

HOUSE BILL 579

By Ragan

AN ACT to amend Tennessee Code Annotated, Title 4 and Title 68, relative to the Tennessee Medical Laboratory Act.

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

SECTION 1. Tennessee Code Annotated, Section 68-29-105, is amended by adding the following as a new subdivision:

() Standardization of quality control and electronic recordkeeping programs for use in each medical laboratory, including the use of, where applicable, reference or control sera or other biological samples, concurrent calibration standards, and control charts recording. The board may utilize nationally recognized standards or comparable internationally recognized standards, or develop, as needed, its own standards of equal or greater stringency to existing nationally or internationally recognized standards.

SECTION 2. Tennessee Code Annotated, Section 68-29-121, is amended by deleting subsection (b) and substituting:

Except as provided in § 68-29-125, the results of a test must be reported directly to the physician, optometrist, dentist, chiropractic physician, designated entity, or other healthcare professional who requested it. The report must comply with the electronic-reporting standards set by the board.

SECTION 3. Tennessee Code Annotated, Section 68-29-125, is amended by deleting the section and substituting:

Each medical laboratory director must transmit a laboratory quality control report electronically to the board in the manner prescribed by the board. The report must include an electronic copy of the quality control data of equipment and personnel used in

the test. The board may also require an electronic copy of quality control test results reported to the department so that the department may enter the quality control test results into a consolidated database for research purposes. Quality control test results and information containing patient data stored, used, or released for research purposes must reflect compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (42 U.S.C. § 1320d et seq.). Costs associated with the department creating, maintaining, using, and allowing authorized research from a consolidated database may be defrayed through user and participant fees or cost-sharing agreements with research organizations as determined by the board in conjunction with the department.

SECTION 4. Tennessee Code Annotated, Section 68-29-119, is amended by deleting the language "The fee," and substituting the language "The fee, including any reporting fees set by the board,".

SECTION 5. The medical laboratory board is authorized to promulgate rules to effectuate the purposes of this act. The rules must be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in Tennessee Code Annotated, Title 4, Chapter 5.

SECTION 6. For rule promulgation purposes, this act takes effect upon becoming a law, the public welfare requiring it. For all other purposes, this act takes effect January 1, 2022, the public welfare requiring it, and applies to all laboratory records created on or after that date.