/Administrator
Jason S. Nolan, MD, Pathologist Non Educator
Michael Johnson, Medical Technologist Generalist

Members Absent: Royce Joyner, MD, Pathologist Educator
Patti J. Walton, Hospital/Lab Manager/Adm. Dir.

VACANT: Non-Pathologist Physician
VACANT: Citizen Representative
VACANT: Hospital Administrator

Staff Present: Lynda S. England, Medical Technologist Consultant, Director, TMLB
Devin Wells, Deputy General Counsel, Office of General Counsel
Julia Daniels, Medical Technologist Consultant/ Surveyor, East Tennessee Regional Office
Richard Carroll, Medical Technologist Consultant/Surveyor, Middle Tennessee Regional Office
Angie Sneed, 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: Taylor Carpenter, Medical Technologist Consultant/Surveyor, East Tennessee Regional Office
VACANT: Medical Technologist Consultant-Administrative Office

CLIA Manager/Representative: Sandra Bogard, CLIA Manager

Presiding Officer: Cheryl Arnott, S.A.-Cytotechnologist, Chairman

Call To Order: The meeting was called to order at 9:05 am CDT by Chair Cheryl Arnott.

Introductions of Board Members: Board members and staff made their introductions to the record.
Note:
New Board Member: Michael Johnson, MT
New Surveyor: Angie Sneed, MT Consultant MTRO

Quorum: At least seven members of the Board were present which constituted a quorum.

Approve Minutes:

P & E Committee Meeting **A motion to approve the April 15, 2015 Personnel & Education Committee minutes was made by: Dr. Calarco**
Second: Ms. Dolsen
Committee Minutes Approved

Full Board Meeting **A motion to approve the April 16, 2015, Board meeting minutes was made by: Ms. Kenwright**
Second: Dr. Nolan
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, July 15, 2015.

Motion to ratify Committee actions: Dr. Davis
Second: Mr. Johnson
Report 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 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, Executive Director of TNPAP presented the TNPAP Report.

The statistical report for July 1, 2014 to June 30, 2015 presented to board members showed zero (0) individuals being monitored. There were zero (0) referrals. There was one (1) completed file and one (1) being monitored but in noncompliance. The noncompliant individual was reported to the Tennessee Department of Health. Mr. Harkreader gave a brief description of the program utilized as an advocacy tool for impaired health care providers including TN licensed medical laboratory professionals. The TNPAP staff is willing to make presentations in any licensed hospital, independent laboratory, or training program if requested.

**Move to accept the TN PAP report: Ms. Kenwright
Second: Dr. Nolan**

Report accepted as presented.

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

The financial report had not changed from the April meeting when Ms. Tittle's verbal presentation was given to board members. Because there were no changes noted within the report the document was accepted as presented during the earlier quarterly meeting.

**Motion: Ms. Kenwright
Second: Dr. Calarco**

Report accepted as presented in April 2015.

**Investigations Report
Nichelle Dorroh
Presentation/Discussion**

The investigations report was accepted as presented by Devin Williams in the absence of Ms. Dorroh. Ms. Nichelle Dorroh was present during the meeting but came in too late to actually present the report herself. The report was presented by Devin Wells, Deputy Counsel for the Board. There was one (1) opened complaint in May; seven (7) opened complaints in June. The complaint in May was for alleged malpractice/negligence while the complaints in June were for unprofessional conduct. These complaints will be reviewed by counsel and board director before the next quarterly meeting. There were no questions or requests concerning the information presented.

**Motion: Dr. Nolan
Second: Ms. Kenwright
Report accepted.**

Compliance Orders

There were no compliance orders discussed during the meeting.

Q8

Review/Revise Policy for Patient Test Management Pertaining to Release of Lab Reports

Board members reviewed a revised policy statement concerning access of patients to their medical records. After discussion a revised policy relating to CLIA §493.1291, 45CFR§164-524 the revised document allows patients access to their own medical records as provided by the laboratory. Tennessee Code Annotated Section 68-29-121 (b) and 68-29-129(5) are noted in the revision.

Motion: Dr. Nolan

Second: Ms. Kenwright

Policy Revision Approved.

Note: See Attachment

Revisit Laboratory Licensure Relative To Testing of Mother's Milk Distribution

No representatives were present for this discussion. The item has been kept on the agenda for at least 2 quarterly meetings and will be removed from the agenda for the October 2015 meeting.

No board action was taken on this subject.

Consider Rule Making for 1200-06-01-.1(22) and 1200-06-03-.08(d) (5) relative to pathologists reading slides/location of diagnosis.

This topic was tabled pending the formulation of an advisory task force at a later date. The delay caused by a lack of staff to afford maximum time and effort toward the discussion and dissemination of materials necessary for a complete review.

Motion: Ms. Kenwright

Second: Ms. Dolsen

Approved: To table until further notice.

Revisit status of Rules Rewrite 1200-06-01 Rules Governing Medical Laboratory Personnel

Devin Wells, Deputy General Counsel reviewed the process of bringing the revision of these rules to rulemaking hearing. The rules are currently in internal review process, reviewed for clarity and statutory compliance. When released back to the medical laboratory board's legal office, a rulemaking hearing for public participation can be held.

No action taken.

Request Advisory Opinion Regarding Use of Central Medical Laboratory by Multiple Hospitals

C. Timothy Gray, Attorney, appeared before board members to ask for an advisory opinion on the following subject:

There are several rural hospitals that are continually having problems with staffing a clinical laboratory partly because of a low volume of laboratory testing procedures performed in the facility. Several issues were raised not limited to the Rules and Regulations pertaining to the operation of hospitals (1200-08-01-06 (8) (a) and whether a hospital actually had to maintain a laboratory within the facility. The discussion centered on having a hospital with a larger central laboratory and multiple hospitals sending their laboratory specimens to the larger facility via courier. The time between collection at the one hospital and time to get the lab specimen to the feeder laboratory would be approximately fifteen (15) minutes. Point of Care testing would still remain a viable part of patient care in each hospital facility. The question's for board members: can two or more hospitals via contract or joint ownership utilize one centrally located, medical laboratory and if so could that central feeder laboratory would only need one medical laboratory director

and one supervisor to comply with Rules and Regulations Governing Medical Laboratories 1200-06-03-.14?

After a lengthy discussion, it was decided any decision by Board would follow after a ruling by the Health Care Facilities as to the interpretation of 1200-08-01 per laboratories in hospitals.

Note: This was not an advisory opinion as the board does not have the regulatory authority to perform such decisions, but merely a preliminary discussion on the subject.

No action taken at this time.

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: Mid-South Transplant Foundation, INC. Memphis, TN 38018

This licensed facility requested a modification of previous exemptions granted in (2009 and 2012) to allow a Certified Organ Procurement Specialist to perform and report Blood Gass and Troponin utilizing the Abbott i-Stat instrument and methodologies.

After discussion in April, board members tabled this request until this meeting for further information concerning the education and training of the certified organ procurement specialist.

After the second discussion, today, members denied the request on the basis of lack of formal educational training in laboratory medicine.

Motion to deny request: Ms. Kenwright

Second: Ms. Dolsen

Request Denied

2: Region One Health Systems and Outpatient Center Memphis, TN 38013

The Board reviewed the exemption request utilizing the Abbott i-STAT instrument and methodologies to permit Registered Nurses (RN's) to perform and report activated clotting times (ACT's) to a previously granted exemption in the Burn OR of this licensed facility.

Motion to approve: Ms. Kenwright

Second: Mr. Johnson

Exemption: Approved

3. Williamson Medical Center Franklin, TN 37067

The Board reviewed this exemption request utilizing the Alere Epical Meter:

Permits Registered Nurses (RN's) to perform and report stat testing procedures for hematocrit, blood gases (pH, pCO₂, pO₂), sodium, potassium, ionized calcium, glucose and lactate in the Monroe Carell, Jr. Children's Hospital (Vanderbilt) in the Williamson Medical Center.

Motion to approve exemption: Dr. Calarco

Second: Ms. Kenwright

Exemption approved

**4. University Health Systems,
Inc. POCT
Knoxville, TN 37920**

This facility requested an exemption to permit Registered Nurses (RN's) to perform and report the following liver function testing in the Viral Hemorrhagic Fever & Ebola Unit, at the patient bedside, utilizing the Piccolo Express Analyzer:

Liver Panel to include: Albumin, Alkaline Phosphatase, ALT,
Amylase, AST, Total Bilirubin, GGT and
Total Protein

Motion to approve: Dr. Davis

Second: Dr. Nolan

Exemption Request Approved.

**5. Tri-Star StoneCrest
Medical Center
Smyrna, TN 37167**

This request was to permit Respiratory Therapists (ABG endorsed) to perform and report pH and blood gas analyses throughout the hospital utilizing the Abbot i-STAT instrument and methodologies.

Motion: Ms. Dolsen

Second: Dr. Nolan

Exemption Request Approved.

**6. Methodist Medical Center
Oak Ridge, TN 37830**

This licensed facility made the following requests of board members:

1-permit Respiratory Therapists (ABG endorsed) to perform and report activated clotting times in the Critical Care Unit.

Motion: Ms. Kenwright

Second: Dr. Davis

2-permit Registered Nurses (RN's) to perform and report activated clotting times in the Cardiac Cath Laboratory (Critical Care Nurses).

Motion: Ms. Dolsen

Second: Dr. Nolan

3-permits Interventional Radiology Specialists (RCIS) to perform and report activated clotting times in the Specialties/Interventional Radiology Department.

Motion: Ms. Kenwright

Second: Mr. Johnson

Exemptions 1-3: Approved

4-permit Registered Nurses (RN's) to perform and report AmniSure Rom® testing system in the Family Birthing Unit.

Motion: Dr. Davis

Second: Dr. Calarco

Exemption Request: Approved

Direct more than three (3) Laboratories

The direction of more than three (3) laboratories (clinical or anatomic, or both) in Tennessee mandates approval by the Medical Laboratory Board.

Timothy J. Collins, M.D. appeared before board members to request such approval.

Current Laboratories Directed by Dr. Collins:

- 1-Riverview Medical Center-Carthage, TN
- 2-Jamestown Regional Hospital-Jamestown, TN
- 3-Pioneer Community Hospital Scott County-Oneida, TN

Request the addition of:

Trousdale Medical Center-Hartsville, TN

Motion to approve 4th laboratory: Ms. Kenwright

Second: Dr. Davis

Approved: Dr. Collins can serve as the medical laboratory director for the 4th laboratory.

Note: Dr. Nolan recused himself from the discussion and vote.

RECEIVE REPORTS AND /OR REQUESTS:

Board Director's Report

Ms. England gave her report for the quarter April 1, 2015 thru June 30, 2015.

The report included a statistical report of activities of licensure for personnel and laboratory facilities.

Motion to accept Director's report: Ms. Kenwright

Second: Mr. Johnson

Report accepted

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

REINSTATEMENT OF LICENSES

Nothing to present

ADDITIONS/DELETIONS TO THE BOARD'S WAIVED TEST LIST

Nothing to present

LEGISLATIVE UPDATE

Nothing was presented at this time. Will have report in October.

Office of General Counsel's Report: Mr. Wells

Counsel Wells report was previously incorporated into the discussion about the rules rewrite and the revision of the policy concerning release of information to patients. One (1) open case is currently in the Office of General Counsel at this time. 1200-06-03-.22 Special Regulations Regarding Laboratories Licensed under T.C.A. § 68-29-138 became effective on June 30, 2015.

Motion: Ms. Dolsen

Second: Ms. Kenwright

Report: Accepted As Presented.

Review/Discuss Approval Licensure of Medical Laboratory Director

Jennifer M. Colby, Ph.D.
Nashville, TN 37206
Director: Chemistry

Dr. Colby appeared before the board to answer questions concerning her qualifications to become a medical laboratory director in clinical chemistry. Review of her application was affirmative in compliance with qualifications for licensure.

Motion: Dr. Calarco

Second: Dr. Davis

Approved.

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 second quarter of 2015.

Unsatisfactory/ Unsuccessful Proficiency Testing: Zero (0)
Complaint Investigations: One (1) Investigation Ongoing

**MTRO Report
Richard Carroll**

Middle TN Regional Office: Richard Carroll for the second quarter of 2015.

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

**WTRO Report
Mary Hamblen**

West TN Regional Office: Karon Hathcoat for the second quarter of 2015.

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

Move to accept regional surveyor's reports as presented:

Ms. Kenwright

Second: Dr. Davis

Reports accepted as presented

**Board Ratification of Laboratory
Initial License:**

**PCLS @ Scales Nutrition &
Wellness Center
1010 Fourth Avenue
Nashville, TN 37219**

Medical Director:

Phillip A. Newman, D.O.
Osteopathic Physician

Specialties:

Collection Station

Surveyor:

Richard Carroll
Consultant 2/Surveyor MTRO

Move to approve license: Ms. Kenwright

Second: Ms. Dolsen

License Approved

**Atherotech Diagnostic Laboratory
260 16th Avenue Suite 120
Dayton, TN 37321**

Medical Director:

Michael Prostco, M.D.

Specialties:

Collection Station

Surveyor:

Julia Daniels
Consultant 2/Surveyor ETRO

Move to approve license: Dr. Davis

Second: Ms. Kenwright

License Approved

Tennessee Blood Services Corporation
4330 American Way
Memphis, TN 38118

Medical Director: Edward P. Scott, M.D.
Internal Medicine
Hematology

Specialties: Spun Hematocrit

Surveyor: Mary Hamblen
Consultant 2/Surveyor WTRO

Move to approve license: Dr. Nolan

Second: Ms. Cox

License Approved

Advanced Laboratory Services
4845 W. A. Johnson Hwy.
Morristown, TN 37814

Medical Director: Kevin Catney, M.D.
Medicine & Surgery

Specialties: Collection Station

Surveyor: Julia Daniels
Consultant 2/Surveyor ETRO

Move to approve license: Ms. Kenwright

Second: Dr. Davis

License Approved

PCLS @ Cannady Medical Center
1535 Parr Avenue
Dyersburg, TN 38024

Medical Director: Phillip Newman, D.O.
Osteopathic Physician
Emergency Medicine

Specialties: Collection Station

Surveyor: Mary Hamblen
Consultant 2/Surveyor WTRO

Move to approve license: Mr. Johnson

Second: Ms. Dolsen

License Approved

Athens Donor Center-Blood Assurance
213 Washington Avenue
Athens, TN 37303

Medical Director: Elizabeth Duller, M.D.
Anatomic/Clinical Pathology

Specialty: Hemoglobin
Surveyor Julia Daniels
Consultant 2/Surveyor ETRO

Move to approve license: Ms. Dolsen
Second: Dr. Calarco

License Approved

Total Diagnostics, LLC
3740 Business Drive
Germantown, TN 38125

Medical Director: Ryan Brock Neal, Ph.D.
Director: General

Specialty: Hematology
General Immunology

Surveyor: Mary Hamblen
Consultant 2/Surveyor WTRO

Move to approve license: Ms. Kenwright
Second: Dr. Nolan

License Approved

BioReference Laboratories,
Inc.
820 N. Thompson Lane #A-1
Murfreesboro, TN 37129

Medical Director: Rajendra Persad, M.D.
Anatomic/Clinical Pathology
Pathology-Hematology

Specialty: Collection Station

Surveyor: Angie Sneed
Consultant 1/Surveyor MTRO

Move to approve license: Ms. Dolsen
Second: Mr. Johnson

License Approved

BioReference Laboratories,
Inc-Tullahoma Site Today's
Woman
1805 N. Jackson St. Bldg.31
Tullahoma, TN 37388

Medical Director: Rajendra Persad, M.D.
Anatomic/Clinical Pathology
Pathology-Hematology

Specialty: Collection Station

Surveyor: Angie Sneed
Consultant 1/Surveyor MTRO

Move to approve license: Mr. Johnson

Second: Ms. Cox

License Approved

OTHER BUSINESS:

Clarification of questions submitted to director:

Item 1

A currently licensed laboratory within a hospital as asked if the current testing menu is limited to board approved waived tests is a license necessary? There would be no functioning laboratory on the premises.

Discussion among board members was that the facility where testing was performed must have some oversight because non-laboratory licensed personnel were performing the waived tests without proper laboratory personnel (director-supervisor) oversight. No further action taken on this matter. Rules and Regulations Governing Medical Laboratories 1200-06-03-.17 will prohibit the license from surrendered.

Item 2

Laboratory testing (reporting) equipment reports as part of the menu, tests that are not ordered by the primary care physician or other health care provider authorized to present such an order to a laboratory.

Which, if any, tests are reported back to the physician if not ordered by that individual?

Board members reached the following conclusions after discussion:

1-Abormal results must be reported back to the physician, or other authorized health care individual. The lab result may be reported orally (panic values) via laboratory policy (followed by written report) or written report for possible immediate follow-up.

STD's and HIV's must be reported to the ordering physician. STD's and HIV's must also be reported to the TN Dept. of Health Reportable Disease Program via current state established reporting policies. Genetic testing abnormal results should be reported to the authorized ordering health care professional.

It was noted instruments can be programed/interfaced to print lab reports suppressing laboratory (tests/values) reports not ordered by the physician. Whoever orders a laboratory test is legally responsible for the interpretation of the results.

Board members expressed concern for billing issues may arise with the running of tests not ordered by a physician. No payment for test will be made if test is not ordered by authorized individuals. The discussion ended with no action taken.

Item 3

Board members and surveyors reviewed the Rules and Regulations 1200-06-03-.22 Special Regulations Regarding Laboratories Licenses Under T.C.A. §68-29-138 which became effective June 30,

2015.
No action was taken.

Statement of Next Meeting

The next Board Meeting will be October 15, 2015, and will begin at 9AM CDT in the Iris Conference Rood, Ground Floor, MetroCenter Complex, 665 Mainstream Drive, Nashville, TN 37243

Record of Adjournment

With no further business to discuss, the meeting was adjourned at 12:30 PM CDT on a motion properly presented by **Ms. Kenwright** and seconded by **Dr. Nolan**.
The motion to adjourn was approved.