



State of Tennessee

PUBLIC CHAPTER NO. 1046

SENATE BILL NO. 2230

By Jackson, Crowe, Walley

Substituted for: House Bill No. 2545

By Brock Martin, Haston, Hurt, Shaw

AN ACT to amend Tennessee Code Annotated, Title 68, relative to medical laboratory operations in a hospital setting.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Section 68-29-103, is amended by inserting the following as a new subdivision:

() "Rural hospital-based laboratory" means a medical laboratory located within a rural hospital licensed in this state that primarily provides testing services to patients of the hospital, including, but not limited to, patients in emergency, inpatient, and outpatient settings;

SECTION 2. Tennessee Code Annotated, Section 68-29-106, is amended by designating the existing language as subsection (a) and adding the following as a new subsection:

(b) Notwithstanding subsection (a), a rural hospital-based laboratory shall maintain, in addition to a license issued by the board, at least one (1) of the following:

(1) An active Clinical Laboratory Improvement Amendments of 1988 (CLIA) license that includes a certificate of accreditation from an approved accrediting organization recognized under CLIA or by the applicable state agency with designated authority to grant CLIA certification;

(2) An active certificate of registration;

(3) An active certificate of compliance; or

(4) A certificate of hospital accreditation as described in subsection (c).

(c) Hospital accreditation may be obtained from the health facilities commission, the department of health, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), DNV Healthcare, or another organization that is authorized to survey hospitals for medicare enrollment purposes by the United States department of health and human services to comply with a condition of participation in the medicare program in accordance with current requirements of the medicare program.

SECTION 3. Tennessee Code Annotated, Section 68-29-111, is amended by designating the existing language as subsection (a) and adding the following as a new subsection:

(b)(1) A person shall not conduct, maintain, or operate a rural hospital-based laboratory in this state unless a license has been obtained as described in this part, except for laboratories exempt under § 68-29-104.

(2) Consistent with the federal requirements of § 353 of the Public Health Service Act (42 U.S.C. § 263a), a medical laboratory supervisor may supervise up to five (5) separate rural hospital-based medical laboratories when the rural hospital-based laboratories are located within hospitals designated as rural hospitals in

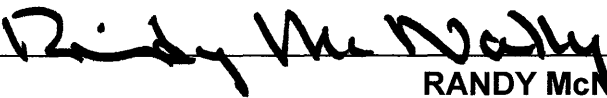
accordance with the current federal health resources and services administration's definition of rural areas.

(3) A medical laboratory director shall not direct more than five (5) rural hospital-based laboratories, consistent with the federal requirements of § 353 of the Public Health Service Act.

SECTION 4. This act takes effect upon becoming a law, the public welfare requiring it.

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PASSED: April 24, 2024



RANDY McNALLY
SPEAKER OF THE SENATE



CAMERON SEXTON, SPEAKER
HOUSE OF REPRESENTATIVES

APPROVED this 25th day of May 2024



BILL LEE, GOVERNOR