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 and new rules pursuant to T.C.A. §§ 4-5-202, 4-5-204, 63-1-138, 68-29-103, 68-29-105, 68-29-110, 68-29-116, 68-29-117, 68-29-126, 68-29-127, 68-29-129, and Public Chapters 234, 467 and 479 of the Public Acts of 2005. 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 Jackson Room of the Cordell Hull Building located at 425 Fifth Avenue North, Nashville, TN at 2:30 p.m. (CDT) on the 29th day of September, 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

1200-6-1-.03 Necessity of Licensure, is amended by adding the following language as new paragraph (3):

(3) Use of Titles - Any person who possesses a valid, unsuspended and unrevoked license issued by the Board has the right to use the title or acronym that represents being a medical laboratory director (Ph.D), medical technologist (M.T.), medical laboratory technician (M.L.T.), special analyst (S.A.), or cytotechnologist (C.T.) as defined in T.C.A. §§ 68-29-103. Violation of this rule regarding use of titles shall constitute unethical conduct and subject the licensee to disciplinary action.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-103, 68-29-105, 68-29-116, 68-29-127, and Public Chapter 467 of the Public Acts of 2005.

Rule 1200-6-1-.13 Temporary License, is amended by deleting paragraph (4) in its entirety and substituting instead the following language, and is further amended by deleting paragraphs (5), (6), and (7) in their entirety and substituting instead the following language, so that as amended, the new paragraph (4) shall read:

(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, 68-29-117, and Public Chapter 479 of the Public Acts of 2005.

1200-6-1-.19 Board Meetings, Officers, Consultants, and Declaratory Orders, is amended by deleting the catchline in its entirety and substituting instead the following language, and is further amended by adding the following language as new paragraphs (6) and (7), so that as amended, the new catchline and the new paragraphs (6) and (7) shall read:

1200-6-1-.19 Board Meetings, Officers, Consultants, Declaratory Orders, and Screening Panels.

(6) Screening Panels - The Board adopts, as if fully set out herein, rule 1200-10-1-.13, of the Division of Health Related Boards and as it may from time to time be amended, as its rule governing the screening panel process.

(7) The board authorizes the member who chaired the board for any contested case to be the agency member to make the decisions authorized pursuant to rule 1360-4-1-.18 regarding petitions for reconsiderations and stays

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-1-138, 68-29-105, 68-29-127, and Public Chapter 234 of the Public Acts of 2005.

Rule 1200-6-3-.05 Licensure Discipline, Civil Penalties, Assessment of Costs, and Subpoenas, is amended by deleting the catchline in its entirety and substituting instead the following language, and is further amended by adding the following language as new paragraph (8), so that as amended, the new catchline and the new paragraph (8) shall read:

Rule 1200-6-3-.05 Licensure Discipline, Civil Penalties, Assessment of Costs, Subpoenas, and Screening Panels.

(8) Screening Panels - The Board adopts, as if fully set out herein, rule 1200-10-1-.13, of the Division of Health Related Boards and as it may from time to time be amended, as its rule governing the screening panel process.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-1-138, 68-29-105, 68-29-126, and Public Chapter 234 of the Public Acts of 2005.

New Rules

Table of Contents

1200-6-2-.08 Advertising
1200-6-3-.20 Advertising

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

(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.

(d) 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).

(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.

(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 materials 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.

(q) 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.

(r) 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.

(s) Stating or implying that a certain licensee provides all services when any such services are performed by another licensee.

(t) 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) 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 in applicability 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, 68-29-105, 68-29-110, 68-29-129, and Public Chapter 467 of the Public Acts of 2005.

1200-6-3-.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.

(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.

(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).

(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 materials 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:

3. A realistic assessment of the safety and efficiency of those procedures or products; and

4. 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.

(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 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.

(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) 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 in applicability 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, 68-29-105, 68-29-126, 68-29-129, and Public Chapter 467 of the Public Acts of 2005.

Contact who can answer questions concerning this notice of rulemaking hearing, technical contact for disk acquisition, and person who will approve final copy for publication: Jerry Kosten, Regulations Manager, Division of Health Related Boards, 1st Floor, Cordell Hull Building, 425 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 July, 2005.

Notary Public

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

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

Riley C. Darnell
Secretary of State

RECEIVED
2005 JUL 14 PM 4:10
SECRETARY OF STATE
PUBLICATIONS

By: