

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, 68-29-103, 68-29-104, 68-29-105, 68-29-107, 68-29-116, 68-29-118, and 68-29-125. 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 Tennessee Room of the Cordell Hull Building located at 425 Fifth Avenue North, Nashville, TN at 2:30 p.m. (CDT) on the 8th day of July, 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-.20 Qualifications and Duties of the Medical Laboratory Director, is amended by deleting part (5) (e) 15. in its entirety and substituting instead the following language, so that as amended, the new part (5) (e) 15. shall read:

- (5) (e) 15. Ensure, in writing, the responsibilities and duties of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results; and

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-103, 68-29-105, 68-29-116, and 68-29-118.

Rule 1200-6-1-.21 Qualifications and Duties of the Medical Laboratory Supervisor, is amended by deleting subparagraph (2) (b) but not its parts, and substituting instead the following language, so that as amended, the new subparagraph (2) (b) but not its parts shall read:

- (2) (b) The medical laboratory supervisor may delegate, pursuant to written policy, to the medical laboratory supervisor specific duties that do not comprise the practice of medicine, including but not limited to the following:

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-103, 68-29-105, and 68-29-116.

Rule 1200-6-3-.09 Quality Control, is amended by deleting paragraph (8) but not its subparagraphs, and substituting instead the following language, so that as amended, the new paragraph (8) but not its subparagraphs shall read:

- (8) Standard: Control Procedures – Control procedures are performed on a routine basis to monitor the stability of the method or test system; control materials provide a means to indirectly assess the accuracy and precision of patient test results. Control procedures must be performed as defined in this paragraph unless otherwise specified in paragraphs 1200-6-3-.09 (12) through 1200-6-3-.09 (34).

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

Rule 1200-6-3-.12 Referrals of Cultures to the Department of Health, is amended by deleting subparagraph (1) (o) in its entirety and substituting instead the following language, and is further amended by adding the following language as new subparagraphs (1) (u), (1) (v), (1) (w), (1) (x) and (1) (y), so that as amended, the new subparagraphs (1) (o), (1) (u), (1) (v), (1) (w), (1) (x) and (1) (y) shall read:

(1) (o) Escherichia coli O157:H7

(1) (u) Bacillus anthracis

(1) (v) Burkholderia mallei

(1) (w) Burkholderia pseudomallei

(1) (x) Vancomycin resistant staphylococcus aureus (VRSA)

(1) (y) Vancomycin intermediate staphylococcus aureus (VISA)

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, and 68-29-107.

Rule 1200-6-3-16 Alternate Site Testing, is amended by deleting part (1) (c) 5. in its entirety and substituting instead the following language, so that as amended, the new part (1) (c) 5. shall read:

- (1) (c) 5. The Medical Laboratory Director, once having established critical values, shall have the discretion to determine if, consistent with good patient care, whether there is a need for verification by the clinical laboratory when values fall above or below the established critical values.

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

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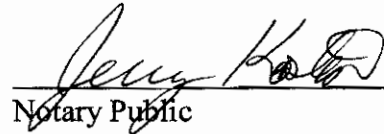
Contact who can answer questions concerning this notice of rulemaking hearing, technical contact for disk acquisition, and person who will approve final copy for publication: Jerry Kosten, Regulations Manager, Division of Health Related Boards, First Floor, Cordell Hull Building, 425 Fifth Avenue North, 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 14th day of April, 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 15 day of April, 2005.



Riley C. Darnell
Secretary of State

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PUBLICATIONS

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