

ID# 2281

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

Chapter 1200-6-3
General Rules Governing Medical Laboratories

Amendments

Rule 1200-6-3-.02 Licensing Procedures, is amended by adding the following language as new subparagraph (4) (h):

(4) (h) T.C.A. § 68-29-112 Fee – A nonrefundable fee to be paid when there \$ 100.00 is a change in laboratory ownership, directorship, or location.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, 68-29-111, 68-29-112, and 68-29-113.

Rule 1200-6-3-.03 Change in Location, Director, Owner, Supervisor or Testing in a Medical Laboratory, is amended by deleting the language of the rule in its entirety and substituting instead the following language as new paragraphs (1) through (3):

- (1) It shall be the responsibility of the owner of a laboratory to notify the Department in writing of a change in the location, director, owners or supervisor of the laboratory within fifteen (15) days of the actual change.
- (2) If the matter involves a change of the owner, and/or director and/or the location an application for a new license, including payment of the T.C.A. § 68-29-112 Fee as provided in Rule 1200-6-3-.02 (4), must be filed and a new license obtained before the laboratory may provide services. That new license may be applied for and issued prior to the actual change but will be void should the change not actually take place.
- (3) It shall be the responsibility of the owner to notify the Department in writing in order to add a specialty or subspecialty not presently authorized by the facility's license prior to the commencement of testing and reporting patient test results. The Department must conduct an on-site inspection prior to the issuance of authorization for the specialty or subspecialty. A replacement license which includes the new specialty or subspecialty shall be issued by the Department at no cost to the facility.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, 68-29-112 and 68-29-114.

Rule 1200-6-3-.16 Alternate Site Testing, is amended by deleting paragraph (2) in its entirety and substituting instead the following language, so that as amended, the new paragraph (2) shall read:

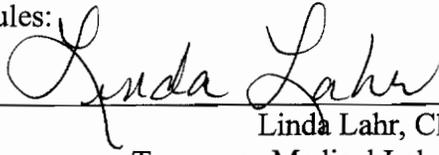
- (2) Physician's Office Laboratories - Physician Office Laboratories (POLs) are exempt from licensure requirements of the Medical Laboratory Act
 - (a) To be eligible for this exemption, the following conditions must be met:
 - 1. The laboratory collects, accepts and tests only specimens from the private and personal patients of the physician who owns the practice or from the private and personal patients of any physician who is a member of a medical/physician group practice that owns and operates the laboratory regardless of the distance of any member physician's practice location from the group practice's laboratory or the number of specimens collected, accepted and/or tested; and
 - 2. The laboratory must be operated by the physician who owns the practice or through his own employees. In a medical/physician group practice, one (1) of the group's physicians must be designated to operate the laboratory. The designated physician is responsible for actual supervision and direct responsibility for the performance of the laboratory and its personnel which includes, but is not limited to, actual supervision and direct responsibility for quality assurance, quality control, and test management; and
 - 3. The tests performed in the laboratory are used only for diagnosis and/or treatment of patients of the individual or group practice and are maintained in the practice's medical records for the patients for whom the test were performed.
 - (b) In the case of a medical/physician group practice, proof of affiliation with the group practice must be maintained at all offices in which the laboratory is not physically located and produced upon request by an authorized agent of the Department.
 - (c) Industrial or company physician practices, student health services and other arrangements in which a licensed physician is responsible for the continuing care of a group of patients on an ongoing basis will be designated to be POLs.

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

Legal Contact: Robert J. Kraemer, Jr., Deputy General Counsel, Office of General Counsel, 26th Floor, William R. Snodgrass Tennessee Tower, 312 Eighth Avenue North, Nashville, TN 37247-0120, (615) 741-1611.

Contact for disk acquisition and/or party 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.

Signature of the agency officer or officers directly responsible for proposing and/or drafting these rules:


 Linda Lahr, Chair
 Tennessee Medical Laboratory Board

The roll call vote by the Tennessee Medical Laboratory Board on these rulemaking hearing rules was as follows:

Board Members	Aye	No	Abstain	Absent
Thomasa Cooper	<u>X</u>	___	___	___
Norman Crowe	<u>X</u>	___	___	___
Yvonne Davis	<u>X</u>	___	___	___
Martha Duncan	<u>X</u>	___	___	___
Linda Lahr	<u>X</u>	___	___	___
Alison K. McDonald-Spakes	<u>X</u>	___	___	___
Trudy A. Papuchis, M.D.	<u>X</u>	___	___	___
Delores W. Voigt	<u>X</u>	___	___	___
Dennis C. Carter, M.D.	___	___	___	<u>X</u>
Jere Ferguson, M.D.	<u>X</u>	___	___	___
Edward McDonald, M.D.	<u>X</u>	___	___	___
John C. Neff, M.D.	<u>X</u>	___	___	___
Gloria L. Jenkins	<u>X</u>	___	___	___

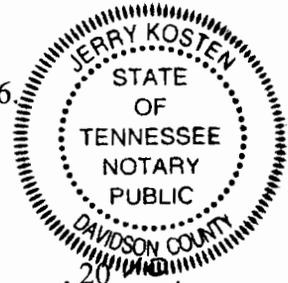
I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Tennessee Medical Laboratory Board on the 13th day of April, 2006.

Further, I certify that the provisions of T.C.A. § 4-5-222 have been fully complied with, that these rules are properly presented for filing, a notice of rulemaking hearing has been filed in the Department of State on the 13th day of January, 2006 and such notice of rulemaking hearing having been published in the February 15th, 2006 issue of the Tennessee Administrative Register, and such rulemaking hearing having been conducted pursuant thereto on the 17th day of March, 2006.

[Signature]
Robbie H. Bell, Director
Health Related Boards

Subscribed and sworn to before me this the 13th day of April, 2006

[Signature]
Notary Public



My commission expires on the 20th day of MARCH, 2007.

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

[Signature]
Robert E. Cooper, Jr.
Attorney General and Reporter

The rulemaking hearing rules set out herein were properly filed in the Department of State on the 27th day of December, 2006, and will become effective on the 12th day of MARCH, 2007.

[Signature]
Riley C. Darnell
Secretary of State

By: [Signature]

2006 DEC 27 PM 4: 12