Tennessee Medical Laboratory Board August 2, 2024 Full Board Meeting Minutes

Meeting Date:	August 2, 2024
Time:	11:04 a.m. CDT
Location:	Tennessee Department of Health Division of Health Licensure and Regulations Metro Center Complex, Poplar Room, Ground Floor 665 Mainstream Drive Nashville, TN 37243
Members Present:	Jerry Barker, MT-Hosp Lab Mgr/Admin. DirVice-Chair Penny Asbell, MD- Non-Pathologist Physician LeeAnne Briggs, MT- Med. Technologist Educator Danielle Gibson, MD-Pathologist Matthew Hardison, Ph.D., Independent Lab Mgr/Adm. Michael Johnson, MT-Medical Technologist-General Marilyn (Buffy) Key, MT-Hospital Administrator Andrew Stanton, CT-Cytotechnologist James A. Vaughan, MD-Pathologist Educator Diana Wagh-Citizen
Vacant Positions:	Pathologist
Members Absent:	Jennifer Gidcomb, MT-Med. Technologist General Chris Litle, MT-Medical Laboratory Supervisor
Staff Present:	Sandra S. Bogard, MT Consultant, Director Nina V. Smith, MT Consultant Administrative Office Ellen Gose, Assistant 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 Frederick, 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:	Ten (10) board members were present, which constituted a quorum.					
Call To Order:	The meeting was called to order at 11:04 a.m. CDT by Jerry Barker, the Board Vice-Chairman.					
Presiding Officer:	Mr. Barker conducted the meeting.					
Approve Minutes:						
P & E Committee Meet	ng A motion to approve the April 25, 2024, Personnel & Education Committee minutes was made by Dr. Vaughan. Second: Dr. Gibson					
	The minutes were approved as written.					
Full Board Meeting	A motion to approve the April 26, 2024, Full Board meeting minutes was made by Mr. Stanton. Second: Ms. Briggs					
	The Board minutes were approved as written.					
Ratification of Initial De P & E Committee Meeti						
	Motion to ratify Committee actions: Mr. Johnson. Second: Mr. Stanton					
	The report was accepted as presented by Ms. Briggs.					
Consent, Agreed, Compliance Orders, and Letters of Reprimand:						
	Nothing to present.					
Presentations to the Board:						
Tennessee Professional Assistance Program (TNF 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.					

Investigations Report

Disciplinary Intake Coordinator

Barbara Granum

Motion to accept the TNPAP report: Mr. Johnson. Second: Ms. Briggs

The report was accepted as given.

Ms. Granum's investigative report included the following:

Monitored Practitioners (Facilities): (January-July 2024)

Investigative Licensed Laboratory Facilities: (2024) Six (6) new complaints Six (6) closed complaints

- Two (2) insufficient evidence
- Two (2) closed warning letters
- Two (2) closed

Six (6) currently open complaints

- One (1) substance abuse
- One (1) outside scope
- Four (4) unprofessional conduct

Motion to accept the report: Ms. Briggs. Second: Mr. Stanton

The investigation report was accepted as given.

No report was given.

Financial Report

Emily Godwin Fiscal Director

Legislative Update

Holt Whitt Assistant Commissioner of Legislative Affairs Holt Whitt, the Assistant Commissioner of Legislative Affairs, presented an update from the 2024 legislative session.

PC.1046 SB2230/HB2545

As enacted, defines "hospital-based laboratory" and "hospital-based laboratory supervisor" for purposes of the Tennessee Medical Laboratory Act; provides hospital-based laboratory supervisors the authority to supervise up to four hospital-based laboratories located in rural counties; makes certain other changes relative to hospital-based laboratories.

PC.557 SB2074/HB1678

As enacted, transfers certain duties and authority regarding data reported by health facilities from the executive director of the health facilities commission to the department; requires licensed birthing centers to

> report claims data on discharges to the department at least quarterly; removes requirement that an owner of a hospital that closes must submit to the department a report of the statistical particulars relative to the hospital's patients for the fiscal year.

PC.561 SB2075/HB1679

As enacted, generally prohibits a licensed dentist from allowing, under general supervision, more than three dental hygienists to work at any one time; authorizes a dentist to supervise, under direct supervision, no more than five dental hygienists while the dentist and each hygienist are providing dental services on a volunteer basis through a nonprofit provider of free mobile clinics; authorizes a dentist to supervise, under general supervision, no more than five dental hygienists if the dentist and dental hygienists work for the department of health, a county or metropolitan health department, or an entity that participates in the state safety net program for the uninsured. Board of Dentistry Rules

PC.566 SB1595/HB1635

As enacted, prohibits emotional support animals that are not trained, or being trained, to perform tasks or work for a person with a disability from indoor areas of food service establishments.

PC678 SB1787/HB2327

As enacted, by May 31, 2025 and by each May 31 thereafter, requires the department of health to publish an annual report stating the total number of attempted suicides and completed suicides that have occurred in this state in the previous calendar year; requires the department to submit the report electronically to all members of the general assembly within seven calendar days of the publication.

PC.680 SB1843/HB2004

As enacted, requires the department to investigate reports of the number of diagnoses of cancer and Parkinson's disease based on data currently available to the department in Maury County and Lawrence County; requires the department to submit a report to legislative committees no later than July 1, 2025.

PC.703 SB2445/HB2254

As enacted, adds three persons to the state child fatality review team who are each state residents with a child

> under 18 (The Governor, Speaker of the House, and Speaker of the Senate each get one of the 3 appointments) ; requires the state child fatality review team to distribute the team's annual report to each local education agency and to the board of the Tennessee Chapter of the American Academy of Pediatrics. PC.714 SB2810/HB2622

As enacted, allows the board of pharmacy to license ambulatory surgical treatment centers if certain criteria are met. An ambulatory surgical treatment center that applies to the board for licensure shall designate to the board either a pharmacist-in-charge, as defined in § 63-10-204, or a medical director who is licensed as a physician under part 6 or part 9 of this title, as the person who has the authority and responsibility for compliance with laws and rules pertaining to the practice of pharmacy at the ambulatory surgical treatment center.

PC.749 SB2362/HB2122

As enacted, requires the department to collaborate with a Tennessee organization approved by the Board of Medical Examiners for the creation of a continuing education program for the purpose of providing healthcare professionals with information and training relative to public and office safety.

PC.759 SB2549/HB2537

As enacted, requires former and current district attorneys general, to solemnize the rite of matrimony, to opt in by filing notice of intention to solemnize the rite of matrimony with the office of vital records.

PC.761 SB2482/HB2773

As enacted, enacts the "Cassie Wright Act," which makes changes to law relative to a parent, legal guardian, or legal custodian having access to certain medical information of their unemancipated minor. Requires a health care professional who reports a threat of bodily harm or threat of committing suicide, by a service recipient who is an unemancipated minor, to law enforcement must also report to the unemancipated minors parent, legal guardian, or legal custodian. Requires access to an unemancipated minors prescription records unless the provider is required to report abuse or access to this information is reasonably likely to endanger the life or physical safety of the minor.

PC.768 SB1791/HB1973

As enacted, requires the department, when screening for a condition is not implemented within 36 months of being added to the Recommended Uniform Screening Panel, to provide a report on the status and the reason for delay to the health and welfare committee of the senate, the health committee of the house, the genetics advisory committee of the department, and the Tennessee rare disease advisory council.

PC.783 SB1673/HB1625

As enacted, requires a qualified mental health professional or behavior analyst to warn or protect an identified victim or group of people when the professional or analyst determines that a service recipient has communicated an intent for actual threat of bodily harm; requires the professional or behavior analyst to report such threat; provides immunity from civil, criminal, and regulatory liability for a professional or analyst who takes reasonable action to warn or protect identified victims or groups and to report such threat.

PC.831 SB1766/HB1882

As enacted, requires a healthcare provider to provide to a patient or the patient's authorized representative a full copy of the patient's medical records within 10 working days of receipt of a written request by the patient or representative, instead of providing a full copy or a summary of the records; requires a healthcare provider to provide to a principal or an attorney in fact acting pursuant to a durable power of attorney for health care a full copy of the principal's medical records within 10 working days of receipt of a written request by the principal or attorney in fact, instead of providing a full copy or a summary of the records.

PC.840 SB1945/HB2174

As enacted, redefines "food service establishment" to exclude an establishment whose primary business is other than food service, that incidentally makes casual, occasional food sales for two days or less while an organized temporary event is being conducted less than one-quarter mile from the establishment, for the purposes of exempting such establishments from regulation by the department of health and local governments.

PC.906 SB2020/HB1695

As enacted, specifies that reports of county medical examiners and autopsy reports of victims who are minors and who's manner of death is listed as homicide are not public documents; allows a parent or legal guardian of a minor who's death is listed as homicide to the release of the report of the county medical examiner or autopsy report of the minor victim if the parent or legal guardian is not a suspect in the circumstances of the minor's death.

PC.921 SB2850/HB2900

As enacted, requires verification of U.S. citizenship or lawful presence for applicants of professional licenses. Outlines that BME shall grant a full and unrestricted license to temporary licensee who is in good standing 2 years after the date of the initial temporary licensure.

PC.924 SB0734/HB0628

As enacted, allows the Licensing Board to enter into an executive session for the discussion or deliberation of health conditions of a licensee or prospective licensee, including mental health conditions, career fatigue, substance use disorders, revealed during an application process. The proceedings of the executive session, minutes and recordings of such executive session, portions of an application involving an applicant's health condition, and records involving an applicant's health condition are confidential, privileged, and not public records subject to inspection by citizens of this state. The board may not vote during an executive session. An applicant or licensee may access records of the applicant's or licensee's own application and related proceedings, as may the applicant's or licensee's authorized representative or attorney, or an attorney for this state An attorney for the state may be present for the entirety of the 3 proceeding and may advocate on behalf of the department as is reasonably necessary during such proceeding, including the executive session. (c) At the discretion of an applicant for a license, an authorized representative or attorney for the applicant for a license before a board established pursuant to this title or title 68, may be present for the entirety of any proceeding, including an executive session, and may advocate on behalf of the applicant as is reasonably necessary during such proceeding or executive session.

PC.944 SB2588/HB2097

As enacted, requires state regulatory boards within the department of commerce and insurance and state health related boards within the department of health to issue advisory opinions upon request.

PC.1027 SB1881/HB2857

As enacted, removes from the definition of "providerbased telemedicine" the requirement that the healthcare service provider or the provider's practice group or healthcare system have an established provider-patient relationship that is documented by an in-person encounter within 16 months prior to the interactive visit.

PC.1030 SB1963/HB2176

As enacted, permits a court to award the reasonable court costs and attorney's fees to a petitioner successfully proving that a governing body knowingly and willfully violated the public meetings laws in this state.

PC.1032 SB1971/HB1895

As enacted, creates the criminal offense of abortion trafficking of a minor; provides for a civil action against a person committing the offense of abortion trafficking of a minor for the wrongful death of an unborn child that was aborted.

PC.1043 SB2151/HB2861

As enacted, clarifies that a healthcare practitioner shall not coerce a person, including a person who has legal authority to make healthcare decisions for a child, to consent to a vaccination; Mislead or misrepresent that a vaccination is required by state law, when state law provides an exemption; or (3) Mislead or misrepresent that a newborn screening test is required by state law, when state law does not require such screening without providing an exemption to such requirement.

PC.1061 SB2749/HB2936

As enacted, enacts the "Families' Rights and Responsibilities Act." This act outlines that parental consent must be given to a healthcare provider to render certain treatment or services unless under certain circumstances such as emergency medical or surgical treatment or if blanket consent has been given.

Motion to accept the report: Dr. Hardison. Second: Mr. Stanton

Surveyor Update

CLIA Director

Tracy McLemore, MT

The report was accepted as given.

Mr. McLemore presented a written report to the Board regarding the surveyor workload.

Motion to accept the report: Dr. Gibson. Second: Ms. Briggs

The report was accepted as given.

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

1. Baptist Memorial Hospital Memphis Memphis, TN Karen S. Clark, BS, MT(ASCP)SH Point of Care Supervisor The request was to permit Registered Nurses to perform and report Sonic Estimation of Elasticity in Intensive Care Units (ICU, CVICU, Neuro ICU, Transplant, Myelo ICU), and Transplant Clinic utilizing Resonance (SEER) instrument and methodology.

Motion: Ms. Briggs Second: Mr. Johnson

The exemption request was approved.

The request was to permit Perfusionists in the Operating Room (OR) to perform and report ACT testing utilizing the Abbott i-STAT System instrument and methodology.

Motion: Dr. Gibson Second: Dr. Hardison

The exemption request was approved.

The first request was to permit Registered Nurses to perform and report Sodium, Potassium, Chloride, ionized Calcium, TCO2, Glucose, BUN, Creatinine, Hemoglobin, and Hematocrit in the Transplant & Cellular Therapy Department utilizing the Abbott i-STAT (CHEM8+ cartridge) instrument and methodology.

Motion: Ms. Briggs Second: Mr. Johnson

The exemption request was approved.

 Lab Plus, LLC – Saint Thomas Rutherford Murfreesboro, TN Melanie White, BSMT(ASCP) Point of Care Coordinator

3. University Health Systems, Inc-POCT Knoxville, TN Patricia Cole, MT(ASCP) Point of Care Coordinator The second request was to permit Registered Nurses to perform and report Creatinine in the Radiation Oncology Department utilizing the Abbott i-STAT instrument and methodology.

Motion: Mr. Johnson Second: Dr. Hardison

The exemption request was approved.

The third request was to permit Nurse Midwives, Nurse Practitioners, and Physician Assistants to perform and report Fern testing, Potassium Hydroxide testing, and Wet Preps in the Labor & Delivery Department.

Motion: Ms. Key Second: Ms. Briggs

The exemption request was approved.

The request was to permit Registered Nurses in the Cardiovascular Lab to perform and report Total Hemoglobin and O2 sat. testing utilizing the Avoximeter 1000E System instrument and methodology.

Motion: Mr. Johnson Second: Dr. Vaughan

Nothing to present.

and provided two scenarios.

The exemption request was approved.

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

Discuss, Review, And Take Action, if Needed:

Discuss collection station licensure of contracted phlebotomists in physician offices.

Quest Diagnostics

The Board discussed the licensure of collection stations

Scenario #1:

If a State of Tennessee licensed laboratory oversees the phlebotomist in the physician's office, a collection station license is not required.

The Board further clarified that not all of the samples are required to go to the licensed laboratory.

Scenario #2:

 Lab Plus, LLC – St. Thomas West Roxanne Willadsen, MBA, MLS Point of Care Coordinator Discuss what is required of out-of-state providers to order laboratory testing in Tennessee.

Aegis Sciences Corporation

Discuss if collection stations can perform laboratory testing for employment purposes.

Review and Discuss the Licensure of Medical Laboratory Directors:

 Jean Popwell, Ph.D. San Francisco, CA Director-Andrology and Embryology If a contracted phlebotomist in a physician's office is under the supervision of an out-of-state laboratory, then a collection station license is needed.

The Board provided clarification, so no motion was needed.

The Board discussed out-of-state provider's ordering privileges. It was decided that out-of-state providers can order laboratory tests in Tennessee, provided the testing laboratory maintains documentation that the state where the provider resides authorizes the ordering of laboratory tests.

The Board provided clarification, so no motion was needed.

After discussion, the Board decided that employment testing is not under the Board's purview therefore, it is acceptable to perform that testing in a collection station.

The Board provided clarification, so no motion was needed.

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.

During the April 26, 2024 meeting, 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.

Dr. Popwell is requesting that an additional analyte of Anti-Mullerian Hormone (AMH) be added to her approved test menu.

After the discussion, the Board decided to add AMH to Dr Popwell's approved test menu under her directorship.

Motion: Dr. Vaughan Second: Dr. Hardison

The motion was approved.

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

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

Staffing updates:

None to report.

Board meeting dates for 2024 and 2025 were presented.

Reports/Requests:

Board Director's Report Sandra Bogard, MS, MT(ASCP) QLC ^{cm}

New Board member:

• Diana Wagh-Citizen.

Vacancies on the Board:

Pathologist

Board positions that expired on December 31, 2023:

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

Board positions that will expire on December 31, 2024:

- Andrew Stanton-Cytotechnologist
- Jennifer Gidcomb-Medical Technologist
- Jerry Barker-Hospital Laboratory Manager/Administrative Director

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-June 2024 (completed biennial, initial, & complaint surveys only): West TN – 36 surveys Middle TN – 24 surveys East TN – 20 surveys

January-June 2024 (completed all survey types): West TN – 52 surveys Middle TN – 34 surveys East TN – 21 surveys

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

Motion to approve the report: Mr. Johnson. Second: Ms. Briggs

The report was accepted.

Board Attorney Report Ellen Gose

Assistant General Counsel

Disciplinary Report

Ellen Gose Assistant General Counsel

Assistant General Counsel Ellen Gose gave her Office of General Counsel report for the Second 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.

Assistant General Counsel Ellen Gose gave the Disciplinary Report for the Second 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: Ms. Briggs. Second: Dr. Hardison

The reports were accepted as given.

Regional Surveyor Reports:

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

ETRO Report: 2nd Quarter

Fowlen lvey, MT Consultant/Surveyor East Tennessee Regional Office –Second Quarter 2024:

Complaint Investigations: Two (2)

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)

		MTRO Report: 2nd Quarter Robert Sommer, MT Consultant/Surveyor	 Middle Tennessee Regional Office–Second Quarter 2024: Complaint Investigations: Zero (0) Unsuccessful Proficiency Testing: One (1) First Occurrence (two in a row or two out of three) unsatisfactory scores: One (1) Second Occurrence (three in a row or three out of five) unsatisfactory scores: Zero (0)
		WTRO Report: 2nd Quarter Debbie Haggard, MT Consultant/Surveyor	 West Tennessee Regional Office –Second Quarter 2024: Complaint Investigations: Zero (0) Unsuccessful Proficiency Testing: Zero (0) First Occurrence (two in a row or two out of three) unsatisfactory scores: One (1) Second Occurrence (three in a row or three out of five) unsatisfactory scores: Zero (0)
	elet	ions to the Board's Health Screening	Motion to accept the reports with a revision: Mr. Stanton. Second: Mr. Johnson Reports were accepted as presented.
Test List:			Nothing to present.
Board Ratifi	icati	ions Initial Facility Applications:	
	1.	Parkridge Soddy Daisy ER Laboratory Soddy Daisy, TN 37379	Clinical Laboratory Specialties: Bacteriology (limited), Virology (limited), Hematology, General Immunology, Clinical Chemistry, Arterial Blood Gases & pH, and Transfusion Services. Medical Laboratory Director: Eugene Fong, M.D. ABP/Clinical Pathology Surveyor: Fowlen Ivey, MT-Consultant/Surveyor/ETRO
	2.	PathAl, Inc. Memphis, TN 38125	Anatomic Laboratory

Specialty: Histopathology and Immunohistochemistry Page **15** of **17**

Medical Laboratory Director: Richard S. Kinsey, MD ABP/Anatomic Pathology & Clinical Pathology

Surveyor: Debbie Haggard, MTConsultant/Surveyor/WT

3. Vanderbilt Medical Laboratories-Metrocenter Nashville, TN 37228 Anatomic Laboratory

Specialties: Pathology, Histopathology, Oral Pathology, Cytology, and Immunohistochemistry

Medical Laboratory Director: Jennifer Gordetsky, MD ABP/Anatomic Pathology

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

4. Vanderbilt Medical Laboratories-Metrocenter Nashville, TN 37228

Clinical Laboratory

Specialties: Bacteriology, Mycobacteriology, Mycology, Parasitology, Virology, Hematology, Cytogenetics, Diagnostic Immunology, Syphilis Serology, General Immunology, Routine Chemistry, Urinalysis, Endocrinology, Toxicology, Molecular Diagnostics, Molecular Genetics, Molecular Pathology, and Hematopathology.

Medical Laboratory Director: Adam Seegmiller, MD ABP/Anatomic Pathology & Clinical Pathology

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

After discussion, the Board decided to ratify the four (4) laboratories listed above since they had no deficiencies cited during their initial inspection.

Motion: Mr. Johnson Second: Dr. Gibson

The licenses were approved.

5. Chronetyx Laboratories Memphis, TN **Clinical Laboratory**

Specialty: Molecular Diagnostics

Medical Laboratory Director: Abdallah Azouz, MD ABP/Anatomic, Clinical Pathology, & Hematopathology

	Surveyor: Debbie Haggard, MTConsultant/Surveyor/WT
	Motion: Dr. Vaughan Second: Mr. Johnson
	The license was approved.
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 1:10 p.m. CDT with no further business to discuss.
	Motion to adjourn: Dr. Gibson. Second: Dr. Hardison
	The meeting was adjourned.