Department of Health
Notice of Rulemaking Hearing
Tennessee Medical Laboratory Board
Division of Health Related Boards

There will be a hearing before the Tennessee Medical Laboratory Board to consider the promulgation of amendments to rules pursuant to T.C.A. §§ 4-5-202, 4-5-204, and 68-29-104, 68-29-105, 68-29-116, 68-29-117, 68-29-118, 68-29-125, and 68-29-127. The hearing will be conducted in the manner prescribed by the Uniform Administrative Procedures Act, Tennessee Code Annotated, Section 4-5-204 and will take place in the Cumberland Room of the Cordell Hull Building located at 425 Fifth Avenue North, Nashville, TN at 2:30 p.m. (CST) on the 24th day of March, 2005.

Any individuals with disabilities who wish to participate in these proceedings (review these filings) should contact the Department of Health, Division of Health Related Boards to discuss any auxiliary aids or services needed to facilitate such participation or review. Such initial contact may be made no less than ten (10) days prior to the scheduled meeting date (the date such party intends to review such filings), to allow time for the Division to determine how it may reasonably provide such aid or service. Initial contact may be made with the ADA Coordinator at the Division of Health Related Boards, First Floor, Cordell Hull Building, 425 Fifth Avenue North, Nashville, TN 37247-1010, (615) 532-4397.

For a copy of the entire text of this notice of rulemaking hearing contact:

Jerry Kosten, Regulations Manager, Division of Health Related Boards, 425 Fifth Avenue North, First Floor, Cordell Hull Building, Nashville, TN 37247-1010, (615) 532-4397.

Substance of Proposed Rules

Amendments

Rule 1200-6-1-.05 Procedures for Personnel Licensure, is amended by adding the following language as subparagraph (1) (m) and re-lettering the remaining subparagraphs accordingly, and is further amended by deleting subparagraph (2) (a) in its entirety and substituting instead the following language, so that as amended, the new subparagraphs (1) (m) and (2) (a) shall read:

(1) (m) The applicant shall cause to be submitted to the Board's administrative office directly from the vendor identified in the Board's licensure application materials, the result of a criminal background check.

(2) (a) In addition to fulfilling the above requirements in paragraph (1), an internationally trained applicant must also:

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, 68-29-116, 68-29-117, 68-29-118, and 68-29-127.

Rule 1200-6-3-.01 Definitions, is amended by deleting paragraph (23) in its entirety and renumbering the remaining paragraphs accordingly, and is further amended by adding the following language as new paragraph (6) and renumbering the remaining paragraphs accordingly:

(6) CLSI – The Clinical Laboratory and Standards Institute.

Authority: T.C.A. §§ 4-5-202, 4-5-204, and 68-29-105.

Rule 1200-6-3-.09 Quality Control, is amended by deleting subparagraph (4) (a) and part (8) (e) 4. in their entirety and substituting instead the following language, so that as amended, the new subparagraph (4) (a) and the new part (8) (e) 4. shall read:

(4) (a) A written procedure manual for the performance of all analytical methods used by the laboratory must be readily available and followed by laboratory personnel. Textbooks may be used as supplements to these written descriptions but may not be used in lieu of the laboratory's written procedures for testing or examining specimens. Procedure should be substantially in compliance with the CLSI, GP-2A, current version, or any subsequent version.

(8) (e) 4. The laboratory must check each batch or shipment of media for sterility, if it is intended to be sterile and if sterility is required for testing. Media must also be checked for its ability to support growth, and as appropriate, selectivity/inhibition and/or biochemical response. The laboratory may use manufacturer's control checks of media provided the manufacturer's product insert specifies that the manufacturer's quality control checks meet the current standards of the Clinical and Laboratory Standards Institute (CLSI) for media quality control. The laboratory must document that the physical characteristics of the media are not compromised and report any deterioration in the media to the manufacturer. The laboratory must follow the manufacturer's specifications for using the media and be responsible for the test results.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, and 68-29-125.

Rule 1200-6-3-.16 Alternate Site Testing, is amended by deleting paragraph (3) but not its subparagraphs and substituting instead the following language, and is further amended by adding the following language as new subparagraph (3) (a) and re-lettering the remaining subparagraphs accordingly, so that as amended, the new paragraph (3) but not its subparagraphs and the new subparagraph (3) (a) shall read:

(3) Screening Programs – Screening programs are offerings of specified medical laboratory tests to the general public, the purpose of which is educational rather than for diagnosis disease, and the results of which are immediately available on the site of the program to the person being tested except for those tests which for methodological reasons must be submitted to a medical laboratory in which case they shall be sent to a Tennessee licensed medical laboratory.

(3) (a) Screening programs conducted by for-profit hospitals or nonprofit organizations are exempt from the licensure requirements of the Medical Laboratory Act, pursuant to T.C.A. § 68-29-104(6), when the following conditions are met:

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-104, and 68-29-105.

Contact who can answer questions concerning this notice of rulemaking hearing, technical contact for disk acquisition, and person who will approve final copy for publication: Jerry Kosten, Regulations Manager, Division of Health Related Boards, 1st Floor, Cordell Hull Building, 425 5th Avenue North, Nashville, TN 37247-1010 615-532-4397.

I certify that this is an accurate and complete representation of the intent and scope of rulemaking proposed by the Tennessee Medical Laboratory Board.

Robbie H. Bell, Director
Health Related Boards

Subscribed and sworn to before me this the 13th day of January, 2005.

Notary Public

My commission expires on the 25th day of March, 2006.

The notice of rulemaking set out herein was properly filed in the Department of State on the 14 day of Jan., 2005.

Riley C. Darnell
Secretary of State

By: