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Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing. TCA Section 4-5-205

Agency/Board/Commission:	Department of Health
Division:	Division of Laboratory Licensing
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Revision Type (check all that apply):

- Amendment
 New
 Repeal

Rule(s) Revised (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables. Please enter only ONE Rule Number/Rule Title per row)

Chapter Number	Chapter Title
1200-06-01	General Rules Governing Medical Laboratory Personnel
Rule Number	Rule Title
1200-06-01-.12	Continuing Education
1200-06-01-.22	Qualifications, Responsibilities and Duties of Testing Personnel

Chapter Number	Chapter Title
1200-06-02	Training Programs for Medical Laboratory Personnel
Rule Number	Rule Title
1200-06-02-.08	Advertising

Chapter Number	Chapter Title
1200-06-03	General Rules Governing Medical Laboratories
Rule Number	Rule Title
1200-06-03-.20	Advertising

Amendments
Chapter 1200-06-01
General Rules Governing Medical Laboratory Personnel
Chapter 1200-06-02
Training Programs for Medical Laboratory Personnel
Chapter 1200-06-03
General Rules Governing Medical Laboratories

Rule 1200-06-01-.12 Continuing Education is amended by deleting paragraph (4) in its entirety and substituting instead the following language, and is further amended by adding the following language as new subparagraph (6)(e), so that as amended, the new paragraph (4) and the new subparagraph (6)(e) shall read:

- (4) Continuing Education Formats
 - (a) Continuing education courses may be presented in the traditional lecture and classroom formats or, with successful completion of a written post experience examination to evaluate material retention, in multi-media and/or electronic formats.
 - (b) Notwithstanding the provisions of subparagraph (4)(a), if a continuing education course includes a laboratory experience as a component of the course, the laboratory experience must occur at or be provided by a CLIA-approved site or an accredited college or university.
- (6) (e) Unless the licensee has actively practiced in another state while the licensee's Tennessee license has been retired, revoked or expired, then no more than one-half of the required continuing medical education for licensure reinstatement or reactivation shall be taken via the Internet, in multi-media and/or electronic formats as provided in subparagraph (4) (a).

Authority: T.C.A. § 68-29-105.

Rule 1200-06-01-.22 Qualifications Responsibilities and Duties of Testing Personnel is amended by adding the following language as new subparts (1)(h)4. and (1)(h)5.:

- 4. Only the laboratory experience which occurs at a CLIA-approved site or at an accredited college or university.
- 5. Only the laboratory experience which has been properly documented to the Board's satisfaction.

Authority: T.C.A. §§ 68-29-105 and 68-29-118.

Rule 1200-06-02-.08 Advertising is amended by inserting the following language as new paragraph (6) and renumbering the existing paragraph (6) as paragraph (7):

- (6) Use of Titles in Advertisements. Any medical laboratory training program licensed by the Board which includes in its advertisements the names of its laboratory personnel must, in every "advertisement" [as that term is defined in rule 1200-06-02-.08(2)(a)] it publishes, use an appropriate personnel title for each such licensee as authorized by rule 1200-06-01-.03(3) of this rule. Failure to do so may constitute an omission of a material fact which makes the advertisement misleading and deceptive and subjects the medical laboratory training program to disciplinary action pursuant to T.C.A. § 68-29-126(9), 68-29-126(11), 68-29-126(13), 68-29-127(8), 68-29-127(9), 68-29-127(10), and/or 68-29-129(8).

Authority: T.C.A. §§ 63-1-145, 63-1-146, 68-29-105, 68-29-126, 68-29-127, and 68-29-129.

Rule 1200-06-03-.20, Advertising, is amended by inserting the following language as new paragraph (6) and renumbering the existing paragraph (6) as paragraph (7):

- (6) Use of Titles in Advertisements. Any medical laboratory licensed by the Board which includes in its advertisements the names of its laboratory personnel must, in every "advertisement" [as that term is defined in rule 1200-06-03-.20(2)(a)] it publishes, use an appropriate personnel title for each such licensee as authorized by rule 1200-06-01-.03(3) of this rule. Failure to do so may constitute an omission of a material fact which makes the advertisement misleading and deceptive and subjects the medical laboratory to disciplinary action pursuant to T.C.A. § 68-29-126(9), 68-29-126(11), 68-29-126(13), 68-29-127(8), 68-29-127(9), 68-29-127(10), and/or 68-29-129(8).

Authority: T.C.A. §§ 63-1-145, 63-1-146, 68-29-105, 68-29-126, and 68-29-129.

* If a roll-call vote was necessary, the vote by the Agency on these rulemaking hearing rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Darius Wilson	X				
Norman Crowe	X				
Yvonne Davis	X				
Christopher H. Seay	X				
Gloria L. Jenkins				X	
Alison K. McDonald-Spakes	X				
Trudy A. Papuchis, M.D.	X				
Delores W. Voigt	X				
Jere Ferguson, M.D.	X				
John C. Neff, M.D.	X				
Annie Washington	X				
Dennis Carter, M.D.				X	
Edward McDonald, M.D.				X	

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 10/09/2008, and is in compliance with the provisions of TCA 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 07/29/2008

Notice published in the Tennessee Administrative Register on: 08/15/2008

Rulemaking Hearing(s) Conducted on: (add more dates). 10/09/2008

Date: 3/6/09

Signature: Ernest Sykes, Jr.

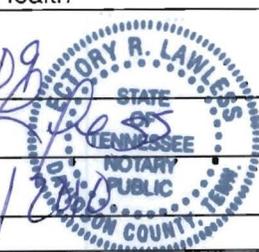
Name of Officer: Ernest Sykes, Jr.
Assistant General Counsel

Title of Officer: Tennessee Department of Health

Subscribed and sworn to before me on: 3/6/09

Notary Public Signature: [Signature]

My commission expires on: 1/23/2010



My Commission Expires JAN. 23, 2010

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.

RE Cooper, Jr.
Robert E. Cooper, Jr.
Attorney General and Reporter

4-19-20
Date

Department of State Use Only

Filed with the Department of State on: 4/22/10

Effective on: 7/21/10

Tre Hargett

Tre Hargett
Secretary of State

Public Hearing Comments

One copy of a document containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A. §4-5-222. Agencies shall include only their responses to public hearing comments, which can be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

COMMENTS AND BOARD RESPONSE:

At the October 9, 2008 rulemaking hearing of these rules, the Medical Laboratory Board received and responded to comments, both written and verbal, from Dr. David L. Smalley, Director of the Department of Health's Division of Laboratory Services and Ms. Sean O'Connell, State Training Coordinator for the Department of Health's Division of Laboratory Services.

Dr. Smalley conveyed his and the Public Health Laboratory Advisory Committee's objections to the rule amendment's cap on the amount of multimedia education hours which are acceptable for CE credit for certain reinstatement applicants. Dr. Smalley suggested instead that the Board place no restrictions on the amount of required CE that could be obtained online or other electronic formats, as opposed to in-person classroom settings. Ms. O'Connell made substantially the same comments as Dr. Smalley.

Specifically, Dr. Smalley and Ms. O'Connell recommended that the Board delete that phrase "no more than one-half of the continuing education of" from proposed rule 1200-1-.12(6)(e), which reads:

Unless the licensee has actively practiced in another state while the licensee's Tennessee license has been retired, revoked or expired, then no more than one-half of the required continuing medical education for licensure reinstatement shall be taken via the Internet, in multi-media and/or electronic formats as provided in subparagraph (4) (a).

Dr. Smalley's argument rested on the points that on-line and other forms of distance learning are increasingly prevalent throughout education, and that such courses are more affordable than traditional lecture formats because they require no travel expenses.

The Board unanimously declined to incorporate Dr. Smalley and Ms. O'Connell's recommended rule change. In responding to Dr. Smalley's comments, the Board noted that the on-line CE cap would apply only to those reinstatement applicants who have not been actively practicing in the medical laboratory field and whose skills and/or knowledge are therefore presumed to be somewhat "rusty." The Board members felt that requiring such reinstatement applicants to obtain at least one-half of their reinstatement continuing education credits in person was a reasonable requirement in that it would ensure that such applicants have polished their skills and knowledge base sufficiently and in a manner which best protects the health care consumers of Tennessee. The Board also felt that any economic hurdles which the in-person CE requirement might conceivably entail for such applicants would be minimal and would be more than off-set by the benefits of traditional educational formats. The Board also noted in responding to Dr. Smalley's and Ms. O'Connell's comments that similar – indeed, frequently more onerous – in-person CE requirements are in place for most if not all other Tennessee health care professionals, as well as other types of licensed Tennessee professionals.

Regulatory Flexibility Addendum

Pursuant to Public Chapter 464 of the 105th General Assembly, prior to initiating the rule making process as described in § 4-5-202(a)(3) and § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

(If applicable, insert Regulatory Flexibility Addendum here)

Regulatory flexibility analysis

Tennessee medical laboratory board; rule nos. 1200-6-1-.12, .22, 1200-6-2-.08, 1200-6-3-.20.

Pursuant to the Regulatory Flexibility Act of 2007, T.C.A. §§ 4-5-401, *et seq.*, the Department of Health submits the following regulatory flexibility analysis:

- (1) The proposed rule amendment does not overlap, duplicate, or conflict with other federal, state, and local governmental rules.
- (2) The proposed rule amendment exhibits clarity, conciseness, and lack of ambiguity.
- (3) The proposed rule amendment clarifies existing licensure requirements pertaining to advertising and training requirements, and it mandates that certain reinstatement applicants must obtain a greater percentage of their CE credits through traditional in-person formats rather than on-line. The proposed rules thereby very slightly reduce the flexible compliance or reporting requirements for former licensed medical laboratory personnel who apply to reinstate their Tennessee licensure. The Department of Health and the Tennessee Medical Laboratory Board believe that this is necessary to better protect the health and safety of the citizens of the state.
- (4) The proposed rule amendment does not affect any schedules or deadlines for compliance and/or reporting requirements for small businesses.
- (5) The proposed rule amendment does not affect compliance or reporting requirements for small businesses.
- (6) The proposed rule amendment does not establish performance standards for small businesses as opposed to design or operational standards; and
- (7) The proposed rule amendment ensures that all medical laboratory personnel reinstatement applicants will have a sufficient amount and type of continuing education to ensure that they are up-to-date with the ever evolving technological improvements that characterize this industry. The Department of Health and the Medical Laboratory Board believe that this requirement that a certain percentage continuing education must be via traditional, in-person formats better serves the interest of public health, and that it does so without causing a meaningful entry barrier for former practitioners who are looking to reinstate their practices.

STATEMENT OF ECONOMIC IMPACT TO SMALL BUSINESSES

Tennessee Medical Laboratory Board; Rule Nos. 1200-6-1-.12, .22, 1200-6-2-.08, 1200-6-3-.20.

1. Name of Board, Committee or Council: Tennessee Medical Laboratory Board

2. Rulemaking hearing date: October 9, 2008

3. Types of small businesses that will be directly affected by the proposed rules:

These rule changes affect licensed medical laboratories, licensed medical laboratory personnel, and the various types of health care facilities in which labs are located. Those types of business entities can include nursing homes, hospitals and independent medical laboratories.

The rule changes also might minimally affect CE course providers.

4. Types of small businesses that will bear the cost of the proposed rules:

The rule changes might minimally impact individuals who have allowed their medical lab personnel licenses to lapse, in that the rule changes cap the number of CE hours which certain reinstatement applicants may obtain online. That said, there are numerous options for traditional lecture and/or laboratory format CE courses that would all but completely mitigate any such economic hardship.

The rule changes mandate the use of certain title(s) in all advertisements for professional services by licensed medical laboratories and licensed laboratory personnel. It is possible that such requirement could entail printing expenses for some businesses.

5. Types of small businesses that will directly benefit from the proposed rules:

The rule changes might minimally benefit businesses which provide CE in the traditional lecture and/or laboratory (rather than multi-media) format. That is so because under the new rules certain reinstatement applicants must obtain a greater percentage of their CE credits through such traditional formats. That said, any such impact would likely be mitigated by the fact that many CE providers put on courses in both traditional and multi-media formats.

6. Description of how small business will be adversely impacted by the proposed rules:

The rule changes might minimally impact small businesses that house and/or run medical laboratories, in that the rule changes mandate the use of certain title(s) in all advertisements for professional services by licensed medical laboratories and such facility's licensed lab personnel. It is possible that the new "titles" requirement could entail printing expenses for some businesses.

The rule changes also might very minimally impact small businesses which provide CE courses via the Internet or other multi-media formats. That is so because under the new rules certain reinstatement applicants must obtain a greater percentage of their CE credits through traditional in-person formats rather than on-line. That said, any such impact would likely be mitigated by the fact that many CE providers put on courses in both traditional and multi-media formats.

7. Alternatives to the proposed rule that will accomplish the same objectives but are less burdensome, and why they are not being proposed:

The Medical Laboratory Board does not believe there are less burdensome alternatives to the proposed rule amendments.

8. Comparison of the proposed rule with federal or state counterparts:

- Federal: The Medical Laboratory Board is not aware of any federal counterparts that directly regulate the advertising requirements and/or CE requirements of licensed medical labs and/or medical lab personnel. CMS' Clinical Laboratory Improvement Amendments (CLIA) is a federal scheme by which labs are certified and accredited, but it does not purport to regulate CE requirements, advertising, or personnel training requirements. Such regulation is up to the various States, and in Tennessee is properly regulated by the Medical Laboratory Board.
- State: The proposed rule amendments will have no state counterpart because the Medical Laboratory Board is the only agency charged with regulating this class of health care facility and its licensed lab personnel.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to TCA 4-5-226(i)(1).

- (A)** A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

The proposed rule amendment clarifies existing licensure requirements pertaining to advertising and training requirements, and it mandates that certain reinstatement applicants must obtain a greater percentage of their CE credits through traditional in-person formats rather than on-line. The proposed rules thereby very slightly reduce the flexible compliance or reporting requirements for former licensed medical laboratory personnel who apply to reinstate their Tennessee licensure.

- (B)** A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

None known.

- (C)** Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

Medical laboratory personnel and medical laboratories would be the most affected.

Dr. David L. Smalley, Director of the Department of Health's Division of Laboratory Services and Ms. Sean O'Connell, State Training Coordinator for the Department of Health's Division of Laboratory Services, suggested removal of the cap which these rules place on multi-media CE hours for certain reinstatement applicants.

- (D)** Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule;

None known.

- (E)** An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars (\$500,000), whichever is less;

No impact expected on government revenues or expenditures.

- (F)** Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Ernest Sykes, Jr., Assistant General Counsel, Tennessee Department of Health

- (G)** Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Ernest Sykes, Jr., Assistant General Counsel, Tennessee Department of Health

- (H)** Office address and telephone number of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Tennessee Department of Health, Office of General Counsel; Plaza One, Suite 210; 220 Athens Way; Nashville, TN 37243

- (I)** Any additional information relevant to the rule proposed for continuation that the committee requests.

(Rule 1200-06-01-.11, continued)

(c) Submit evidence of successful completion of the continuing education requirements pursuant to Rule 1200-06-01-.12.

(4) Licensure reactivation applications shall be treated as licensure applications and review and decisions shall be governed by Rule 1200-06-01-.07.

Authority: T.C.A. §§4-5-202, 4-5-204, 63-1-111, 68-29-105, and 68-29-119. **Administrative History:** Original rule filed September 9, 1996; effective November 23, 1996. Amendment filed August 8, 2005; effective October 22, 2005.

1200-06-01-.12 CONTINUING EDUCATION. Continuing education is planned, organized learning acts acquired during licensure to maintain, improve or expand a licensee's knowledge and skills relevant to medical laboratory practice in order for the licensee to develop new knowledge and skills relevant to the practice, education or theory development to improve the safety and welfare of the public.

(1) Basic requirements – Beginning January 1, 2006, the Tennessee Medical Laboratory Board requires each licensee to successfully complete twenty-four (24) hours of approved continuing education pertaining to laboratory technology or laboratory management for the two (2) calendar year (January 1-December 31) period that precedes the licensure renewal year.

(a) The following organizations, entities, and their affiliates and chapters are authorized to present, sponsor, or approve continuing education courses:

1. American Association of Blood Banks.
2. American Board of Bioanalysis.
3. American Board of Clinical Chemistry.
4. American Board of Histocompatibility and Immunogenetics.
5. American Board of Medical Genetics.
6. American Board of Medical Laboratory Immunology.
7. American Board of Medical Microbiology.
8. American Board of Oral and Maxillofacial Pathology.
9. American Board of Pathology.
10. American College of Health Care Executives.
11. American Medical Association.
12. American Medical Technologists (AMT).
13. American Osteopathic Board of Pathology.
14. American Red Cross.
15. American Society for Clinical Laboratory Science.
16. American Society for Clinical Pathologists (ASCP).

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(Rule 1200-06-01-.12, continued)

17. American Society of Cytopathology.
18. American Society for Cytotechnology.
19. American Society for Microbiology.
20. Center for Phlebotomy Education.
21. Centers for Disease Control.
22. Centers for Medicare and Medicaid Services.
23. Clinical Laboratory Management Association.
24. Clinical and Laboratory Standards Institute (CLSI).
25. College of American Pathologists.
26. Greater Memphis Association of Blood Banks.
27. International Academy of Cytology.
28. National Credentialing Agency for Medical Laboratory Professionals (NCA).
29. National Laboratory Training Network (NLTN).
30. Southern Association of Clinical Microbiologists.
31. Southern Association of Cytotechnologists.
32. Tennessee Association of Blood Banks.
33. Tennessee Department of Health.
34. Tennessee Hospital Association.
35. Tennessee Medical Association.
36. Tennessee Professional Assistance Program (TN-PAP) or any Board-approved peer assistance program.
37. Tennessee Society of Pathologists.
38. Tennessee State Society of American Medical Technologists.
39. Accredited colleges and universities.
40. Hospitals licensed by the Tennessee Department of Health, Division of Health Care Facilities.
41. Laboratories, blood donor centers, plasmapheresis centers, ambulatory surgical treatment centers, and collection stations licensed by the Board whose continuing education courses have been approved by the medical laboratory director or his/her designee.

(Rule 1200-06-01-.12, continued)

42. Organizations and entities approved by other state laboratory personnel licensing agencies.
 43. Organizations and entities approved as P.A.C.E.[®] (Professional Acknowledgment for Continuing Education) course providers.
- (b) Continuing education credit for preparing and teaching continuing education courses – Credit may be earned by preparing and teaching a course presented, sponsored, or approved by an organization or entity listed in subparagraph (a). Documentation of preparing and teaching continuing education courses shall be required as provided in paragraph (3).
1. Courses that were prepared by developing thorough, high quality, readable and carefully prepared written materials will qualify for continuing education credit on the basis of four (4) hours of credit for each hour taught.
 2. Courses that were prepared by developing less than five (5) pages of outlines, or not accompanied by written materials, will qualify for continuing education credit on the basis of two (2) credits for each hour taught.
 3. Repeat courses qualify for one-half (½) of the credits awarded for the initial course.
 4. On-site commentators at multi-media courses will receive credit at the rate of two (2) hours for each hour of the program if they have either viewed the course in advance or otherwise engaged in preparation appropriate to the role of commentator.
 5. Each teacher involved in a joint or panel portion of an approved activity shall receive credit as though he or she were the only teacher.
 6. No more than eight (8) hours of continuing education credit shall be awarded for preparing and teaching continuing education courses during any two (2) calendar year period.
- (c) Continuing education credit for published articles – Four (4) hours credit may be earned by preparing and writing an article pertaining to laboratory technology or laboratory management that is published in a peer review journal.
- (d) Continuing education credit will be assigned on the following basis:
1. Any single session lasting not less than two and one-half (2½) clock hours will be assigned three (3) hours of continuing education credit.
 2. Any single session lasting not less than one (1) clock hour and forty (40) clock minutes will be assigned two (2) hours of continuing education credit.
 3. Any single session lasting not less than fifty (50) clock minutes will be assigned one (1) hour of continuing education credit.
 4. The hours assigned shall be based on actual instruction or program time, excluding registration time and breaks, but including question and answer time.

(2) New licensee requirements

(Rule 1200-06-01-.12, continued)

- (a) Continuing education is not required until the new licensee has twenty-four (24) months to successfully complete the two (2) calendar year requirement.
- (b) The continuing education that may be required to become licensed as a medical laboratory supervisor or as a cytology general supervisor, as provided in Rules 1200-06-01-.21 and 1200-06-01-.23 shall not count towards completion of the reoccurring continuing education required by this rule.

(3) Documentation

- (a) Each licensee must retain proof of attendance and completion of all continuing education requirements for a period of three (3) years from the end of the two (2) calendar year period in which the continuing education was required. This documentation must be produced for inspection and verification, if requested in writing by the Board during its verification process. The Board will not maintain continuing education files for individual licensees.
- (b) The individual must, within thirty (30) days of a request from the board, provide evidence of continuing education activities. Such evidence must be by submission of one (1) or more of the following:
 - 1. Photocopies of certificates verifying the licensee's attendance at continuing education program(s). The certificate photocopies must include the following: continuing education program's provider, date, clock hours awarded (continuing education units must be converted to clock hours), program title, and licensee's name.
 - 2. Photocopies of original letters on official stationery from the continuing education program's provider indicating, date, clock hours awarded (continuing education units must be converted to clock hours), program title, and licensee's name.
 - 3. Photocopies of certificates or letters verifying successful completion of a written post experience examination to evaluate material retention upon completion of a multi-media and/or electronic course, as provided in paragraph (4). The certificate or letter photocopies must include the clock hours awarded (continuing education units must be converted to clock hours), program title, and licensee's name.
 - 4. Preparing and teaching continuing education courses [subparagraph (1) (b)] – A letter from the education director, laboratory director, department head, dean of the institution, or officer of the approved organization attesting that the course was presented and including time spent in classroom, date and location of course presentation, course title, and licensee's name; and
 - (i) Copy of written course materials or course outline; or
 - (ii) Copy of summary of on-site commentary at multi-media courses.
 - 5. Published articles [subparagraph (1) (c)] – Copies of published articles.
- (c) If a licensee submits documentation for training that is not clearly identifiable as appropriate continuing education, the Board will request a written description of the training and its applicability. If the Board determines that the training can not be considered appropriate continuing education, the individual will be given ninety (90) days to replace the hours not allowed. Those hours will be considered replacement

(Rule 1200-06-01-.12, continued)

hours and cannot be counted toward completion of any other continuing education requirement.

~~(4) Continuing Education Formats — Continuing education courses may be presented in the traditional lecture and classroom formats or, with successful completion of a written post experience examination to evaluate material retention, in multi-media and/or electronic formats.~~

(4) Continuing Education Formats

- (a) Continuing education courses may be presented in the traditional lecture and classroom formats or, with successful completion of a written post experience examination to evaluate material retention, in multi-media and/or electronic formats.
- (b) Notwithstanding the provisions of subparagraph (4)(a), if a continuing education course includes a laboratory experience as a component of the course, the laboratory experience must occur at or be provided by a CLIA-approved site or an accredited college or university.

(5) Continuing education credit will not be allowed for the following:

- (a) Membership in, holding office in, or participation on boards or committees, business meetings of professional organizations, or banquet speeches.
- (b) Regular work activities, administrative staff meetings, case staffing/reporting, etc., except as provided in subparagraph (1) (b).

(6) Continuing Education for Reactivation or Reinstatement of Retired, Revoked, or Expired License.

- (a) Reactivation of Retired Licensure - An individual whose license has been retired for two (2) years or less will be required to fulfill continuing education requirements as outlined in this rule.
- (b) Reinstatement of Revoked Licensure – No person whose license has been revoked for failure to comply with continuing education may be reinstated without complying with these requirements. Continuing education requirements will accumulate at the same rate as that for those licenses which are active. The required clock hours of continuing education must have begun and been successfully completed before the date of reinstatement.
- (c) Reinstatement of Expired Licensure – No person whose license has expired may be reinstated without submitting evidence of continuing education. The continuing education hours documented at the time of reinstatement must equal the hours required, had the license remained in an active status, and must have begun and been successfully completed before the date of reinstatement.
- (d) Continuing education hours obtained as a prerequisite for reactivating or reinstating a license may not be counted toward completion of any current two (2) calendar year requirement.
- (e) Unless the licensee has actively practiced in another state while the licensee's Tennessee license has been retired, revoked or expired, then no more than one-half of the required continuing medical education for licensure reinstatement or reactivation shall

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(Rule 1200-06-01-.12, continued)

be taken via the Internet, in multi-media and/or electronic formats as provided in subparagraph (4) (a).

(7) Violations

- (a) Any licensee who falsely certifies attendance and completion of the required hours of continuing education requirements, or who does not or can not adequately substantiate completed continuing education hours with the required documentation, may be subject to disciplinary action.
- (b) Prior to the institution of any disciplinary proceedings, a letter shall be issued to the last known address of the individual stating the facts or conduct which warrant the intended action.
- (c) The licensee has thirty (30) days from the date of notification to show compliance with all lawful requirements for the retention of the license.
- (d) Any licensee who fails to show compliance with the required continuing education hours in response to the notice contemplated by subparagraph (b) may be subject to disciplinary action.
- (e) Continuing education hours obtained as a result of compliance with the terms of a Board Order in any disciplinary action shall not be credited toward any continuing education requirement.

(8) Deadline Extension of Continuing Education Requirements

- (a) The Board may grant for no more than six (6) months an extension of the deadline to complete the required hours of continuing education if it can be shown that compliance was beyond the physical or mental capabilities of the licensee seeking the deadline extension.
- (b) Extension of the deadline will be considered only on an individual basis and may be requested by submitting the following items to the Board's administrative office:
 - 1. A written request for a deadline extension which specifies which deadline is sought to be extended and a written and signed explanation of the reason for the request; and
 - 2. Any documentation which supports the reason(s) for the deadline extension requested or which is subsequently requested by the Board.
- (c) A deadline extension approved by the Board is effective only for the two (2) calendar year period for which the deadline extension is sought.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, and 68-29-119. **Administrative History:** Original rule filed August 8, 2005; effective October 22, 2005. Amendment filed April 17, 2007; effective July 1, 2007. Amendment filed April 1, 2009; effective June 15, 2009.

1200-06-01-.13 TEMPORARY LICENSE.

(Rule 1200-06-01-.12, continued)

- (1) Applicants who have applied and are approved pursuant to Rule 1200-06-01-.05 to challenge a specific national certification examination and meet the minimum education and/or experience requirements as described in Rule 1200-06-01-.22 will be issued a temporary license by the Board administrative office upon approval.
- (2) No application other than required by Rule 1200-06-01-.05 is required.
- (3) Individuals who possess a state laboratory personnel license in one category will not be eligible for a temporary license in a different category.
- (4) The validity and duration of temporary licenses shall be governed by T.C.A. § 68-29-117 (d).

Authority: T.C.A. §§4-5-202, 4-5-204, 68-29-105, and 68-29-117. **Administrative History:** Original rule filed September 9, 1996; effective November 23, 1995. Amendment filed March 4, 1998; effective May 20, 1998. Amendment filed March 16, 2007; effective May 30, 2007.

1200-06-01-.14 TRAINEE PERMITS.

- (1) Each trainee must submit a trainee application when he begins his practice training in a medical laboratory.

3. The management and technical hours submitted for continuing education must be completed subsequent to qualifying as a medical technologist or special analyst as defined in subparagraph (1) (c).
 4. Proof of attendance must be documented and submitted with all continuing education.
- (2) Duties. The medical laboratory supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.
- (a) The medical laboratory supervisor -
1. Must be a full-time employee of the facility and be on the laboratory premises during the regular working day. The employee must be readily available for personal or telephone consultations during all other hours when tests are performed.
 2. Must be responsible for providing day-to-day supervision of test performance by testing personnel.
 3. Must be responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.
- (b) The medical laboratory director 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:
1. Assuring that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;
 2. Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is properly functioning;
 3. Providing orientation to all testing personnel, and
 4. Annually evaluating and documenting the performance of all testing personnel.

Authority: T.C.A. §§4-5-202, 4-5-204, 68-29-103, 68-29-104, 68-29-105, 68-29-116, and 68-29-118.
Administrative History: Original rule filed May 3, 1995; effective July 17, 1995. Amendment filed September 11, 1996; effective November 25, 1996. Amendment filed August 25, 2003; effective November 8, 2003. Amendment filed February 15, 2006; effective May 1, 2006.

1200-06-01-.22 QUALIFICATIONS, RESPONSIBILITIES AND DUTIES OF TESTING PERSONNEL.

(Rule 1200-06-01-.22, continued)

- (1) Qualifications. All testing personnel must hold a valid Tennessee license issued by the Board to perform or report a laboratory test.
 - (a) To become licensed as a medical laboratory technologist an applicant must:
 1. Submit satisfactory evidence of successfully completing and passing a national certifying examination and being nationally certified at the technologist level by either the ASCP, NCA, NRCC, NRM, ABB, AMT or any other national certifying agency recognized by the Board (Successful completion of the Health and Human Services proficiency examination in clinical laboratory science does not meet this criteria for licensure); and
 2. In addition to possessing the national certification required by part 1. of this subparagraph, submit satisfactory evidence of having met one (1) of the following educational criteria:
 - (i) A baccalaureate degree in medical technology or in one of the biological, chemical or physical sciences, and completion of a medical laboratory technologist training program that was, at the time of graduation, either
 - (I) approved or under the auspice of the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS); or
 - (II) approved by a national accrediting agency acceptable to the Board; or
 - (III) completed in a specialty program conducted by a hospital or other institution approved pursuant to Rule 1200-06-02-.04; or
 - (ii) A baccalaureate degree from an accredited college/university, completion of an accredited MLT/CLT training program and three (3) years of full time clinical laboratory work experience as defined in subparagraph (1) (h); the individual must have completed science coursework equivalent to that required in a laboratory science education program as defined by subparagraph (1) (g); or
 - (iii) A baccalaureate degree from an accredited college/university, completion of an official military laboratory procedures course of at least fifty (50) weeks duration in residence and have held the military enlisted occupational specialty of Medical Laboratory Specialist, and three (3) years of full time clinical laboratory work experience as defined in subparagraph (1) (h); the individual must have completed science coursework equivalent to that required in a laboratory science education program as defined by subparagraph (1) (g); or
 - (iv) A baccalaureate degree from an accredited college/university and five (5) years of full time clinical laboratory work experience as defined in subparagraph (1) (h); the individual must have completed science coursework equivalent to that required in a laboratory science education program as defined by subparagraph (1) (g).
 - (b) Those applicants for medical laboratory technologist licensure who do not possess a baccalaureate degree may be approved for licensure upon having submitted to the Board's administrative office directly from the national certifying agency satisfactory proof of having successfully completed on or before September 1, 1997 (the date on

(Rule 1200-06-01-.22, continued)

which CLIA required at a minimum an associate's degree or its equivalent for those who would be performing high complexity testing and the date on which the Board ceased providing the state licensure examination) a medical laboratory technologists national certification examination and submission to the Board's administrative office directly from the issuing authorities of satisfactory proof that the applicant met one (1) of the following criteria:

1. The applicant had, on or before September 1, 1997, received a passing grade on a Health and Human Services proficiency examination in clinical laboratory science and had completed five (5) years of full time clinical laboratory work experience as defined in subparagraph (1) (h); or
2. The applicant had, on or before September 1, 1997, completed a minimum of ninety (90) semester hours including science course work equivalent to that required in a laboratory science education program as defined by (1) (g) of this rule; and had, on or before September 1, 1997, completed a medical laboratory technologist training program that was approved at the time of graduation by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) or a national accrediting agency acceptable to the Board.

(c) To become licensed as a medical laboratory technician an applicant must:

1. Submit satisfactory evidence of successfully completing and passing a national certifying examination and being nationally certified at the technician level; and
2. In addition to possessing the national certification required by part 1. of this subparagraph, submit satisfactory evidence of one (1) of the following educational criteria:
 - (i) Having received an associate degree from an accredited college/university and having completed an accredited medical laboratory technician training program that was approved at the time of graduation by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) or a national accrediting agency acceptable to the Board; or
 - (ii) Having received an associate degree from an accredited college/university and having completed an official military laboratory procedures course of at least fifty (50) weeks duration in residence and having held the military enlisted occupational specialty of Medical Laboratory Specialist; or
 - (iii) An associate degree from an accredited college/university which included at least six (6) semester hours of chemistry and six (6) semester hours of biology and three (3) years of full time clinical laboratory work experience as defined in subparagraph (1)(h).

(d) A medical laboratory technologist may obtain a license in any of the following categories: chemistry, hematology, immunohematology, or microbiology. The applicant must:

1. Present proof of national certification by a certifying body acceptable to the Board in the laboratory specialty in which licensure is being sought at the technologist level; and
2. Meet one of the additional qualifications referred to in subparagraph (1) (a).

(Rule 1200-06-01-.22, continued)

- (e) An individual may be issued a special analyst license to perform tests in only a limited range (as listed on the license) if the procedure(s) for which licensure is being sought is a new, emerging technology in the clinical laboratory or represents a subspecialty not otherwise regulated. The procedure(s) must not be a component of the traditional clinical laboratory science body of knowledge contained in chemistry, hematology, microbiology or immunohematology; and
1. The individual must be certified by a national certification body approved by the Board, where such certification or qualification exists and must possess a baccalaureate degree from an accredited college/university relevant to the subspecialty in which licensure is being sought, or
 2. In the absence of national certification the individual must possess at least a baccalaureate degree from an accredited college/university relevant to the subspecialty in which licensure is being sought and proof of three (3) years of relevant work experience as approved by the Board. The Board shall approve all individuals qualifying in this manner. Individuals must obtain national certification at such time as it becomes available and must request that proof of said national certification be sent directly to the Board's administrative office from the certifying agency in order to continue licensure. Failure to obtain national certification shall result in revocation of the license.
- (f) Testing personnel performing blood gas (pCO₂, pO₂, and pH) analysis and co-oximetry analysis (measurement of oxygen saturation) and reporting of the measurement(s) to include carboxyhemoglobin, total hemoglobin, methemoglobin, and oxyhemoglobin and sulfhemoglobin on automated instruments shall:
1. Hold a valid laboratory license permitting performance of tests in the chemistry specialty, or
 2. Hold a valid license as a special analyst limited to blood gases, or
 3. Hold a valid arterial blood gas (ABG) endorsement issued by the Board of Respiratory Care, pursuant to the Respiratory Care Practitioner Act and rules promulgated by that board.
- (g) The science coursework equivalent to that required in a laboratory science education program includes:
1. Sixteen (16) semester hours or twenty-four (24) quarter hours of chemistry which shall include one (1) full academic year of general chemistry courses including lectures and laboratory and one (1) course in organic chemistry or biochemistry including lectures and laboratory,
 2. Sixteen (16) semester hours or twenty-four (24) quarter hours of biological sciences. Microbiology is required, including lectures and laboratory, and
 3. Three (3) semester hours or six (6) quarter hours of mathematics.
 4. The college courses must be acceptable toward a major in those fields of study. Survey, audit, remedial, college level examination program, advanced placement, and clinical courses do not qualify as fulfillment of the chemistry, biology, or mathematics requirements.
- (h) Clinical laboratory work experience includes:

(Rule 1200-06-01-.22, continued)

1. That obtained in a medical laboratory which has a director at the doctoral level licensed under the Medical Laboratory Act and the regulations promulgated thereunder, or
2. That obtained in other laboratory facilities in which there is a director at the doctoral level and testing is done at least at a moderately complex level. The Board must approve these facilities for the purpose of clinical lab work experience.
3. For individuals seeking licensure in one of the following categories: chemistry, hematology, immunohematology, or microbiology, acceptable clinical laboratory work experience must be predominately in the category in which licensure is being sought.
4. Only the laboratory experience which occurs at a CLIA-approved site or at an accredited college or university.
5. Only the laboratory experience which has been properly documented to the Board's satisfaction.

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(2) Responsibilities and Duties of Testing Personnel

(a) Responsibilities and duties of the medical laboratory technologist include:

1. Collecting and preparing specimens for analysis. Storing or transporting specimens using appropriate preservation methods.
2. Following prescribed procedures, performing any of the tests within any of the laboratory specialties. Calculating the results of the tests performed if necessary.
3. Operating, calibrating, conducting performance checks, and maintaining any clinical laboratory instrument or equipment.
4. Recognizing and correcting basic instrument malfunctions. Notifying supervisory personnel when appropriate.
5. Preparing reagents or media from a prescribed procedure, making any adjustments needed.
6. Evaluating media, reagents, and calibrators according to established criteria.
7. Conducting established quality control procedures on analytical tests, equipment, reagents, media, and products; evaluating results of quality control and implements corrective action when indicated.
8. Determining performance specifications for new methods.
9. Establishing basic quality control procedures.
10. Performing comparison studies of precision, accuracy, linearity, cost, suitability, etc. on new or existing procedures and reporting results in an established format.

(Rule 1200-06-01-.22, continued)

11. Correlating and interpreting data based on knowledge of physiological conditions affecting test results. Assessing plausibility of laboratory results through correlation of data.
 12. Indicating the need for additional laboratory tests for definitive diagnostic information in prescribed instances.
 13. Confirming and verifying results through knowledge of techniques, principles, and instruments.
 14. Recognizing problems, identifying the cause, developing alternatives and determining solutions where no preset criteria are available.
 15. Establishing and monitoring quality assurance/continuous quality improvement programs,
 16. Establishing and monitoring safety programs in compliance with laboratory regulations.
 17. Maintaining records that demonstrate the proficiency testing samples are tested in the same manner as patient specimens.
 18. Utilizing laboratory information systems or other methods to accurately and effectively report patient results.
 19. Writing laboratory procedures conforming to standardized format.
 20. Performing clinical orientation and supervision for students and new or less skilled laboratory personnel.
 21. Reporting test results conforming to established procedures.
- (b) Responsibilities and duties of the medical laboratory technician include:
1. Collecting and preparing specimens for analysis. Storing and transporting specimens using appropriate preservation methods.
 2. Following prescribed methods, performing high volume, less difficult analytical tests in laboratory specialties.
 3. Making calculations as needed to report test results.
 4. Operating equipment or instruments necessary to perform high volume, less difficult analytical tests. Recognizing instrument malfunction and making simple corrections using preset strategies or notifying a technologist or supervisor.
 5. Preparing reagents and media according to prescribed procedures.
 6. Performing and recording all quality control procedures required for tests assayed. Recognizing unacceptable quality control results. Correcting problems according to preset strategies or notifies a technologist or supervisor.
 7. Recognizing abnormal or unusual test results and following institutional procedures for reporting critical values.
 8. Reporting test results conforming to established procedures.

(Rule 1200-06-01-.22, continued)

9. Performing and recording routine instrument checks and maintenance procedures.
 10. Performing inventory of supplies according to prescribed lists.
 11. Observing all established laboratory safety procedures.
 12. Participating in laboratory quality assurance/continuous quality improvement activities.
 13. Maintaining records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens.
- (c) Responsibilities and duties of the special analyst include:
1. Collecting and preparing specimens for analysis. Storing or transporting specimens using appropriate preservation methods.
 2. Following prescribed procedures, performing any of the tests within the laboratory specialty's designated by licensure.
 3. Operating, calibrating, conducting performance checks, and maintaining any clinical laboratory instrument or equipment in designated area.
 4. Recognizing and correcting basic instrument malfunctions. Notifying supervisory personnel when appropriate.
 5. Preparing reagents or media from a prescribed procedure, making any adjustments needed.
 6. Evaluating media, reagents, and calibrators according to established criteria.
 7. Conducting established quality control procedures on analytical tests, equipment, reagents, media, and products; evaluating results of quality control and implements corrective action when indicated.
 8. Determining performance specifications for new methods.
 9. Establishing basic quality control procedures.
 10. Performing comparison studies of precision, accuracy, linearity, cost, suitability, etc. on new or existing procedures and reporting results in an established format.
 11. Correlating and interpreting data based on knowledge of physiological conditions affecting test results. Assessing plausibility of laboratory results through correlation of data.
 12. Indicating the need for additional laboratory tests for definitive diagnostic information in prescribed instances.
 13. Confirming and verifying results through knowledge of techniques, principles, and instruments.
 14. Recognizing problems, identifying the cause, developing alternatives and determining solutions where no present criteria are available.

(Rule 1200-06-01-.22, continued)

15. Establishing and monitoring quality assurance/continuous quality improvement programs.
16. Establishing and monitoring safety programs in compliance with laboratory regulations.
17. Maintaining records that demonstrate the proficiency testing samples are tested in the same manner as patient specimens.
18. Utilizing laboratory information systems or other methods to accurately and effectively report patient results.
19. Writing laboratory procedures conforming to standardized format.
20. Performing clinical orientation and supervision for students and new or less skilled laboratory personnel.
21. Reporting test results conforming to established procedures.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-103, 68-29-105, and 68-29-118. **Administrative History:** Original rule filed May 3, 1995; effective July 17, 1995. Amendment filed September 9, 1996; effective November 23, 1996. Amendment filed January 7, 1997; effective March 23, 1997. Amendment filed March 25, 1997; effective June 6, 1997. Amendment filed March 4, 1998; effective May 20, 1998. Amendment filed August 23, 2001; November 6, 2001. Amendment filed January 31, 2003; effective April 16, 2003. Amendment filed August 25, 2003; effective November 8, 2003. Amendment filed April 17, 2007; effective July 1, 2007. Amendment filed April 1, 2009; effective June 15, 2009.

(Rule 1200-6-2-.07, continued)

- (f) Mathematics;
 - (g) Medical Terminology; and
 - (h) Phlebotomy
- (2) After completion of the appropriate training, the Public Health Clinic Laboratory Practitioner must competently:
- (a) Prepare and/or instruct a patient correctly for collection of laboratory specimens;
 - (b) Obtain specimens from patients, including specimens to be sent to referral laboratories, and process them according to acceptable procedures for the given test methodology;
 - (c) Record appropriate information that will correctly identify the patient and test performed, or referred, according to acceptable standards;
 - (d) Perform tests designated in Rule 1200-6-1-.25(4);
 - (e) Explain and perform quality control procedures appropriate for a Public Health Clinic Laboratory Practitioner. If quality control results are outside established limits, the Public Health Clinic Laboratory Practitioner must document that the appropriate corrective action has been taken before any test result is reported;
 - (f) Document quality control and instrument preventive maintenance according to acceptable standards;
 - (g) Demonstrate satisfactory performance on unknown sample(s);
 - (h) Follow safe laboratory practices to prevent infection and/or exposure to self and others; and
 - (i) Implement an appropriate inventory control system-
- (3) All Training will be performed by qualified instructors under the direction of the Training Section of the Tennessee Department of Health, Laboratory Services, 630 Hart Lane, Nashville, TN 37247-0801.

Authority: T.C.A. §§4-5-202, 4-5-204, 68-29-105, and 68-29-110. **Administrative History:** Original rule filed October 26, 1979; effective December 10, 1979. Repeal and new rule filed January 7, 1997; effective March 23, 1997.

1200-6-2-.08 ADVERTISING.

- (1) Policy Statement. The lack of sophistication on the part of many of the public concerning medical laboratory personnel training programs, the importance of the interests affected by the choosing of a medical laboratory personnel training program and the foreseeable consequences of unrestricted advertising by medical laboratory personnel training programs which is recognized to pose special possibilities for deception, require that special care be taken by medical laboratory personnel training programs to avoid misleading the public. Medical laboratory personnel training programs must be mindful that the benefits of advertising depend upon its reliability and accuracy. Since advertising by medical laboratory personnel training programs is calculated and not spontaneous, reasonable regulation designed to foster compliance with appropriate standards serves the public interest without impeding the flow of useful, meaningful, and relevant information to the public.
- (2) Definitions

(Rule 1200-6-2-.08, continued)

- (a) Advertisement. Informational communication to the public in any manner designed to attract public attention to medical laboratory personnel training programs that are approved to educate in Tennessee.
 - (b) Licensee - Any medical laboratory personnel training programs holding a Certificate of Approval to educate in the State of Tennessee. Where applicable this shall include partnerships and/or corporations.
 - (c) Material Fact - Any fact which an ordinary reasonable and prudent person would need to know or rely upon in order to make an informed decision concerning the choice of medical laboratory personnel training programs to serve his or her particular needs.
- (3) Advertising Tuition Fees and Services
- (a) Fixed Tuition Fees - Fixed tuition fees may be advertised.
 - (b) Discount Tuition Fees. Discount tuition fees may be advertised if:
 - 1. The discount tuition fee is in fact lower than the licensee's customary or usual tuition fee; and
 - 2. The licensee provides the same quality and components of education at the discounted tuition fee that are normally provided at the regular, non-discounted tuition fee.
 - (c) Related Services and Additional Fees. Related services which may be required in conjunction with the advertised services for which additional fees will be charged must be identified as such in any advertisement.
 - (b) Time Period of Advertised Fees.
 - 1. Advertised fees shall be honored for those seeking the advertised services during the entire time period stated in the advertisement whether or not the services are actually rendered or completed within that time.
 - 2. If no time period is stated in the advertisement of fees, the advertised fee shall be honored for thirty (30) days from the last date of publication or until the next scheduled publication whichever is later whether or not the services are actually rendered or completed within that time.
- (4) Advertising Content. The following acts or omissions in the context of advertisement by any licensee shall constitute unethical conduct, and subject the licensee to disciplinary action pursuant to T.C.A. § 68-29-127(9) and (10).
- (a) Claims that the education offered is professionally superior to that which is ordinarily offered, or that convey the message that one licensee is better than another when superiority of services, personnel, materials or equipment cannot be substantiated.
 - (b) The misleading use of an unearned or non-health degree in any advertisement.
 - (c) Promotion of professional services which the licensee knows or should know is beyond the licensee's ability to perform.
 - (d) Techniques of communication which intimidate, exert undue pressure or undue influence over a prospective client.

(Rule 1200-6-2-.08, continued)

- (e) Any appeals to an individual's anxiety in an excessive or unfair manner.
- (f) The use of any personal testimonial attesting to a quality of competency of a service or treatment offered by a licensee that is not reasonably verifiable.
- (g) Utilization of any statistical data or other information based on past performances for prediction of future services, which creates an unjustified expectation about results that the licensee can achieve.
- (h) The communication of personal identifiable facts, data, or information about a patient without first obtaining patient consent.
- (i) Any misrepresentation of a material fact.
- (j) The knowing suppression, omission or concealment of any material fact or law without which the advertisement would be deceptive or misleading.
- (k) Statements concerning the benefits or other attributes of medical procedures or products that involve significant risks without including:
 - 1. A realistic assessment of the safety and efficiency of those procedures or products; and
 - 2. The availability of alternatives; and
 - 3. Where necessary to avoid deception, descriptions or assessment of the benefits or other attributes of those alternatives.
- (l) Any communication which creates an unjustified expectation concerning the potential results of any treatment.
- (m) Failure to comply with the rules governing advertisement of fees and services, or advertising records.
- (n) Misrepresentation of a licensee's credentials, training, experience, or ability.
- (o) Failure to include the corporation, partnership or individual licensee's name, address, and telephone number in any advertisement. Any corporation, partnership or association which advertises by use of a trade name or otherwise fails to list all licensees practicing at a particular location shall:
 - 1. Upon request provide a list of all licensees practicing at that location; and
 - 2. Maintain and conspicuously display at the licensee's office, a directory listing all licensees practicing at that location.
- (p) Failure to disclose the fact of giving compensation or anything of value to representative of the press, radio, television or other communicative medium in anticipation of or in return for any advertisement (for example, newspaper article) unless the nature, format or medium of such advertisement make the fact of compensation apparent.
- (q) After thirty (30) days of a personnel departure, the use of the name of any medical laboratory personnel formerly practicing at or associated with any advertised location or on office signs or buildings. This rule shall not apply in the case of a retired or deceased former associate who practiced in association with one or more of the present occupants if the status of the former associate is disclosed in any advertisement or sign.

(Rule 1200-6-2-.08, continued)

- (r) Stating or implying that a certain licensee provides all services when any such services are performed by another licensee.
 - (s) Directly or indirectly offering, giving, receiving, or agreeing to receive any fee or other consideration to or from a third party for the referral of a patient in connection with the performance of professional services.
- (5) Advertising Records and Responsibility
- (a) Each licensee who is a principal partner, or officer of a firm or entity identified in any advertisement, is jointly and severally responsible for the form and content of any advertisement. This provision shall also include any licensed professional employees acting as an agent of such firm or entity.
 - (b) Any and all advertisement are presumed to have been approved by the licensee named therein.
 - (c) A recording of every advertisement communicated by electronic media, and a copy of every advertisement communicated by print media, and a copy of any other form of advertisement shall be retained by the licensee for a period of two (2) years from the last date of broadcast or publication and be made available for review upon request by the Board or its designee.
 - (d) At the time any type of advertisement is placed, the licensee must possess and rely upon information which, when produced, would substantiate the truthfulness of any assertion, omission or representation of material fact set forth in the advertisement or public information.
- (6) Use of Titles in Advertisements. Any medical laboratory training program licensed by the Board which includes in its advertisements the names of its laboratory personnel must, in every "advertisement" [as that term is defined in rule 1200-06-02-.08(2)(a)] it publishes, use an appropriate personnel title for each such licensee as authorized by rule 1200-06-01-.03(3) of this rule. Failure to do so may constitute an omission of a material fact which makes the advertisement misleading and deceptive and subjects the medical laboratory training program to disciplinary action pursuant to T.C.A. § 68-29-126(9), 68-29-126(11), 68-29-126(13), 68-29-127(8), 68-29-127(9), 68-29-127(10), and/or 68-29-129(8).
- (67) Severability. It is hereby declared that the sections, clauses, sentences and part of these rules are severable, are not matters of mutual essential inducement, and any of them shall be rescinded if these rules would otherwise be unconstitutional or ineffective. If any one or more sections, clauses, sentences or parts shall for any reason be questioned in court, and shall be adjudged unconstitutional or invalid, such judgment shall not affect, impair or invalidate the remaining provisions thereof, but shall be confined in its operation to the specific provision or provisions so held unconstitutional or invalid, and the inapplicability or invalidity of any section, clause, sentence or part in any one or more instance shall not be taken to affect or prejudice in any way its applicability or validity in any other instance.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-1-145, 63-1-146, 68-29-105, 68-29-110, 68-29-126, 68-29-127 and 68-29-129. **Administrative History:** Original rule filed March 16, effective May 30, 2007.

(Rule 1200-06-03-.19, continued)

- (2) The following are considered to be preparatory portions of tests to be performed in a medical laboratory that may be assigned to persons not licensed under the Medical Laboratory Act:
 - (a) centrifuging, pouring off and preparing specimens for testing.
 - (b) preparing peripheral smears at bedside or in the laboratory.
 - (c) staining peripheral smears by automated methods.
 - (d) loading primary bar-coded specimens on analyzers.
 - (e) automated process of sorting, decapping, aliquoting and archiving of specimens.
 - (f) primary inoculation of microbiology specimens.
 - (g) Any activities required prior to microscopic evaluation of cytology specimens.
- (3) A medical laboratory director, as defined by T.C.A. § 68-29-103, must approve preparatory portions of tests performed by individuals not licensed under the Tennessee Medical Laboratory Act.
- (4) The laboratory must identify personnel responsible for performing preparatory portions of tests and those with responsibility for supervising them.
- (5) Personnel performing preparatory portions of tests must have adequate, specific training and orientation and must demonstrate satisfactory levels of competency before performing preparatory portions of tests, and a competency demonstration must be performed at least annually thereafter.
- (6) Laboratory surveyors will evaluate preparatory portions of tests at the time of inspection.

Authority: §§ 4-5-202, 4-5-204, 68-29-105, and 68-29-129. **Administrative History:** Original rule filed April 10, 2003; effective June 24, 2003. Amendment filed September 17, 2003; effective December 1, 2003. Amendment filed April 17, 2007; effective July 1, 2007.

1200-06-03-.20 ADVERTISING.

- (1) Policy Statement. The lack of sophistication on the part of many in the health care community concerning medical laboratories, the importance of the interests affected by the choosing of a medical laboratory and the foreseeable consequences of unrestricted advertising by medical laboratories which is recognized to pose special possibilities for deception, require that special care be taken by medical laboratories to avoid misleading the health care community. Medical laboratories must be mindful that the benefits of advertising depend upon its reliability and accuracy. Since advertising by medical laboratories is calculated and not spontaneous, reasonable regulation designed to foster compliance with appropriate standards serves the public interest without impeding the flow of useful, meaningful, and relevant information to the health care community.
- (2) Definitions
 - (a) Advertisement – Informational communication to the health care community in any manner designed to attract attention to the medical laboratories which are licensed to practice in Tennessee.

(Rule 1200-06-03-.19, continued)

- (b) Licensee - Any entity holding a license to operate as a medical laboratory in the State of Tennessee. Where applicable this shall include partnerships and/or corporations.
 - (c) Material Fact - Any fact which a health care provider would need to know or rely upon in order to make an informed decision concerning the choice of medical laboratories to serve its particular needs.
 - (d) Bait and Switch Advertising - An alluring but insincere offer to sell a product or service which the advertiser in truth does not intend or want to sell. Its purpose is to switch consumers from buying the advertised service or merchandise, in order to sell something else, usually for a higher fee or on a basis more advantageous to the advertiser.
 - (e) Discounted Fee - Shall mean a fee offered or charged by a medical laboratory or a product or service that is less than the fee the medical laboratory usually offers or charges for the product or service. Products or services expressly offered free of charge shall not be deemed to be offered at a "discounted fee."
 - (f) Health Care Community - Shall mean hospitals, ambulatory surgical treatment centers, medical practices, individual physicians, and other health care providers with legal authority to order laboratory tests.
- (3) Advertising Fees and Services
- (a) Fixed Fees - Fixed fees may be advertised for any service. It is presumed unless otherwise stated in the advertisement that a fixed fee for a service shall include the cost of all professional recognized components within generally accepted standards that are required to complete the service.
 - (b) Range of Fees. A range of fees may be advertised for services and the advertisement must disclose the factors used in determining the actual fee, necessary to prevent deception of the health care community.
 - (c) Discount Fees. Discount fees may be advertised if:
 - 1. The discount fee is in fact lower than the licensee's customary or usual fee charged for the service; and
 - 2. The licensee provides the same quality and components of service and material at the discounted fee that are normally provided at the regular, non-discounted fee for that service.
 - (d) Related Services and Additional Fees. Related services which may be required in conjunction with the advertised services for which additional fees will be charged must be identified as such in any advertisement.
 - (e) Time Period of Advertised Fees.
 - 1. Advertised fees shall be honored for those seeking the advertised services during the entire time period stated in the advertisement whether or not the services are actually rendered or completed within that time.
 - 2. If no time period is stated in the advertisement of fees, the advertised fee shall be honored for thirty (30) days from the last date of publication or until the next scheduled publication whichever is later whether or not the services are actually rendered or completed within that time.

(Rule 1200-06-03-.19, continued)

- (4) Advertising Content. The following acts or omissions in the context of advertisement by any licensee shall constitute unethical conduct, and subject the licensee to disciplinary action pursuant to T.C.A. § 68-29-127(9) and (10).
- (a) Claims that the services performed, personnel employed, materials or office equipment used are professionally superior to that which is ordinarily performed, employed, or used, or that convey the message that one licensee is better than another when superiority of services, personnel, materials or equipment cannot be substantiated.
 - (b) The misleading use of an unearned or non-health degree in any advertisement.
 - (c) Promotion of professional services which the licensee knows or should know is beyond the licensee's ability to perform.
 - (d) Techniques of communication which intimidate, exert undue pressure or undue influence over a prospective client.
 - (e) Any appeals to an individual's anxiety in an excessive or unfair manner.
 - (f) The use of any personal testimonial attesting to a quality of competency of a service or treatment offered by a licensee that is not reasonably verifiable.
 - (g) Utilization of any statistical data or other information based on past performances for prediction of future services, which creates an unjustified expectation about results that the licensee can achieve.
 - (h) The communication of personal identifiable facts, data, or information about a patient without first obtaining patient consent.
 - (i) Any misrepresentation of a material fact.
 - (j) The knowing suppression, omission or concealment of any material fact or law without which the advertisement would be deceptive or misleading.
 - (k) Statements concerning the benefits or other attributes of medical procedures or products that involve significant risks without including:
 - 1. A realistic assessment of the safety and efficiency of those procedures or products; and
 - 2. The availability of alternatives; and
 - 3. Where necessary to avoid deception, descriptions or assessment of the benefits or other attributes of those alternatives.
 - (l) Any communication which creates an unjustified expectation concerning the potential results of any laboratory test.
 - (m) Failure to comply with the rules governing advertisement of fees and services, or advertising records.
 - (n) The use of "bait and switch" advertisements. Where the circumstances indicate "bait and switch" advertising, the Board may require the licensee to furnish data or other evidence pertaining to those sales at the advertised fee as well as other sales.

(Rule 1200-06-03-.19, continued)

- (o) Misrepresentation of a licensee's credentials, training, experience, or ability.
 - (p) Failure to include the corporation, partnership or individual licensee's name, address, and telephone number in any advertisement. Any corporation, partnership or association which advertises by use of a trade name or otherwise fails to list all licensed laboratory personnel practicing at a particular location shall:
 - 1. Upon request provide a list of all licensed laboratory personnel practicing at that location; and
 - 2. Maintain and conspicuously display at the licensee's office, a directory listing all licensed laboratory personnel practicing at that location.
 - (q) Failure to disclose the fact of giving compensation or anything of value to representatives of the press, radio, television or other communicative medium in anticipation of or in return for any advertisement (for example, newspaper article) unless the nature, format or medium of such advertisement make the fact of compensation apparent.
 - (r) After thirty (30) days of the licensee's departure, the use of the name of any licensed laboratory personnel formerly practicing at or associated with any advertised location or on office signs or buildings. This rule shall not apply in the case of a retired or deceased former associate who practiced in association with one or more of the present licensees if the status of the former associate is disclosed in any advertisement or sign.
 - (s) Stating or implying that a certain licensee provides all services when any such services are performed by another licensee.
- (5) Advertising Records and Responsibility
- (a) Each licensee who is a principal partner, or officer of a firm or entity identified in any advertisement, is jointly and severally responsible for the form and content of any advertisement. This provision shall also include any licensed professional employees acting as an agent of such firm or entity.
 - (b) Any and all advertisement are presumed to have been approved by the licensee named therein.
 - (c) A recording of every advertisement communicated by electronic media, and a copy of every advertisement communicated by print media, and a copy of any other form of advertisement shall be retained by the licensee for a period of two (2) years from the last date of broadcast or publication and be made available for review upon request by the Board or its designee.
 - (d) At the time any type of advertisement is placed, the licensee must possess and rely upon information which, when produced, would substantiate the truthfulness of any assertion, omission or representation of material fact set forth in the advertisement or public information.
- (6) Use of Titles in Advertisements. Any medical laboratory licensed by the Board which includes in its advertisements the names of its laboratory personnel must, in every "advertisement" [as that term is defined in rule 1200-06-03-.20(2)(a)] it publishes, use an appropriate personnel title for each such licensee as authorized by rule 1200-06-01-.03(3) of this rule. Failure to do so may constitute an omission of a material fact which

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(Rule 1200-06-03-.19, continued)

makes the advertisement misleading and deceptive and subjects the medical laboratory to disciplinary action pursuant to T.C.A. § 68-29-126(9), 68-29-126(11), 68-29-126(13), 68-29-127(8), 68-29-127(9), 68-29-127(10), and/or 68-29-129(8).

(7) Severability. It is hereby declared that the sections, clauses, sentences and parts of these rules are severable, are not matters of mutual essential inducement, and any of them shall be rescinded if these rules would otherwise be unconstitutional or ineffective. If any one or more sections, clauses, sentences or parts shall for any reason be questioned in court, and shall be adjudged unconstitutional or invalid, such judgment shall not affect, impair or invalidate the remaining provisions thereof, but shall be confined in its operation to the specific provision or provisions so held unconstitutional or invalid, and the inapplicability or invalidity of any section, clause, sentence or part in any one or more instance shall not be taken to affect or prejudice in any way its applicability or validity in any other instance.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-1-145, 63-1-146, 68-29-105, 68-29-126, and 68-29-129.
Administrative History: Original rule filed March 16, 2007; filed May 30, 2007.