

HOUSE BILL 2545

By Martin B

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 new subdivisions:

() "Hospital-based laboratory" means a medical laboratory within a 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;

() "Hospital-based laboratory supervisor" means a professional licensed by the board who:

(A) Possesses a minimum of an associate's degree in medical laboratory science, biology, chemistry, or a related field from an accredited institution, or has at least two (2) years of equivalent practical experience as determined by the board;

(B) Has completed a federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) training module and a state training module as approved by the board; and

(C) Works under the general supervision of a medical laboratory director as described in this chapter;

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):

(1) A hospital-based laboratory is not required to obtain a separate license for each location it maintains as long as the off-site laboratory maintains at least one (1) of the following pursuant to an inspection conducted by an organization described in subdivision (b)(2):

- (A) An active CLIA license;
- (B) An active certificate of registration;
- (C) An active certificate of compliance; or
- (D) A certificate of accreditation; and

(2) A hospital-based laboratory may be inspected by the health facilities commission, the joint commission on accreditation of health care organizations, Det Norske Veritas, or another organization that is authorized to inspect laboratories for medicare enrollment purposes by the United States department of health and human services.

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 hospital-based laboratory in this state unless a license has been obtained from the board, except laboratories exempt under § 68-29-104, or as permitted pursuant to § 68-29-106(b).

(2) Except as provided in subdivision (b)(3), or unless specifically authorized by the board, an individual shall not direct more than one (1) hospital-based laboratory.

(3) A hospital-based laboratory supervisor may supervise more than one (1) hospital medical laboratory when the hospital-based laboratories are located within hospitals designated as rural hospitals by the board. A hospital-based laboratory supervisor may supervise up to four (4) separate rural hospital laboratories.

(4) A separate license must be obtained for each hospital-based laboratory location, except those permitted pursuant to § 68-29-106(b).

(5) A hospital-based laboratory supervisor may supervise technical personnel, perform tests requiring special scientific skills, and in the absence of the medical laboratory director, be responsible for the proper performance of all medical laboratory procedures and the reporting of results.

SECTION 4. Tennessee Code Annotated, Section 68-29-116(a), is amended by deleting the language "supervisor, technologist" and substituting "supervisor, hospital-based laboratory supervisor, technologist".

SECTION 5. Tennessee Code Annotated, Section 68-29-116(b), is amended by deleting the language "medical laboratory supervisor, or" and substituting "medical laboratory supervisor, hospital-based laboratory supervisor, or".

SECTION 6. This act takes effect July 1, 2024, the public welfare requiring it.