

Tennessee Medical Laboratory Board
April 26, 2024
Full Board Meeting
Minutes

Meeting Date: April 26, 2024

Time: 9:02 a.m. 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:

Jennifer Gidcomb, MT-Med. Technologist, Gen.-Chairman
Jerry Barker, MT-Hospital Lab Mgr/Admin. Dir.
Danielle Gibson, MD-Pathologist
Marilyn (Buffy) Key, MT-Hospital Administrator
Chris Litle, MT-Medical Laboratory Supervisor
Andrew Stanton, CT-Cytotechnologist
James A. Vaughan, MD-Pathologist Educator

Vacant Positions: Citizen Representative
Pathologist

Members Absent: Penny Asbell, MD- Non-Pathologist Physician
LeeAnne Briggs, MT- Med. Technologist, Educator
Matthew Hardison, Ph.D., Independent Lab Mgr/Adm.
Michael Johnson, MT-Medical Technologist-General

Staff Present: Sandra S. Bogard, MT Consultant, Director
Nina V. Smith, MT Consultant Administrative Office
Ronda Webb-Stewart, Senior General Counsel
Mina Girgis, Board Administrator
Debbie Haggard, MT Consultant/Supervisor WTRO
Fowlen Anders, MT Consultant/Supervisor ETRO
Robert Sommer, MT Consultant/Supervisor MTRO
Misty Rector, MT Consultant/Surveyor WTRO
Kathy Dunn-McPhall, MT Consultant/Surveyor MTRO
Pam Frederickson, MT Consultant/Surveyor ETRO

Staff Absent: None

CLIA Manager/Representative: Tracy McLemore, MT CLIA Director

Introduction of Board Members: Board members and staff made their introductions to the audience.

Quorum: Seven (7) board members were present, which constituted a quorum.

Call To Order: The meeting was called to order at 9:02 a.m. CDT by Jennifer Gidcomb, the Board Chairman.

Presiding Officer: Ms. Gidcomb conducted the meeting.

Approve Minutes:

P & E Committee Meeting
A motion to approve the January 25, 2024, Personnel & Education Committee minutes was made by Mr. Litle.
Second: Mr. Barker

The minutes were approved as written with the chairman voting.

Full Board Meeting
A motion to approve the January 26, 2023, Full Board meeting minutes was made by Mr. Stanton.
Second: Mr. Litle

The Board minutes were approved as written with the chairman voting.

Ratification of Initial Determinations
P & E Committee Meeting:
Ms. Gidcomb reported the actions of the Personnel & Education Committee meeting, April 25, 2024.

Motion to ratify Committee actions: Dr. Vaughan.
Second: Dr. Gibson

The report was accepted as presented by Ms. Gidcomb with the chairman voting.

Consent, Agreed, Compliance Orders, and Letters of Reprimand:

Nothing to present.

Presentations to the Board:

Tennessee Professional Peer Assistance Program (TNPAP)
Teresa Phillips, Executive Director
The statistical report for July 1, 2023-March 31, 2024, was presented by Ms. Teresa Phillips, Executive Director.
Two (2) individuals were monitored during this period, one (1) regulatory and one (1) non-regulatory.

Two (2) agreements activated.

One (1) discharge - was monitored for noncompliance.

Motion to accept the TNPAP report: Mr. Stanton.

Second: Mr. Litle

The report was accepted as given with the chairman voting.

Investigations Report

Barbara Granum

Disciplinary Intake Coordinator

Ms. Granum's investigative report included the following:

Monitored Practitioners (Personnel and Facilities):
(January-April 2024)

Investigative Licensed Laboratory Personnel: (2024)

Zero (0) new complaints

Zero (0) complaints closed

Two (2) currently open complaints

Investigative Licensed Laboratory Facilities: (2024)

Five (5) new complaints

Four (4) closed complaints

- One (1) insufficient evidence
- One (1) referred to OGC
- One (1) closed letter of concern
- One (1) closed

Five (5) currently open complaints

- One (1) outside investigation's scope
- One (1) specimen handling
- Three (3) unprofessional conduct

Investigative Licensed Laboratory Schools: (2024)

Zero (0) new complaints

Zero (0) complaints closed

Zero (0) currently open complaints

Motion to accept the report: Mr. Litle.

Second: Mr. Barker

The investigation report was accepted as given with the chairman voting.

Financial Report

Emily Godwin

Fiscal Director

Ms. Godwin presented the Mid-Year Fiscal Report (July 1, 2023-April 26, 2024), which compared the actual revenue and expenditures for the past three (3) years (FY2022, FY2023, FY24(to date)). The values were

compared with little change from year to year. She also presented information regarding the expenditure sources for all three years, which included the following: salaries, travel, printing, maintenance/repairs, professional services, supplies/materials, grants, computer-related issues, and state professional services.

Motion: Dr. Vaughan
Second: Mr. Litle.

The report was accepted as given with the chairman voting.

No report was given.

Legislative Update
Holt Whitt
Legislative Liaison

Surveyor Update
Tracy McLemore, MT
CLIA Director

Mr. McLemore presented a written report to the Board regarding the surveyor workload. One new surveyor in East Tennessee surveyor in East Tennessee, Pam Frederickson, was hired.

Motion to accept the report: Dr. Gibson.
Second: Mr. Litle

The report was accepted as given with the chairman voting.

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

- 1. Bristol Regional Medical Center-Point of Care**
Bristol, TN
Neeley N. Guinn, BS, MLS(ASCP)
POCT Coordinator

The request was to permit Certified Registered Nurse Anesthetist, Certified Clinical Perfusionist, Registered Nurses, and Licensed Practical Nurses to perform and report Sodium, Potassium, ionized Calcium, Glucose, Hemoglobin, Hematocrit, pH, PO₂, PCO₂, HCO₃, TCO₂, BE, and sO₂ in Surgery Department utilizing Abbott i-STAT 1 System (CG8+ cartridge) instrument and methodology.

Motion: Mr. Barker
Second: Mr. Stanton

The exemption request was approved with the chairman voting.

- 2. Baptist Memorial Hospital for Women Laboratory**

The request was to permit ABG-endorsed Respiratory Therapists and Registered Nurses on the Ambulance

Memphis, TN
Nancy Crosby, MT(ASCP)
POCT Coordinator
Karen S. Clark, BS, MT(ASCP)SH
POCT Supervisor

Transport Team to perform and report Sodium, Potassium, ionized Calcium, Glucose, Hemoglobin, Hematocrit, pH, PO₂, PCO₂, HCO₃, TCO₂, BE, and sO₂ on an ambulance utilizing Abbott i-STAT 1 System (CG8+ cartridge) instrument and methodology.

Motion: Dr. Vaughan
Second: Dr. Gibson

The exemption request was approved with the chairman voting.

3. Saint Francis Hospital-Memphis
Ricky Tucker, BS, MT(ASCP), DLM(ASCP)
Administrative Laboratory Director

The request was to permit Registered Nurses in the Oncology Urgent Care Center to perform and report Sodium, Potassium, Chloride, ionized Calcium, Glucose, Urea Nitrogen, Creatinine, Anion Gap, Hemoglobin, Hematocrit, and TCO₂ utilizing Abbott i-STAT 1 System (Chem8+ cartridge) instrument and methodology.

Motion: Mr. Litle
Second: Dr. Vaughan

The exemption request was approved with the chairman voting.

4. Lab Plus, LLC – St. Thomas Rutherford
Kevin Adcock, MT(ABB)HHS
Regional Laboratory Operations Manager

The first request was to permit Perfusionists and Certified Registered Nurse Anesthetists in Surgery, Cath Lab, and areas with postoperative cardio patients (OR, CCU, Cath Lab, PACU, & 8th Flr) to perform and report Sodium, Potassium, Glucose, ionized Calcium, Hematocrit, pH, PCO₂, PO₂, TCO₂, HCO₃, BE, and sO₂ utilizing Abbott i-STAT System (CG8+ cartridge) instrument and methodology.

The second request was to permit Radiologic Technologists and Cardiovascular Technologists, in the Cath Lab, to perform and report ACT, pH, PCO₂, PO₂, TCO₂, HCO₃, BE, sO₂, and lactate utilizing the Abbott i-STAT System (ACT and CG4+ cartridge) instrument and methodology.

Motion: Dr. Vaughan
Second: Mr. Stanton

The exemption requests were approved with the chairman voting.

Direct More Than Three (3) Labs 1200-06-03-.13(5):

Nothing to present.

Discuss, Review, And Take Action, if Needed:

Discuss Rule 1200-06-03-.07 Participation in Proficiency Testing regarding who can sign the proficiency testing attestation pages.

The Board discussed proficiency testing and who can sign the attestation statements. The Board interpreted Rule 1200-06-03-.07 to allow medical laboratory directors to delegate to a licensed laboratory supervisor the ability to sign the proficiency testing (PT) attestation statements provided there is a written delegation policy.

Motion: Mr. Litle
Second: Mr. Barker

The motion was approved with the chairman voting.

Discuss Rule 1200-06-03-.07 Participation in Proficiency Testing regarding successful participation and possible sanctions.

The Board discussed possible sanctions for laboratories with their second unsuccessful (two out of three PT events or three in a row). The Board decided that any of the three (3) options available in Rule 1200-06-03-.07 (3)(a) are acceptable sanctions. The three (3) options include:

- Laboratory license suspended (reserved for severe cases)
- Laboratory license placed on probation
- Laboratory license limited per the CLIA regulations

The Board provided clarification, so no motion was needed.

Discuss Rule 1200-06-03-.18 Collection Stations and if Chiropractors are eligible to direct a collection station.

After discussing Rule 1200-06-03-.18, the Board decided that Chiropractors do not meet the requirements to direct a collection station. Guidance was provided to Accurate Testing and Wellness regarding their initial collection station application. The Board requested that they obtain a director who meets the regulations.

Accurate Testing and Wellness

Motion: Mr. Barker
Second: Mr. Litle

The motion was denied for chiropractors to direct a collection station with the chairman voting.

Discuss Rule 1200-06-03-.18 Collection Stations and if the hub model needs state licensure if it is used by licensed collection

The Board discussed Rule 1200-06-03-.18 Collections Stations. They decided that a hub-only location does not

stations

need a collection station license, provided no collection or testing of patient samples takes place at that location.

LabCorp

The Board provided clarification, so no motion was needed.

Discuss if a contracted phlebotomist in a doctor's office who performs waived testing needs to be licensed as a laboratory.

The Board discussed whether laboratory licensure is required if a contracted phlebotomist performs waived testing in a physician's office. The contracting company, LabCorp, has a state-licensed laboratory in Tennessee. The Board decided that the LabCorp laboratory could submit a Waived Testing Notification form to the Board's Administrative Office and that a laboratory license was not needed for the phlebotomist performing the waived testing.

LabCorp

The Board provided clarification, so no motion was needed.

Discuss Rule 1200-06-01-.21 Qualifications and duties of the medical laboratory supervisor.

The Board discussed Rule 1200-06-01-.21 Rules Qualifications and Duties of the Medical Laboratory Supervisor. The decision was made that regardless of what the CLIA Program requires, state laboratory surveyors will only cite laboratory supervisor credentials if they do not meet the state regulations.

When a laboratory supervisor does not meet the CLIA personnel requirements, the Board mentioned that the Medical Laboratory Director could sign the competency forms.

The Board provided clarification, so no motion was needed.

Review and Discuss the Licensure of Medical Laboratory Directors:

1. Jean Popwell, Ph.D.
San Francisco, CA
Director-Endocrinology

Dr. Popwell received her Ph.D. in Reproductive Physiology from North Carolina State University, Raleigh, NC in 1999.

She received her M.S. degree in Reproductive Physiology from the University of Georgia, Athens, GA in 1995.

Dr. Popwell received her B.S. degree in Animal Science from the University of Georgia, Athens, GA in 1993.

She received her training at the Pacific Fertility Center Andrology and IVF Laboratories in San Francisco, CA from 2000 to 2001.

Dr. Popwell holds national certification from the American Board of Bioanalysis (ABB) as a High Complexity Laboratory Director (HCLD) in the specialties of Andrology, Embryology, and General Knowledge. This certification expires on December 31, 2024.

She is currently licensed as a Director-Andrology and Embryology.

Dr. Popwell is currently an IVF Lab Director at Tennessee Fertility Institute in Franklin, TN.

Dr. Popwell is requesting an exemption to Rule 1200-06-01-.20(1)(e). She does not have certification in Endocrinology but has work experience in the field of Endocrinology.

She is seeking licensure as a Director of Endocrinology.

After discussion, the Board decided to recognize Dr. Popwell's Andrology and Embryology boarding, work experience, and the current laboratory test menu to qualify her to direct reproductive endocrinology testing. The test menu that the Board approved includes the following tests: estradiol, progesterone, Beta-HCG, luteinizing hormone (LH), follicle-stimulating hormone (FSH), thyroid-stimulating hormone (TSH), prolactin, vitamin D, and testosterone.

The Board requested that future requests for Reproductive Endocrinology directorships need to come before the Board and will be reviewed on a case-by-case basis. Consideration will be based on boardings, work experience, and laboratory test menu.

Motion: Dr. Gibson
Second: Mr. Stanton

The motion was approved with the chairman voting.

Reports/Requests:

Board Director's Report

Sandra Bogard, MS, MT(ASCP) QLC ^{cm}

The report included statistical data concerning laboratory personnel, facilities, training programs, and health fair/health screening events during the First Quarter of 2024.

The website continues to be updated daily/or as needed.

Staffing updates:

- New East Tennessee laboratory surveyor Pam Frederick.

Board meeting dates for 2024 and 2025 were presented.

Vacancies on the Board:

- Pathologist
- Citizen Member (in process of being filed)

Board positions that expired on December 31, 2023:

- Chris Litle-Medical Laboratory Supervisor
- Michael Johnson-Medical Technologist Generalists

The Personnel, Laboratory Facility, and Training Program regulations are currently awaiting Rulemaking Hearings.

2024 State Licensure Surveyor Workload Targets:

West TN – 59 surveys

Middle TN – 52 surveys

East TN – 40 surveys

Each region will be incorporating the remote survey process along with onsite surveys.

The target survey workload is three (3) state-licensed laboratory surveys per fully trained surveyor per month.

January-March 2024 (completed biennial, initial, & complaint surveys only):

West TN – 19 surveys

Middle TN – 11 surveys

East TN – 9 surveys

January-March 2024 (completed all survey types):

West TN – 26 surveys

Middle TN – 16 surveys

East TN – 10 surveys

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

Motion to approve the report with a correction to the July meeting date: Mr. Stanton.
Second: Mr. Litle

The report was accepted with the chairman voting.

Board Attorney Report

Ronda Webb-Stewart
Senior Associate General Counsel

Senior Associate General Counsel Ronda Webb-Stewart gave her Office of General Counsel report for the First Quarter of 2024:

- The Conflict-of-Interest Policy was reviewed with the Board members.
- Two (2) open cases.
- OCG is completing its internal review of the Medical Laboratory Board Rules.

Disciplinary Report

Ronda Webb-Stewart
Senior Associate General Counsel

Senior Associate General Counsel Ronda Webb-Stewart gave the Disciplinary Report for the First Quarter of 2024:

Four (4) licensees are being monitored.

- Two (2) with terms of reprimand with \$20,346.81 in fines and fees.
- One (1) on probation.
- One (1) on suspension with \$1,362.96 in fines and fees.

Motion to accept the Office of General Counsel Report and the Disciplinary Report as given: Mr. Litle.
Second: Mr. Stanton

The reports were accepted as given with the chairman voting.

Regional Surveyor Reports:

Complaint Investigations
Proficiency Testing Events
Regional Offices:
East, Middle, and West TN

ETRO Report: 4th Quarter
Fowlen Ivey, MT
Consultant/Surveyor

East Tennessee Regional Office –First Quarter 2024:
Complaint Investigations: One (1)

MTRO Report: 4th Quarter
Robert Sommer, MT
Consultant/Surveyor

Unsuccessful Proficiency Testing: Zero (0)

- First Occurrence (two in a row or two out of three) unsatisfactory scores: Zero (0)
- Second Occurrence (three in a row or three out of five) unsatisfactory scores: Zero (0)

Middle Tennessee Regional Office—First Quarter 2024:

Complaint Investigations: Two (2)

Unsuccessful Proficiency Testing: One (1)

- First Occurrence (two in a row or two out of three) unsatisfactory scores: Zero (0)
- Second Occurrence (three in a row or three out of five) unsatisfactory scores: One (1)

WTRO Report: 4th Quarter
Debbie Haggard, MT
Consultant/Surveyor

West Tennessee Regional Office –First Quarter 2024:

Complaint Investigations: Zero (0)

Unsuccessful Proficiency Testing: Zero (0)

- First Occurrence (two in a row or two out of three) unsatisfactory scores: Zero (0)
- Second Occurrence (three in a row or three out of five) unsatisfactory scores: Zero (0)

Motion to accept the reports with a revision: Dr. Vaughan.

Second: Mr. Litle

Reports were accepted as presented with the chairman voting.

Addition/Deletions to the Board’s Health Screening Test List:

Nothing to present.

Board Ratifications Initial Facility Applications:

1. **Innovative Pathology Services, PLLC**
Knoxville, TN

Anatomic Laboratory

Specialties: Histopathology, Oral Pathology, & Cytopathology

Medical Laboratory Director: Brandon E. Smithey, M.D.
ABP/Clinical Pathology, Anatomic Pathology

Surveyor: Fowlen Ivey, MT-Consultant/Surveyor/ETRO

Motion: Mr. Litle

Second: Mr. Barker

The license was approved with the chairman voting.

**2. University Health System-Jamestown
Jamestown, TN**

Waived Point-of-Care Laboratory

Specialties: Waived testing only

Medical Laboratory Director: James Vaughan, MD
ABP/Anatomic Pathology, Clinical Pathology

Surveyor: Robert Sommer, MT-Consultant/Surveyor/
MTRO

The Board discussed the laboratory license request of this free-standing emergency department. It was determined that since the free-standing emergency department is under the hospital's license, it can submit a Waived Testing Notification form and does not need to be a state-licensed laboratory to perform the waived testing.

The Board provided clarification, so no motion was needed.

Other Business:

No other business was presented.

New Business:

No new business was presented.

Public Comment:

No public comments.

Adjournment:

The meeting was adjourned at 1:36 p.m. CDT with no further business to discuss.

Motion to adjourn: Dr. Vaughan.

Second: Mr. Litle

The meeting was adjourned.