

**RULES
OF
THE TENNESSEE BOARD OF OSTEOPATHIC EXAMINATION**

**CHAPTER 1050-02
GENERAL RULES AND REGULATIONS GOVERNING THE PRACTICE OF OSTEOPATHY**

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1050-02-.01 DEFINITIONS. As used in this Chapter of Rules the following terms and acronyms shall have the following meanings ascribed to them:

- (1) AOA - The American Osteopathic Association.
- (2) Board - The Tennessee Board of Osteopathic Examination
- (3) Board Administrative Office - The office of the administrator assigned to the Tennessee Board of Osteopathic Examination located at the 227 French Landing, Suite 300, Heritage Place, MetroCenter, Nashville, TN 37243.
- (4) Board Consultant/Designee - Any person who has received delegation of authority from the Board to perform Board functions subject to review and ratification by the full Board where provided by these rules.
- (5) COMLEX - The Comprehensive Osteopathic Medical Licensure Exam.
- (6) COMSPEX - The Comprehensive Osteopathic Medical Special Purpose Exam.
- (7) COMVEX - The Comprehensive Osteopathic Medical Variable Purpose Examination
- (8) Division - The Tennessee Department of Health and Environment, Division of Health Related Boards, from which the Board receives administrative support.
- (9) Endorsement/Reciprocity - The method of consideration for licensure for applicants previously licensed in another state.
- (10) Examination - Unless otherwise stipulated, a written and/or oral examination specifically prepared and administered by the Board.

(Rule 1050-02-.01, continued)

- (11) FCVS - The Federation Credentials Verification Service which is a service offered by the Federation of State Medical Boards that provides primary source identification and verification of physician core credentials as required in licensure applications by the states.
- (12) FLEX - The Federation Licensing Examination.
- (13) Licensee - Any person who has been lawfully issued a license to practice osteopathic medicine in Tennessee by the Board.
- (14) Medical Service - An activity that falls within the definition of the "practice of osteopathic medicine" as set forth in Tennessee Code Annotated, Section 63-9-106(a).
- (15) N.B.M.E. - The National Board of Medical Examiners' Examination
- (16) N.B.O.M.E. - The National Board of Osteopathic Medical Examiners' Examination.
- (17) Practice of Medicine - The "practice of osteopathic medicine" as set forth in Tennessee Code Annotated, Section 63-9-106(a). See also "Medical Service" or "Professional Service".
- (18) Professional Service - An osteopathic service.
- (19) Shall or Must - Where these words are used, compliance is mandatory.
- (20) Should or May - Where these words are used, it means a suggestion or a recommendation.
- (21) SPEX - The Special Purpose Examination, as written by the Federation of State Medical Boards.
- (22) Supervising Physician - Where these words are used, it shall include a licensed physician who actively oversees a certified nurse practitioner or a licensed physician assistant; and shall also include any properly authorized alternate or substitute supervising physician.
- (23) U.S.M.L.E. - The United States Medical Licensing Examination.

Authority: T.C.A. §§4-5-202, 4-5-204, 63-9-101, 63-9-105, 63-9-107, and 63-9-111. **Administrative History:** Original rule filed April 29, 1988; effective June 13, 1988. Amendment filed November 30, 1990; effective January 14, 1991. Amendment filed July 12, 1995; effective September 25, 1995. Repeal and new rule filed April 10, 2000; effective June 24, 2000. Amendment filed October 2, 2002; effective December 16, 2002.

1050-02-.02 FEES.

- (1) The fees authorized by the Tennessee Osteopathic Medical Practice Act (T.C.A. §§ 63-9-101 through 63-9-114) and other applicable statutes to be established by the Board are established as follows:
 - (a) Application Fee - A non refundable fee to be paid by all licensure applicants, except Special Training License applicants, regardless of the type of license applied for. It must be paid each time an application for licensure is filed or an application to take the Board examination is filed. \$ 400.00
 - (b) Licensure Renewal Fee - To be paid biennially by all licensees. This fee also applies to licensees who reactivate a retired license. \$ 375.00

(Rule 1050-02-.02, continued)

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| (c) | State Regulatory Fee - To be paid by all licensees upon application and biennially upon renewal. | \$ 10.00 |
| (d) | Late Licensure Renewal Fee - To be paid when a licensee fails to timely renew a licensure. | \$ 200.00 |
| (e) | Duplicate License Fee. | \$ 25.00 |
| (f) | Certificate of Fitness. | \$10.00 |
| (g) | Licensure Exemption Fee. | \$50.00 |
| (h) | Special Training License Fee. | \$50.00 |
- (2) All fees may be paid in person, by mail or electronically by cash, check, money order, or by credit and/or debit cards accepted by the Division. If the fees are paid by certified, personal or corporate check they must be drawn against an account in a United States Bank, and made payable to the Tennessee Board of Osteopathic Examination.

Authority: T.C.A. §§4-3-1011, 4-5-202, 4-5-204, 63-1-106, 63-9-101, 63-9-104, 63-9-105, and 63-9-107.

Administrative History: Original rule filed April 29, 1988; effective June 13, 1988. Amendment filed November 30, 1990; effective January 14, 1991. Amendment filed July 12, 1995; effective September 25, 1995. Amendment filed January 4, 1996; effective March 19, 1996. Suspension filed April 17, 1996; effective April 25, 1996. Repeal and new rule filed August 13, 1999; effective October 27, 1999. Repeal and new rule filed April 10, 2000; effective June 24, 2000. Amendment filed April 19, 2002; effective July 3, 2002. Amendment filed September 17, 2002; effective December 1, 2002. Amendment filed October 2, 2002; effective December 16, 2002. Amendment filed January 14, 2005; effective March 30, 2005.

1050-02-.03 LICENSURE PROCESS. To practice osteopathic medicine in Tennessee, a person must possess a lawfully issued license from the Board. The procedure for obtaining a license is as follows:

- (1) Initial Licensure As An Osteopathic Physician -Consideration for initial licensure as a Doctor of Osteopathic Medicine requires that the applicant shall submit to the Board the following materials:
- (a) An application from the Board Administrative Office in which the applicant responds truthfully and completely to every question or request for information along with all documentation and fees to the Board Administrative Office. It is the intent of this rule that all activities necessary to accomplish the filing of the required documentation be completed prior to filing a licensure application and that all documentation be filed simultaneously. This form will include the applicant's name, current address, social security number and age (which shall not be less than eighteen years of age).
 - (b) A clear and recognizable, recently taken, bust photograph which shows the full head, face forward from at least the top of the shoulders up. The photograph must be signed by the applicant.
 - (c) A graduate transcript from an accredited osteopathic medical school in good standing with the American Osteopathic Association at the time of graduation (or its successor). The transcript must be submitted directly from the school to the Board Administrative Office. The transcript must show that the degree has been conferred based upon the applicant's good repute and personal attendance and must carry the official seal of the institution.

(Rule 1050-02-.03, continued)

- (d) Evidence satisfactory to the Board of successful completion of a one (1) year internship or postgraduate year one (PGY-1) in a hospital approved by the American Osteopathic Association, American Medical Association or its accreditation program for medical education, or the Joint Commission on the Accreditation of Hospitals. Such evidence shall include the program director's notarized verification of post graduate medical training form included in the Board's application packet.
 - (e) Evidence of good moral character. Such evidence shall include at least two (2) letters from physicians who know the applicant and can attest to his or her moral character and professional capability. The letters must be original and on the physician's letterhead.
 - (f) Proof of United States or Canadian citizenship or evidence of being legally entitled to live and work in the United States or evidence of citizenship and residency in a N.A.F.T.A. participating country. Such evidence may include notarized copies of birth certificates, naturalization papers or current H-1 visa status, or voter registration.
 - (g) The applicable application fee and state regulatory fee as provided in rule 1050-02-.02.
 - (h) All applicants shall submit or cause to be submitted a certificate of successful completion of acceptable examination for licensure as governed by rule 1050-02-.06.
 - (i) All applicants shall disclose the circumstances surrounding any of the following:
 - 1. Conviction of any criminal law violation of any country, state, or municipality, except minor traffic violations.
 - 2. The denial of licensure application by any other state or the discipline of licensure in any state.
 - 3. Loss or restriction of hospital privileges.
 - 4. Any other civil suit judgment or civil suit settlement or pending civil lawsuit in which the applicant was a party defendant including, without limitation, actions involving medical malpractice, breach of contract, antitrust activity or any other civil action remedy recognized under any country's or state's statutory, common, or case law.
 - 5. Failure of any medical licensure examination.
 - (j) An applicant shall cause to be submitted to the Board's administrative office directly from the vendor identified in the Board's licensure application materials, the result of a criminal background check.
 - (k) An applicant who has completed all but three (3) or less months of the one (1) year training program required by paragraph (d) of this rule may apply for licensure if all other requirements of this rule are met and the director of the training program submits a letter attesting to the applicant's satisfactory performance in and anticipated successful completion of the training program. However, no license shall be approved or issued until the requirements of paragraph (d) of the rule are met.
- (2) Reciprocity Licensure - Consideration for initial licensure as a Doctor of Osteopathic Medicine based on endorsement/reciprocity requires that the applicant shall submit to the Board the following materials:

(Rule 1050-02-.03, continued)

- (a) Evidence of current licensure in good standing in another state, along with evidence of having passed a written licensure examination of another state licensing board or accepted by another state licensing board, provided the applicant meets all other licensure standards for osteopathic physicians described in T.C.A. §63-9-104 and paragraph (1) of this rule to the satisfaction of the Board.
 - (b) The applicant must comply with all provisions of paragraph (1) of this rule.
 - (c) The applicant shall cause an official transcript or certified copy of licensing examination scores to be provided directly to the Board from the official licensing or examination agency through which the applicant became licensed in another state.
- (3) At the Board's discretion, submission of any document or set of documents required by this rule or submission of verification of the authenticity, validity and accuracy of the content of any document or set of documents required by this rule directly from the FCVS or other Board approved credentialing service to the Board Administrative Office shall be deemed to be submission of originals of those documents or sets of documents by the issuing institution(s).
- (4) Application review and licensure decisions shall be governed by rule 1050-02-.05.

Authority: T.C.A. §§4-5-202, 4-5-204, 63-9-101, 63-9-104, 63-9-105, and 63-9-111. **Administrative History:** Original rule filed April 29, 1988; effective June 13, 1988. Amendment filed November 30, 1990; effective January 14, 1991. Amendment filed July 12, 1995; effective September 25, 1995. Repeal and new rule filed April 10, 2000; effective June 24, 2000. Amendment filed March 14, 2006; effective May 28, 2006.

1050-02-.04 TRAINING. Those persons who pursuant to T.C.A. § 63-9-104 (d) may be eligible to practice osteopathic medicine in Tennessee while participating in a training program such as described in 1050-02-.03 (1) (k) with a training license issued by the Board may secure such license pursuant to paragraph (1) of this rule. Those persons pursuant to T.C.A. §§ 63-9-104(c) who may be eligible to practice osteopathic medicine in Tennessee with a Board issued exemption from licensure may secure such exemptions pursuant to paragraph (2) of this rule. Persons who have been issued a license to practice osteopathic medicine in Tennessee and whose license has not been revoked or suspended need not obtain an exemption from licensure or a training license pursuant to this rule to be able to participate in a training program.

- (1) Osteopathic Interns, Residents and Clinical Fellows - Training Licenses
 - (a) It shall be the responsibility of the program director or the dean responsible for the training program to first compile all of the following on behalf of each applicant for a special training license and then when all necessary documents and fees are compiled, send them directly to the Board's Administrative Office:
 1. A Board approved application for each applicant.
 2. The documentation required by rule 1050-02-.03 subparagraphs (1) (b), (1) (c), (1) (e), (1) (f), (1) (i) and (1) (j) for each applicant.
 3. The special training license fee and the state regulatory fee for each applicant.
 4. The names of the physicians licensed in Tennessee who will have supervisory responsibility for the applicant(s).

(Rule 1050-02-.04, continued)

- (b) A special training license may be issued for a one (1) year period only but may be renewed each year on its anniversary date so long as the applicant is still in training and upon submission of a written renewal request from the training program director and payment of the Special Training License Fee as provided in Rule 1050-02-.02 (1) (h).
 - (c) Upon termination of any special training licensee's participation in the training program for any reason, the special license shall expire and the director of the program shall immediately notify the Board in writing of the termination and the reasons therefore delivered to the Board's Administrative Office. Such notification terminates the individual's authority to practice osteopathic medicine in Tennessee unless and until a full license from the Board has been obtained.
 - (d) Upon approval of applications by the Board, a special training license shall be issued to each qualified applicant.
- (2) Osteopathic Interns, Residents and Clinical Fellows - Exemptions
- (a) Prior to the commencement of practice by any individual in a training program, except individuals covered pursuant to T.C.A. §63-9-104 (d), it shall be the responsibility of the program director or the dean responsible for the training program which meets the requirements of T.C.A. §63-9-104 (c) to make an application to the Board's Administrative Office which contains all of the following:
 - 1. Evidence of how the training program meets the requirements of T.C.A. §63-9-104 (c). Accreditation by the Accreditation Council of Graduate Medical Education or evidence of affiliation with a hospital so accredited is acceptable for purposes of this rule.
 - 2. The names of the physicians licensed in Tennessee who will have supervisory and control responsibility for the program participants.
 - 3. For those requiring exemption, a list of each participant's name, social security number and date of birth.
 - 4. The licensure exemption fee as established in rule 1050-02-.02 (g) for each participant.
 - (b) The application for exemption from licensure is effective, if approved, for a period of no longer than one (1) year from the date of approval. Exemption applications previously approved need not be re-filed for the individuals continuing in the program beyond the one (1) year expiration date. However, the program is subject to payment of the fee provided in rule 1050-02-.02 (g) as the annual deadline expires for each such individual.
 - (c) Upon termination of any listed individual's participation in the training program for any reason, the director of the program shall immediately notify the Board of the termination and the reasons therefore in writing delivered to the Board's Administrative Office. Such notification terminates the individual's authority to practice osteopathic medicine in Tennessee unless and until a new exemption from the Board has been obtained.
 - (d) The Board Administrative Office shall issue written notification of all Board dispositions on licensure exemption applications. Exemption issuance decisions pursuant to this Rule may be made administratively or upon review by any Board member or the Board consultant/designee.

(Rule 1050-02-.04, continued)

- (3) At the Board's discretion, submission of any document or set of documents required by this rule or submission of verification of the authenticity, validity and accuracy of the content of any document or set of documents required by this rule directly from the FCVS or other Board approved credentialing service to the Board Administrative Office shall be deemed to be submission of originals of those documents or sets of documents by the issuing institution(s).
- (4) Application review, approval and/or denial shall be governed by rule 1050-02-.05.

Authority: T.C.A. §§4-5-202, 4-5-204, 63-9-101, 63-9-104, 63-9-107, and 63-9-111. **Administrative History:** Original rule filed July 12, 1995; effective September 25, 1995. Repeal and new rule filed April 10, 2000; effective June 24, 2000. Amendment filed March 14, 2006; effective May 28, 2006. Amendment filed October 21, 2008; effective January 4, 2009.

1050-02-.05 APPLICATION REVIEW, APPROVAL, DENIAL, INTERVIEWS AND CONDITIONED, RESTRICTED AND LOCUM TENENS LICENSURE. Review and decisions on applications for licensure or exemption from licensure shall be governed by this rule.

- (1) Completed licensure or exemption applications received in the Board Administrative Offices by the first day of the month preceding a Board meeting shall be submitted to the Board for review at its next regularly scheduled meeting. An initial determination may be made prior to the next Board meeting after the application is received. Each member of the Board or any Board consultant/designee is vested with the authority to make these initial determinations.
- (2) An authorization to practice osteopathic medicine or an exemption may be issued pursuant to the initial determination made by the Board member or the Board consultant/designee reviewing the application. However, such authorization or exemption may not become fully effective until such time as the full Board ratifies the initial determination.
- (3) If an application is incomplete when received by the Board Administrative Office or the reviewing Board member or the Board consultant/designee determines additional information is required from an applicant before an initial determination is made, the Board Administrative Office shall notify the applicant of the information required.
 - (a) The applicant shall cause the requested information to be received by the Board Administrative Office on or before the ninetieth (90th) day after the initial letter notifying the applicant of the required information is sent.
 - (b) If requested information is not timely received, the application file shall be closed and the applicant notified that the Board will not consider licensure until a new application is received pursuant to the rules governing that process, including another payment of all fees applicable to the applicant's circumstances. The earlier application will not be incorporated by reference.
- (4) If a completed application is initially denied by the reviewing Board member or Board consultant/designee, the applicant shall be informed of that initial decision and that final determination shall be made by the full Board at its next meeting. If the full Board ratifies the initial denial, the action shall become final and the following shall occur.
 - (a) A notification of the denial shall be sent by the Board Administrative Office by certified mail, return receipt requested which shall contain all the specific statutory or rule authorities for the denial.

(Rule 1050-02-.05, continued)

- (b) The notification, when appropriate, shall also contain a statement of the applicant's right to request a contested case hearing under the Tennessee Administrative Procedures Act (T.C.A. §4-5-101, et seq.) to contest the denial and the procedure necessary to accomplish that action.
 1. An applicant has a right to a contested case hearing only if the adverse decision on an application was based upon subjective or discretionary criteria and only if the request is in writing and received on or before the thirtieth (30th) day after receipt of the notice by the applicant.
 2. An applicant may be granted a contested case hearing if licensure denial is based upon objective, clearly defined criteria only if after review and attempted resolution by the Board's administrative staff the licensure application cannot be approved and the reasons for continued denial present genuine issues of fact and/or law which are appropriate for appeal.
- (5) The initial determination procedures of this rule will not apply if the full Board reviews and makes final determination on any application during its meeting.
- (6) If the application and review process identifies an applicant to be deficient in mental, physical, moral or educational capabilities and/or identifies potential risk to the public health, safety and welfare, such applicant may be required to present themselves to the Board or selected member(s) of the Board or the Board consultant/designee for oral examination before final licensure may be granted. If sufficient cause as determined by the full Board exists an applicant may be required pursuant to T.C.A. §63-9-111 to submit to a mental and/or physical examination. Failure to respond to a notification to appear for interview before the Board, a member, or a consultant/designee, shall be treated as a failure to supply necessary information as specified in paragraph (3) above.
- (7) An applicant (except reciprocity applicants) whose examination or combination of examinations, as provided in Rule 1050-02-.06 (3), is certified as having been successfully completed on or before the fifth (5th) year preceding the date of application shall be required to successfully complete the Special Purpose Examination (SPEX), the Comprehensive Osteopathic Medical Special Purpose Examination (COMSPEX), or the Comprehensive Osteopathic Medical Variable Purpose Examination (COMVEX).
- (8) The examination which may be required by paragraph (6) of this Rule shall be considered part of the requirements for licensure pursuant to T.C.A. § 63-9-111.
- (9) The issuance or renewal of licensure to applicants who otherwise may be entitled to full licensure or renewal, may be withheld, denied, conditioned or restricted in any manner the Board deems necessary to protect the public in any of the following circumstances:
 - (a) When an applicant has had licensure disciplinary action taken or is under investigation by another state or territory of the United States for any acts or omissions which would constitute grounds for discipline of a license issued in this state. A certified copy of the initial or final order or other equivalent document memorializing the disciplinary action or investigation from the disciplining state or territory shall constitute prima facie evidence of violation of this section and be sufficient grounds upon which to deny, restrict or condition licensure or renewal and/or discipline a license issued in this state.
 - (b) When any applicant's application indicates a problem in the areas of mental, physical, moral or educational criteria for licensure or renewal which the Board determines may create a potential threat to the public health, safety or welfare.

(Rule 1050-02-.05, continued)

- (c) When any applicant has violated any provision of T.C.A. § 63-9-111 or rules promulgated pursuant thereto.
 - (d) When any applicant fails to fully and timely comply with all licensure application and renewal requirements.
- (10) Any physician licensed by any state or country sponsored by a hospital located in Tennessee and/or at least one physician licensed by the Board may, in the Board's discretion, without further qualifications receive a restricted "single purpose" license under the following circumstances:
- (a) The physician has credentials which indicate that he or she is licensed in good standing in another state or country; and
 - (b) The physician submits satisfactory evidence that he or she is either to engage in advanced study in a particular field of osteopathic medicine in Tennessee or teach or demonstrate a new medical technique to medical professionals in Tennessee; and
 - (c) The physician's credentials are verified by the appropriate national specialty organization in this country or by the American Osteopathic Association or a similar organization acceptable to the Board; and
 - (d) The physician shall cause to be submitted to the Board's administrative office directly from the vendor identified in the Board's licensure application materials, the result of a criminal background check.; and
 - (e) The hospital and/or sponsoring physician must supply all necessary documentation of licensure, credentialing and verification of the same along with a completed Board approved application form; and
 - (f) The hospital and/or sponsoring physician must pay the full cost to the Board of researching, processing and issuing the restricted "single purpose" license which is the application and state regulatory fee provided in rule 1050-02-.02; and
 - (g) The license will be issued authorizing medical practice in the sponsoring hospital or the sponsoring physician's training program only and shall be designated as a restricted "single purpose" license. It will not allow practice outside that hospital or the designated training program; and
 - (h) The restricted "single purpose" license will be issued for a specified period of time not to exceed one (1) year and be subject to any other practice restrictions deemed appropriate by the Board. The training received in any program pursuant to this license shall not be used to qualify for full, unrestricted licensure in Tennessee; and
 - (i) The sponsoring physician has full responsibility for the activities of any physician granted a restricted "single purpose" license.
 - (j) All such restricted "single purpose" licenses are subject to discipline for the same causes and pursuant to the same procedures as active unrestricted licenses.
 - (k) At the Board's discretion, submission of any document or set of documents required by this rule or submission of verification of the authenticity, validity and accuracy of the content of any document or set of documents required by this rule directly from the FCVS or other Board approved credentialing service to the Board Administrative Office

(Rule 1050-02-.05, continued)

shall be deemed to be submission of originals of those documents or sets of documents by the issuing institution(s).

- (11) An applicant who is either licensed in good standing in another state, maintains an unencumbered certification in a recognized specialty area, or is eligible for such certification and indicates an intended residence outside the State of Tennessee but proposes to practice intermittently within the physical boundaries of the State of Tennessee, shall in the discretion of the Board be issued a Locum Tenens license.
- (a) To obtain a Locum Tenens license, an applicant shall compile the following and when completed, submit them to the Board Administrative Office:
1. A Board approved application form; and
 2. All documentation required by rule 1050-02-.03 subparagraphs (1) (b), (1) (f), (1) (i), (1) (j) and (2) (a).
- (b) The practice of any person issued a locum tenens license shall be restricted to the specialty area of osteopathic medicine in which that person is certified or in which the person is eligible for certification.
- (c) Any physician holding a Locum Tenens license shall notify the Board of the location and duration of each Tennessee practice as soon as reasonably possible under the circumstances before that practice occurs.
- (d) All Locum Tenens licenses must be renewed, inactivated or retired according to the same procedure as active unrestricted licenses.
- (e) All Locum Tenens licenses are subject to discipline for the same causes and pursuant to the same procedures as active unrestricted licenses.
- (f) Any person holding a Locum Tenens license who practices in this state for a period of time in any one year that the Board in its discretion feels is inordinate for the purposes of this licensure status may have his or her Locum Tenens license revoked or be required to apply for a full active license.
- (g) At the Board's discretion, submission of any document or set of documents required by this rule or submission of verification of the authenticity, validity and accuracy of the content of any document or set of documents required by this rule directly from the FCVS or other Board approved credentialing service to the Board Administrative Office shall be deemed to be submission of originals of those documents or sets of documents by the issuing institution(s).

Authority: T.C.A. §§4-5-202, 4-5-204, 63-1-142, 63-9-101, 63-9-104, 63-9-105, and 63-9-111.

Administrative History: Original rule filed April 29, 1988; effective June 13, 1988. Amendment filed November 30, 1990; effective January 14, 1991. Amendment filed July 12, 1995; effective September 25, 1995. Repeal and new rule filed April 10, 2000; effective June 24, 2000. Amendment filed October 2, 2002; effective December 16, 2002. Amendment filed March 14, 2006; effective May 28, 2006.

1050-02-.06 EXAMINATION. All persons intending to apply for licensure as an osteopathic physician in Tennessee must successfully complete a written examination pursuant to this rule. Such written examination must be completed prior to application for licensure. Certification of successful completion must be submitted by the examining agency directly to the Board Administrative Office as part of the application process contained in rule 1050-02-.03.

(Rule 1050-02-.06, continued)

- (1) The Board adopts the Comprehensive Osteopathic Medical Licensure Examination (COMLEX), the National Board of Osteopathic Medical Examiners' Examination (NBOME), NBME, FLEX, USMLE, or a Board approved State administered examination taken prior to 1994 as its written licensure examinations. Successful completion of one of these examinations is a prerequisite to licensure.
- (2) An applicant (except reciprocity applicants) whose examination or combination of examinations, as provided in paragraph (3), is certified as having been successfully completed on or before the fifth (5th) year preceding the date of application shall be required to successfully complete the Special Purpose Examination (SPEX), the Comprehensive Osteopathic Medical Special Purpose Examination (COMSPEX), or the Comprehensive Osteopathic Medical Variable Purpose Examination (COMVEX).
- (3) The Board will accept any of the following examinations or combinations of examinations:
 - (a) The NBOME or COMLEX or any combination of their parts; or
 - (b) FLEX Components I and II; or
 - (c) Predecessor FLEX Days I, II and III; or
 - (d) FLEX Component I plus USMLE Step 3; or
 - (e) NBME Part I or USMLE Step 1,
plus
NBME Part II or USMLE Step 2
plus
NBME Part III or USMLE Step 3; or
 - (f) NBME Part I or USMLE Step 1
plus
NBME Part II or USMLE Step 2
plus
FLEX Component II
 - (g) Combinations of the Predecessor FLEX Days I, II and III are not allowed with any other examination.
- (4) Passing Scores - The Board adopts the NBOME's, the NBME's, the FLEX's, COMLEX's and the USMLE's determination of the passing scores for each Part or Step of their examinations.
- (5) All applicants for the examinations shall submit all application inquiries, applications, fees and all necessary admission documentation directly to the examination administering agency. The Board does not distribute or process applications for the any examination administering agency.
- (6) To gain access to U.S.M.L.E Step 3, an applicant must have completed the post-graduate year one (PGY-1) training program.
- (7) At the Board's discretion, submission of any document or set of documents required by this rule or submission of verification of the authenticity, validity and accuracy of the content of any document or set of documents required by this rule directly from the FCVS or other Board approved credentialing service to the Board Administrative Office shall be deemed to be submission of originals of those documents or sets of documents by the issuing institution(s).

(Rule 1050-02-.06, continued)

Authority: T.C.A. §§4-5-202, 4-5-204, 63-9-101, 63-9-104, and 63-9-105. **Administrative History:** Original rule filed January 4, 1990; effective February 18, 1990. Amendment filed November 30, 1990; effective January 14, 1991. Amendment filed July 12, 1995; effective September 25, 1995. Repeal and new rule filed April 10, 2000; effective June 24, 2000. Amendment filed October 2, 2002; effective December 16, 2002.

1050-02-.07 LICENSURE RENEWAL AND REINSTATEMENT.

- (1) All licensees must renew their licenses to be able to legally continue in practice. License renewal is governed by the following:
 - (a) The due date for license renewal is its expiration date which is the last day of the month in which a license holder's birthday falls pursuant to the Division of Health Related Boards "biennial birthdate renewal system" contained in rule 1200-10-1-.10.
 - (b) Methods of Renewal - Licensees may accomplish renewal by one (1) of the following methods:
 1. Internet Renewals - Individuals may apply for renewal and pay the necessary fees via the Internet. The application to renew can be accessed at:

www.tennesseeanytime.org
 2. Paper Renewals - Licensees who have not renewed their authorization online via the Internet, will have a renewal application form mailed to them at the last address provided by them to the Board prior to the expiration date of their current license. Failure to receive such notification does not relieve the individual of the responsibility of timely meeting all requirements for renewal. To be eligible for renewal a licensee must submit to the Division of Health Related Boards on or before the license's expiration date the following:
 - (i) A completed and signed renewal application form.
 - (ii) The renewal and state regulatory fees as provided in Rule 1050-02-.02.
 - (c) Any renewal application received after the expiration date but before the last day of the month following the expiration date must be accompanied by the Late Renewal Fee provided in Rule 1050-02-.02.
 - (d) Any individual who fails to comply with the license renewal rules and/or notifications sent to them concerning failure to timely renew shall have their license processed pursuant to rule 1200-10-01-.10.
 - (e) Anyone submitting a signed renewal form, electronically or otherwise, which is found to be fraudulent or untrue may be subject to disciplinary action.
 - (f) Any licensee who receives notice of failure to timely renew pursuant to rule 1200-10-01-.10, and who, on or before the last day of the month following the month in which the license expires, executes and files in the Board's administrative office an affidavit of retirement pursuant to Rule 1050-02-.08 may have their license retired effective on their licensure expiration date.
- (2) Licenses processed pursuant to rule 1200-10-01-.10 for failure to renew may be reinstated upon meeting the following conditions:

(Rule 1050-02-.07, continued)

- (a) Obtain, complete and submit a renewal/reinstatement/reactivation application; and
 - (b) At the discretion of the Board, either appear before it or submit a notarized statement setting forth the good cause for failure to renew; and
 - (c) Submit, along with the application, payment of all past due renewal fees; state regulatory fee and the late renewal fee provided in rule 1050-02-.02; and
 - (d) Submit evidence of being current in continuing medical education or an acceptable plan for making up all continuing medical education requirements.
 - (e) If derogatory information or communication is received during the renewal process, if requested by the Board or its duly authorized representative, appear before the Board, a Board member, a screening panel when the individual is under investigation or the Board Designee for an interview and/or be prepared to meet or accept other conditions or restrictions as the Board may deem necessary to protect the public.
 - (f) Any licensee who fails to renew licensure prior to the expiration of the second (2nd) year after which renewal is due may be required to meet or accept other conditions or restrictions as the Board may deem necessary to protect the public.
 - (g) Any licensee who fails to renew licensure prior to the expiration of the third (3rd) year after which renewal is due may be required to successfully complete a written or oral examination.
- (3) Renewal issuance and reinstatement decisions pursuant to this Rule may be made administratively subject to review by the Board, any Board member, or the Board Designee.

Authority: T.C.A. §§4-5-202, 4-5-204, 63-1-107, 63-9-101, 63-9-107, 63-19-109, and 63-9-111.
Administrative History: Original rule filed May 14, 1993; effective June 18, 1993. (Formerly 1050-02-3-.06) Repeal and new rule filed April 10, 2000; effective June 24, 2000. Amendment filed October 2, 2002; effective December 16, 2002.

1050-02-.08 LICENSURE RETIREMENT AND REACTIVATION.

- (1) Licensure Retirement
 - (a) Licensees who wish to retain their licenses but not actively practice osteopathic medicine may avoid compliance with the licensure renewal process by obtaining from, completing and submitting to the Board Administrative Office an affidavit of retirement form along with any documentation which may be required by the form.
 - (b) Upon successful application for retirement of licensure with completion and receipt of all proper documentation to the Board's satisfaction, the Board shall register the license as retired. Any person who has a retired license may not practice osteopathic medicine in Tennessee.
- (2) Licensure Reactivation - Any licensee whose license has been retired may re-enter active practice by doing the following:
 - (a) Submit a written request for licensure reactivation to, and receive a reactivation application from, the Board Administrative Office, and
 - (b) Complete the application and submit all applicable fees and penalties, and

(Rule 1050-02-.08, continued)

- (c) If requested, after review by the Board, Board members, or Board consultant/designee, appear before the Board, Board member, or Board consultant/designee for an interview regarding continued competence in the event of licensure retirement in excess of two (2) years.
- (d) The Board may attach other conditions as deemed necessary including, but not limited to:
 - 1. Submission of proof that continuing medical education requirements are current, and
 - 2. Successful completion of the Special Purpose Examination (SPEX) and/or the Comprehensive Osteopathic Medical Special Purpose Licensure Examination (COMSPEX).
- (e) At the Board's discretion, submission of any document or set of documents required by this rule or submission of verification of the authenticity, validity and accuracy of the content of any document or set of documents required by this rule directly from the FCVS or other Board approved credentialing service to the Board Administrative Office shall be deemed to be submission of originals of those documents or sets of documents by the issuing institution(s).

Authority: T.C.A. §§4-5-202, 4-5-204, 63-1-111, 63-9-101, and 63-9-107. **Administrative History:** Original rule filed June 6, 1994; effective August 20, 1994. (Formerly 1050-02-.07) Repeal and new rule filed April 10, 2000; effective June 24, 2000. Amendment filed August 29, 2003; effective November 12, 2003.

1050-02-.09 OFFICERS, RECORDS, MEETING REQUESTS, CERTIFICATES OF FITNESS, REPLACEMENT LICENSES, CONSULTANTS, DECLARATORY ORDERS AND SCREENING PANELS.

- (1) The Board shall annually elect from its members the following officers:
 - (a) President - Who shall preside at all Board meetings.
 - (b) Vice President - Who in the absence of the Board President shall preside at meetings.
 - (c) Secretary - Who, along with the Board Administrator, shall be responsible for all correspondence for the Board.
- (2) Minutes of the Board meetings and all records, documents, applications, and correspondence will be maintained in the Board's Administrative Office.
- (3) All requests, applications, notices, complaints, other communications and correspondence shall be directed to the Board's Administrative Office. Any requests or inquiries requiring a Board decision or official Board action except documents relating to disciplinary actions, declaratory orders or hearing requests must be received fourteen (14) days prior to a scheduled Board meeting and will be retained in the administrative office and presented to the Board at the Board meeting. Such documents not timely received shall be set over to the next Board meeting.
- (4) The Board members or the Board consultant/designee are individually vested with the authority to do the following acts:

(Rule 1050-02-.09, continued)

- (a) Review and make determinations on licensure, exemption renewal, and reactivation of licensure applications subject to the rules governing those respective applications.
- (b) Serve as Consultant to the Division to decide the following:
 1. Whether and what type disciplinary actions should be instituted upon complaints received or investigations conducted by the Division.
 2. Whether and under what terms a complaint, case or disciplinary action might be settled. Any matter proposed for settlement must be subsequently considered by the full Board and either adopted or rejected.
- (5) The Board authorizes the member who chaired the Board for a contested case to be the agency member to make the decisions authorized pursuant to rule 1360-04-01-.18 regarding petitions for reconsiderations and stays in that case.
- (6) Requests for Certificate of Fitness for licensees desiring to practice in another state must be made in writing to the Board Administrative Office and be accompanied by the fee provided in rule 1050-02-.02.
- (7) Requests for duplicate or replacement licenses must be made in writing to the Board Administrative Office and be accompanied by the fee provided in rule 1050-02-.02.
- (8) Declaratory Orders - The Board adopts, as if fully set out herein, rule 1200-10-01-.11, of the Division of Health Related Boards and as it may from time to time be amended, as its rule governing the declaratory order process. All declaratory order petitions involving statutes, rules or orders within the jurisdiction of the Board shall be addressed by the Board pursuant to that rule and not by the Division. Declaratory Order Petition forms can be obtained from the Board's administrative office.
- (9) Screening Panels - Any screening panel(s) established pursuant to T.C.A. § 63-1-138:
 - (a) Shall have concurrent authority with the Board members and any individual designated by the Board pursuant to paragraph (4), to do the acts enumerated in subparagraph (4) (b) subject to the conditions contained therein.
 1. A Screening panel(s) comprised of two (2) or more persons shall elect a chairperson prior to convening to conduct business.
 2. A screening panel(s) comprised of two (2) or more persons is required to conduct the informal hearings authorized in subparagraph (b) immediately below.
 - (b) After completion of an investigation by the Division, may upon request of either the state, or the licensee who is the subject of an investigation with the agreement of the state, or upon request of both the licensee and the state, conduct a non-binding informal hearing and make recommendations as a result thereof as to what, if any, terms of settlement of any potential disciplinary action are appropriate.
 1. Neither the Rules of Civil Procedure, the Rules of Mediation and Arbitration, the Rules of Evidence, or Contested Case Procedural Rules under the Administrative Procedures Act shall apply in informal hearings before the screening panel(s).
 - (i) Evidence may be presented or received in any manner and in whatever order agreed upon by the parties.

(Rule 1050-02-.09, continued)

- (ii) Prior to convening the panel and in the absence of an agreement of the parties, the screening panel chairperson shall determine the manner and order of presentation of evidence.
2. Informal hearings may be conducted without the participation of the licensee who is the subject of the investigation.
3. A licensee who is the subject of an investigation being considered by a screening panel cannot be compelled to participate in any informal hearing.
4. Proposed settlements reached as a result of any informal hearing will not become binding and final unless they are:
 - (i) Approved by a majority of the members of the screening panel which issued them; and
 - (ii) Agreed to by both the Department of Health, by and through its attorney(s), and the licensee; and
 - (iii) Subsequently presented to and ratified by the Board.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-9-101, and 63-9-111. **Administrative History:** Original rule filed April 10, 2000; effective June 24, 2000. Amendment filed July 27, 2000; effective October 10, 2000. Amendment filed October 2, 2002; effective December 16, 2002. Amendment filed March 22, 2007; effective June 5, 2007.

1050-02-.10 LICENSURE DISCIPLINE AND CIVIL PENALTIES.

- (1) Upon a finding by the Board that a licensee has violated any provision of the Tennessee Osteopathic Medical Practice Act (T.C.A. § 63-9-101, et seq.) or the rules promulgated pursuant thereto, the Board may impose any of the following actions separately or in any combination which is deemed appropriate to the offense.
 - (a) Private Censure - This is a written action issued to the licensee for minor or near infractions. It is informal and advisory in nature and does not constitute a formal disciplinary action.
 - (b) Public censure or reprimand - This is a written action issued to a licensee for one time and less severe violations. It is a formal disciplinary action.
 - (c) Probation - This is a formal disciplinary action which places a licensee on close scrutiny for a period of time.
 1. This action may be combined with any other formal disciplinary action and include conditions which must be met before probation can be lifted and/or which restrict or condition the licensee's activities during the probationary period.
 2. Once ordered, probation may not be lifted unless and until the licensee petitions and appears, pursuant to paragraph (2) of this rule, before the Board after the period of initial probation has run and all conditions placed on the probation have been met and the Board is satisfied that a further probationary period is not warranted.

(Rule 1050-02-.10, continued)

- (d) Licensure Suspension - This is a formal disciplinary action which suspends a licensee's right to practice osteopathic medicine for a fixed period of time. It contemplates the reentry of the licensee into practice under the license previously issued.
1. Once ordered, a suspension may not be lifted unless and until the licensee petitions and appears, pursuant to paragraph (2) of this rule, before the Board after the period of initial suspension has run and:
 - (i) All conditions placed on the suspension have been met; and
 - (ii) The Board is satisfied that the licensee is competent to return to practice and that no further period of suspension is warranted.
 2. It is the Board's intent that the licensee not practice osteopathic medicine at all during the period of suspension. If a licensee practices osteopathic medicine in another state during the period of any ordered suspension, the length of time of practice in another state shall not be counted toward fulfilling the suspension ordered by the Board.
 3. It is the Board's intent that during the period of any suspension, a licensee may not practice any health related profession or in any health related field unless permission is sought and granted by the Board.
- (e) Revocation with Leave To Apply - This is a formal disciplinary action which removes a licensee from the practice of osteopathic medicine in Tennessee and terminates the license previously issued. It relegates the licensee to the status possessed prior to initial application for licensure.
1. A revocation of this nature anticipates that if conditions contained in the revocation order are met that person may apply for a new license to practice osteopathic medicine. This does not guarantee that a new license will be issued unless or until the Board is satisfied that the person is competent to re-enter practice and is not a threat to the public health, safety or welfare.
 2. Petitions for reinstatement of licensure will not be accepted or entertained.
 3. Unless a shorter or longer period of time is included in the revocation order, application for a new license will not be accepted or entertained prior to the expiration of at least one (1) year from the effective date of the revocation. Under no circumstances will a new license be issued until the Board is satisfied that the applicant is competent to re-enter the practice of osteopathic medicine and has met all the then existing licensure requirements. Former disciplinary actions against a licensee can and will be considered in any decision on such licensure applications.
- (f) Permanent Licensure Revocation - This is the most severe form of disciplinary action which permanently removes a licensee from the practice of osteopathic medicine in Tennessee and terminates the license previously issued. It is the Board's intent that any licensee whose license is permanently revoked may never practice medicine in Tennessee again. Petitions for reinstatement or new applications for licensure will not be accepted or entertained.
- (g) Conditions - Any action deemed appropriate by the Board to be required of a disciplined licensee in any of the following circumstances:

(Rule 1050-02-.10, continued)

1. During any period of probation, suspension; or
 2. During any period of revocation after which the licensee may petition for an order of compliance to reinstate the revoked license; or
 3. As a prerequisite to the lifting of probation or suspension or as a prerequisite to the reinstatement of a revoked license; or
 4. As a stand-alone requirement(s) in any disciplinary order.
- (h) Civil penalty – A monetary disciplinary action assessed by the Board pursuant to paragraph (4) of this rule.
- (i) Summary Suspension - This is a formal preliminary disciplinary action which immediately suspends a licensee's right to practice osteopathic medicine until a final disposition of the matter is had after a promptly instituted, full hearing before the Board. This type of suspension is ordered ex parte, pursuant to the notice procedures contained in T.C.A. § 4-5-320 and then only upon a finding by the Board that the public health, safety or welfare imperatively requires emergency action.
- (j) Assessment of costs in disciplinary proceedings shall be as set forth in T.C.A. §§ 63-1-144 and 63-9-111.
- (2) Order of Compliance - This procedure is a necessary adjunct to previously issued disciplinary orders and is available only when a petitioner has completely complied with the provisions of a previously issued disciplinary order, including an unlicensed practice civil penalty order, and wishes or is required to obtain an order reflecting that compliance.
- (a) The Board will entertain petitions for an Order of Compliance as a supplement to a previously issued order upon strict compliance with the procedures set forth in subparagraph (b) in only the following two (2) circumstances:
1. When the petitioner can prove compliance with all the terms of the previously issued order and is seeking to have an order issued reflecting that compliance; or
 2. When the petitioner can prove compliance with all the terms of the previously issued order and is seeking to have an order issued lifting a previously ordered suspension or probation.
- (b) Procedures
1. The petitioner shall submit a Petition for Order of Compliance, as contained in subparagraph (c), to the Board's Administrative Office that shall contain all of the following:
 - (i) A copy of the previously issued order; and
 - (ii) A statement of which provision of subparagraph (a) the petitioner is relying upon as a basis for the requested order; and
 - (iii) A copy of all documents that prove compliance with all the terms or conditions of the previously issued order. If proof of compliance requires testimony of an individual(s), including that of the petitioner, the petitioner must submit signed statements from every individual the petitioner intends

(Rule 1050-02-.10, continued)

to rely upon attesting, under oath, to the compliance. The Board's consultant and administrative staff, in their discretion, may require such signed statements to be notarized. No documentation or testimony other than that submitted will be considered in making an initial determination on, or a final order in response to, the petition.

2. The Board authorizes its consultant and administrative staff to make an initial determination on the petition and take one of the following actions:
 - (i) Certify compliance and have the matter scheduled for presentation to the Board as an uncontested matter; or
 - (ii) Deny the petition, after consultation with legal staff, if compliance with all of the provisions of the previous order is not proven and notify the petitioner of what provisions remain to be fulfilled and/or what proof of compliance was either not sufficient or not submitted.
3. If the petition is presented to the Board the petitioner may not submit any additional documentation or testimony other than that contained in the petition as originally submitted.
4. If the Board finds that the petitioner has complied with all the terms of the previous order an Order of Compliance shall be issued.
5. If the petition is denied either initially by staff or after presentation to the Board and the petitioner believes compliance with the order has been sufficiently proven the petitioner may, as authorized by law, file a petition for a declaratory order pursuant to the provisions of T.C.A. § 4-5-223 and rule 1200-10-01-.11.

(c) Form Petition

Petition for Order of Compliance
Board of Osteopathic Examination

Petitioner's Name: _____
Petitioner's Mailing Address: _____

Petitioner's E-Mail Address: _____
Telephone Number: _____

Attorney for Petitioner: _____
Attorney's Mailing Address: _____

Attorney's E-Mail Address: _____
Telephone Number: _____

The petitioner respectfully represents, as substantiated by the attached documentation, that all provisions of the attached disciplinary order have been complied with and I am respectfully requesting: (circle one)

1. An order issued reflecting that compliance; or

(Rule 1050-02-.10, continued)

2. An order issued reflecting that compliance and lifting a previously ordered suspension or probation.

Note – You must enclose all documents necessary to prove your request including a copy of the original order. If any of the proof you are relying upon to show compliance is the testimony of any individual, including yourself, you must enclose signed statements from every individual you intend to rely upon attesting, under oath, to the compliance. The Board's consultant and administrative staff, in their discretion, may require such signed statements to be notarized. No documentation or testimony other than that submitted will be considered in making an initial determination on, or a final order in response to, this petition.

Respectfully submitted this the _____ day of _____, 20____.

Petitioner's Signature

- (3) Order Modifications - This procedure is not intended to allow anyone under a previously issued disciplinary order, including an unlicensed practice civil penalty order, to modify any findings of fact, conclusions of law, or the reasons for the decision contained in the order. It is also not intended to allow a petition for a lesser disciplinary action, or civil penalty other than the one(s) previously ordered. All such provisions of Board orders were subject to reconsideration and appeal under the provisions of the Uniform Administrative Procedures Act (T.C.A. §§ 4-5-301, et seq.). This procedure is not available as a substitute for reconsideration and/or appeal and is only available after all reconsideration and appeal rights have been either exhausted or not timely pursued. It is also not available for those who have accepted and been issued a reprimand.
 - (a) The Board will entertain petitions for modification of the disciplinary portion of previously issued orders upon strict compliance with the procedures set forth in subparagraph (b) only when the petitioner can prove that compliance with any one or more of the conditions or terms of the discipline previously ordered is impossible. For purposes of this rule the term "impossible" does not mean that compliance is inconvenient or impractical for personal, financial, scheduling or other reasons.
 - (b) Procedures
 1. The petitioner shall submit a written and signed Petition for Order Modification on the form contained in subparagraph (c) to the Board's Administrative Office that shall contain all of the following:
 - (i) A copy of the previously issued order; and
 - (ii) A statement of why the petitioner believes it is impossible to comply with the order as issued; and
 - (iii) A copy of all documents that proves that compliance is impossible. If proof of impossibility of compliance requires testimony of an individual(s), including that of the petitioner, the petitioner must submit signed and notarized statements from every individual the petitioner intends to rely upon attesting, under oath, to the reasons why compliance is impossible. No documentation or testimony other than that submitted will be considered in making an initial determination on, or a final order in response to, the petition.

(Rule 1050-02-.10, continued)

2. The Board authorizes its consultant and administrative staff to make an initial determination on the petition and take one of the following actions:
 - (i) Certify impossibility of compliance and forward the petition to the Office of General Counsel for presentation to the Board as an uncontested matter; or
 - (ii) Deny the petition, after consultation with legal staff, if impossibility of compliance with the provisions of the previous order is not proven and notify the petitioner of what proof of impossibility of compliance was either not sufficient or not submitted.
3. If the petition is presented to the Board the petitioner may not submit any additional documentation or testimony other than that contained in the petition as originally submitted.
4. If the petition is granted a new order shall be issued reflecting the modifications authorized by the Board that it deemed appropriate and necessary in relation to the violations found in the previous order.
5. If the petition is denied either initially by staff or after presentation to the Board and the petitioner believes impossibility of compliance with the order has been sufficiently proven the petitioner may, as authorized by law, file a petition for a declaratory order pursuant to the provisions of T.C.A. § 4-5-223 and rule 1200-10-01-.11.

(c) Form Petition

Petition for Order Modification
Board of Osteopathic Examination

Petitioner's Name: _____
Petitioner's Mailing Address: _____

Petitioner's E-Mail Address: _____
Telephone Number: _____

Attorney for Petitioner: _____
Attorney's Mailing Address: _____

Attorney's E-Mail Address: _____
Telephone Number: _____

The petitioner respectfully represents that for the following reasons, as substantiated by the attached documentation, the identified provisions of the attached disciplinary order are impossible for me to comply with:

(Rule 1050-02-.10, continued)

Note – You must enclose all documents necessary to prove your request including a copy of the original order. If any of the proof you are relying upon to show impossibility is the testimony of any individual, including yourself, you must enclose signed and notarized statements from every individual you intend to rely upon attesting, under oath, to the reasons why compliance is impossible. No documentation or testimony other than that submitted will be considered in making an initial determination on, or a final order in response to, this petition.

Respectfully submitted this the _____ day of _____, 20_____.

Petitioner's Signature

(4) Civil Penalties

(a) Schedule of Civil Penalties

1. A "Type A" Civil Penalty may be imposed whenever the Board finds a person who is required to be licensed, certified, permitted, or authorized by the Board, guilty of a willful and knowing violation of the Osteopathic Practice Act, or regulations promulgated pursuant thereto, to such an extent that there is, or is likely to be, an imminent, substantial threat to the health, safety and welfare of an individual patient or the public. For purposes of this section, willfully and knowingly practicing osteopathic medicine without a permit, license, certification, or other authorization from the Board is one of the violations of the Osteopathic Practice Act for which a "Type A" Civil Penalty is assessable.
2. A "Type B" Civil Penalty may be imposed whenever the Board finds the person required to be licensed, certified, permitted, or authorized by the Board is guilty of a violation of the Osteopathic Practice Act or regulations promulgated pursuant thereto in such manner as to impact directly on the care of patients or the public.
3. A "Type C" Civil Penalty may be imposed whenever the Board finds the person required to be licensed, certified, permitted, or authorized by the Board is guilty of a violation of the Osteopathic Practice Act or regulations promulgated pursuant thereto, which are neither directly detrimental to the patients or public, nor directly impact their care, but have only an indirect relationship to patient care or the public.

(b) Amount of Civil Penalties

1. "Type A" Civil Penalties shall be assessed in the amount of not less than \$500 nor more than \$1000.
2. "Type B" Civil Penalties shall be assessed in the amount of not less than \$100 nor more than \$500
3. "Type C" Civil Penalties shall be assessed in the amount of not less than \$50 nor more than \$100.

(c) Procedures for Assessing Civil Penalties

(Rule 1050-02-.10, continued)

1. The Division of Health Related Boards may initiate a civil penalty assessment by filing a Memorandum of Assessment of Civil Penalty. The Division shall state in a memorandum of facts and law upon which it relies in alleging a violation, the proposed amount of the civil penalty and the basis for such penalty. The Division may incorporate the Memorandum of Assessment of Civil Penalty with a Notice of Charges which may be issued attendant thereto.
2. Civil Penalties may also be initiated and assessed by the Board during consideration of any Notice of Charges. In addition, the Board may, upon good cause shown, assess a type and amount of civil penalty which was not recommended by the Division.
3. In assessing the civil penalties pursuant to these rules the Board may consider the following factors:
 - (i) Whether the amount imposed will be a substantial economic deterrent to the violator;
 - (ii) The circumstances leading to the violation;
 - (iii) The severity of the violation and the risk of harm to the public;
 - (iv) The economic benefits gained by the violator as a result of non-compliance; and,
 - (v) The interest of the public.
4. All proceedings for the assessment of civil penalties shall be governed by the contested case provisions of Title 4, Chapter 5, Tennessee Code Annotated.

Authority: T.C.A. §§4-5-202, 4-5-204, 4-5-217, 4-5-223, 63-1-122, 63-1-144, 63-9-101, 63-9-110 and 63-9-111. **Administrative History:** Original rule filed April 10, 2000; effective June 24, 2000. Amendment filed July 27, 2000; effective October 10, 2000. Amendment filed October 2, 2002; effective December 16, 2002. Amendment filed August 27, 2004; effective November 10, 2004. Amendment filed October 21, 2008; effective January 4, 2009.

1050-02-.11 ADVERTISING.

- (1) The lack of sophistication on the part of many of the public concerning osteopathic medical services, the importance of the interests affected by the choice of a physician and the foreseeable consequences of unrestricted advertising by osteopathic physicians which is recognized to pose special possibilities for deception, require that special care be taken by osteopathic physicians to avoid misleading the public. The osteopathic physician must be mindful that the benefits of advertising depend upon its reliability and accuracy. Since advertising by osteopathic physicians 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 the practice of an osteopathic physician who is licensed to practice in Tennessee.

(Rule 1050-02-.11, continued)

- (b) Licensee - Any person holding a license to practice osteopathic medicine 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 practitioners to serve his or her 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 person or organization for any product or service that is less than the fee the person or organization 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."
- (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 public.
 - (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 - 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. 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 content of advertisement by any licensee shall constitute unethical and unprofessional conduct, and subject the licensee to disciplinary action.

(Rule 1050-02-.11, continued)

- (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 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 osteopathic 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) 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

(Rule 1050-02-.11, continued)

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 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 makes the fact of compensation apparent.
- (r) After thirty (30) days of the licensee's departure, the use of the name of any licensee formerly practicing at or associated with any advertised location or on office signs or buildings is prohibited. 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 advertisements 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 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

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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, 63-9-101, and 63-9-111. **Administrative History:** Original rule filed April 10, 2000; effective June 24, 2000.

1050-02-.12 CONTINUING EDUCATION REQUIREMENTS.

- (1) Hours Required, Waiver, and Exemptions
 - (a) During the two (2) calendar years that precede licensure renewal, all licensees must complete forty (40) hours of courses approved by the Board in Category I-A, II-A and/or I-B continuing medical education as defined in the most current annual American Osteopathic Association Yearbook and Directory.
 - (b) At least one (1) of the forty (40) required hours shall be a course designed specifically to address prescribing practices. The course should include, but not be limited to, instruction on controlled substance prescribing practices.
 - (c) Osteopathic physicians serving as preceptors in any AOA approved osteopathic medical education program may be granted one (1) Category I-B credit for each hour of preceptor work actually performed, up to a maximum of fifty percent (50%) of the total biennially required continuing medical education.
 - (d) The Board approves a course for only the number of hours contained in the course. The approved hours of any individual course will not be counted more than once in a calendar year toward the required hourly total regardless of the number of times the course is attended or completed by any individual.
 - (e) Waiver - The Board may waive the requirements of these rules in cases where illness, disability, or other undue hardship beyond the control of the licensee prevents a licensee from complying. Requests for waivers must be sent in writing to the Board prior to the expiration of the calendar year in which the continuing medical education is due.
 - (f) Exemptions:
 1. Anyone whose license is in the retired status pursuant to rule 1050-02-.08 is exempt from the requirements of these continuing medical education rules.
 2. Anyone who obtains licensure in the same calendar year as successful completion of the NBOME, COMLEX, or the USMLE Step 3 is exempt from the provisions of these continuing medical education rules but only for the calendar year in which licensure is issued.
- (2) Proof of Compliance - All licensees must retain independent documentation of completion of all continuing medical education hours and compliance with the provisions of these rules.
 - (a) This documentation must be retained for a period of four (4) years from the end of the calendar year in which the continuing medical education was acquired.
 - (b) This documentation must be produced for inspection and verification, if requested in writing by the Division during its verification process.

(Rule 1050-02-.12, continued)

- (c) Documentation verifying the licensee's completion of the continuing medical education hours may consist of any one (1) or more of the following:
 - 1. Original certificates verifying the individual's attendance at the continuing education programs described above.
 - 2. Original letters on official institution stationary or photocopies of original letters on official institution stationary from the instructor of the graduate level course verifying that the course was completed and listing the number of credit hours of attendance completed by the individual; or
 - 3. Documentation from the American Academy of Family Physicians (hereafter AAFP) indicating acquired continuing medical education hours; or
 - 4. Official transcript verifying credit hours earned. One (1) semester academic credit hour is equivalent to fifteen (15) clock hours for the purpose of licensure renewal. Credit for auditing will be for the actual clock hours in attendance, not to exceed the academic credit.
- (3) Acceptable Continuing Education - To be utilized for satisfaction of the continuing education requirements of this rule, the continuing education hours must comply with the following:
 - (a) They must be approved in content, structure and/or format by the A.O.A., or by the Accreditation Council for Continuing Medical Education (A.C.C.M.E.) or by a state medical association recognized by the A.C.C.M.E. as an intrastate accreditor of sponsors of continuing medical education; or
 - (b) They must be designated by the AAFP as meeting the criteria of the AAFP's prescribed credit.
- (4) Violations and Disciplinary Orders
 - (a) Any licensee who fails to obtain the required continuing medical education hours or otherwise comply with the provisions of these rules will be subject to disciplinary action.
 - (b) Continuing medical education hours obtained as a result of compliance with the terms of Board Orders in any disciplinary action or obtained pursuant to licensure or renewal restriction/conditions mandated by the Board shall not be credited toward the continuing medical education hours required to be obtained in any calendar year.

Authority: T.C.A. §§4-5-202, 4-5-204, 63-9-101, and 63-9-107. **Administrative History:** Original rule filed April 10, 2000; effective June 24, 2000. Amendment filed October 2, 2002; effective December 16, 2002. Amendment filed April 17, 2007; effective July 1, 2007. Amendments filed August 27, 2009; effective November 25, 2009.

1050-02-.13 SPECIFICALLY REGULATED AREAS AND ASPECTS OF MEDICAL PRACTICE.

- (1) The scope of practice of osteopathic physicians in Tennessee is broadly defined in the Osteopathic Medical Act and promulgated rules and includes many aspects which if not particularly regulated could lead to serious ramifications for the consuming public. This rule is to designate specific areas in the practice of osteopathic medicine for regulation the violation of which may result in disciplinary action pursuant to T.C.A. § 63-9-111.
- (2) Pharmaceutical Dispensing - Osteopathic physicians who elect to dispense medication for remuneration must comply with the following:

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- (a) All Federal Regulations (21 CFR 1304 through 1308) for the dispensing of controlled substances.
 - (b) Requirements for dispensing of non-controlled drugs are as follows:
 - 1. Drugs are to be dispensed in an appropriate container labeled with at least, the following:
 - (i) Patient's name.
 - (ii) Date.
 - (iii) Complete directions for usage.
 - (iv) The physician's name and address.
 - (v) A unique number, or the name and strength of the medication.
 - 2. Physicians may dispense only to individuals with whom they have established a physician/patient relationship. It shall be a violation of this rule for a physician to dispense medication at the order of any other physician not registered to practice at the same location.
 - 3. Whenever dispensing takes place, appropriate records shall be maintained. A separate log must be maintained for controlled substances dispensing.
 - (c) It is not the intention of the rule to interfere with the individual physician's appropriate use of professional samples, nor to interfere in any way with the physician's right to directly administer drugs or medicines to any patient.
 - (d) Dispensing or prescribing controlled substances in amounts or for durations not medically necessary, advisable or justified is considered to be practicing beyond the scope of the professional practice.
- (3) Prescription writing shall be governed by Tennessee Code Annotated, Section 63-9-116 and Title 53, Chapter 10, Part 2.
 - (4) Supervision - See Rule 1050-02-.15 The Utilization and Supervision of a Certified Nurse Practitioner or Licensed Physician Assistant.
 - (5) Guidelines for the Use of Controlled Substances for the Treatment of Pain -
 - (a) Purposes and Intent
 - 1. The Board recognizes that principles of quality medical practice dictate that the people of the State of Tennessee have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable

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- about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.
2. Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Accordingly, these guidelines have been developed pursuant to the Tennessee Intractable Pain Treatment Act to clarify the Board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.
 3. The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. Physicians are referred to the U.S. Agency for Health Care and Research Clinical Practice Guidelines for a sound approach to the management of acute and cancer-related pain. The medical management of pain should be based on current knowledge and research and include the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.
 4. The Board is obligated under the laws of the State of Tennessee to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.
 5. Physicians should not fear disciplinary action from the Board for prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. The Board will consider prescribing, ordering, administering or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state and federal law.
 6. Each case of prescribing for pain will be evaluated on an individual basis. The board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs-including any improvement in functioning-and recognizing that some types of pain cannot be completely relieved.
 7. The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following

(Rule 1050-02-.13, continued)

guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.

- (b) Guidelines - The Board adopts the following guidelines when evaluating the use of controlled substances for pain control:
1. Evaluation of the Patient - A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.
 2. Treatment Plan - The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.
 3. Informed Consent and Agreement for Treatment - The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible.
 4. Periodic Review - At reasonable intervals based on the individual circumstances of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives, such as improvement in patient's pain intensity and improved physical and/or psychosocial function, i.e., ability to work, need of health care resources, activities of daily living and quality of social life. If treatment goals are not being achieved, despite medication adjustments, the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.
 5. Consultation - The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. The management of pain in patients with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.
 6. Medical Records - The physician should keep accurate and complete records to include the medical history and physical examination; diagnostic, therapeutic and laboratory results; evaluations and consultations; treatment objectives; discussion of risks and benefits; treatments; medications (including date, type, dosage and quantity prescribed); instructions and agreements; and periodic reviews. Records should remain current and be maintained in an accessible manner and readily available for review.

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- (c) No physician is required to provide treatment to patients with intractable pain with opiate medications but when refusing to do so shall inform the patient that there are physicians whose primary practice is in the treatment of severe, chronic, intractable pain with methods including the use of opiates. If the patient requests a referral to such a physician, and the physician makes such a referral that referral shall be noted in the patient's medical records.
 - (d) If a physician provides medical care for persons with intractable pain, with or without the use of opiate medications, to the extent that those patients become the focus of the physician's practice the physician must be prepared to document specialized medical education in pain management sufficient to bring the physician within the current standard of care in that field which shall include education on the causes, different and recommended modalities for treatment, chemical dependency and the psycho/social aspects of severe, chronic intractable pain.
 - (e) The treatment of persons with an acute or chronic painful medical condition who also require treatment for chemical dependency by a physician shall be governed by subsections T.C.A. § 63-6-1107 (c) and (d).
- (6) Prerequisites to Issuing Prescriptions or Dispensing Medications - In Person, Electronically, and Over the Internet
- (a) Except as provided in subparagraph (b), it shall be a prima facie violation of T.C.A. § 63-9-111 (b) (1), (4), and (11) for a physician to prescribe or dispense any drug to any individual, whether in person or by electronic means or over the Internet or over telephone lines, unless the physician, or his/her licensed supervisee pursuant to appropriate protocols or medical orders, has first done and appropriately documented, for the person to whom a prescription is to be issued or drugs dispensed, all of the following:
 - 1. Performed an appropriate history and physical examination; and
 - 2. Made a diagnosis based upon the examinations and all diagnostic and laboratory tests consistent with good medical care; and
 - 3. Formulated a therapeutic plan, and discussed it, along with the basis for it and the risks and benefits of various treatments options, a part of which might be the prescription or dispensed drug, with the patient; and
 - 4. Insured availability of the physician or coverage for the patient for appropriate follow-up care.
 - (b) A physician, or his/her licensed supervisee pursuant to appropriate protocols or medical orders, may prescribe or dispense drugs for a person not in compliance with subparagraph (a) in circumstances consistent with sound medical practice, examples of which are as follows:
 - 1. In admission orders for a newly hospitalized patient; or
 - 2. For a patient of another physician for whom the prescriber is taking calls or for whom the prescriber has verified the appropriateness of the medication; or
 - 3. For continuation medications on a short-term basis for a new patient prior to the patient's first appointment; or

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4. For established patients who, based on sound medical practices, the physician feels do not require a new physical examination before issuing new prescriptions;
or
 5. In compliance with paragraph (9) of this rule.
- (c) It shall be a prima facie violation of T.C.A. § 63-9-111 (b) (1), (4), and (11) for a physician, or his/her licensed supervisee pursuant to appropriate protocols or medical orders, to prescribe or dispense any drug to any individual for whom the physician, or his/her licensed supervisee pursuant to appropriate protocols or medical orders, has not complied with the provisions of this rule based solely on answers to a set of questions regardless of whether the prescription is issued directly to the person or electronically over the Internet or telephone lines.
- (7) Amphetamines, Amphetamine-Like Substances, and Central Nervous System Stimulants.
- (a) It shall be a prima facie violation of T.C.A. §§ 63-9-111 (b)(1) and 63-9-111 (b)(11) to prescribe, order, administer, sell or otherwise distribute any amphetamine drug except:
1. For treatment of the following:
 - (i) attention deficit disorder;
 - (ii) drug-induced brain dysfunction;
 - (iii) narcolepsy;
 - (iv) dementia or organic brain syndrome with severe psychomotor retardation;
 - (v) Chronic depression refractory to other drugs. Such diagnosis must be included on the prescription.
 2. When the licensee has applied for and received from the Board of Osteopathic Examination a written approval for the clinical investigation of such drugs under a protocol satisfactory to the Board. Any such approval by the Board of Osteopathic Examination will be filed with the Board of Pharmacy and disseminated by the Board of Pharmacy to any pharmacy which would fill prescriptions written during the research.
- (b) The list of amphetamine drugs governed by this rule includes the following controlled substances:
1. Amphetamine, its salts, optical isomers and salts of its optical isomers; (examples are Biphedamine, Dexadrine, Benzedrine and others).
 2. Methamphetamine, its salts, isomers and salts of isomers; (an example is Desoxyn).
 3. Any salt, any type of isomer and salts of such isomers, or any chemical element or any mixture, compound, material or preparation, containing any quantity of any of the substances listed above or their salts, any type of isomers and salts of such isomers, or chemical elements are also governed by this rule.
- (c) It shall be a prima facie violation of T.C.A. §§ 63-9-111 (b)(1) and 63-9-111 (b)(11) to prescribe, order, administer, sell or otherwise distribute any amphetamine-like

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substance listed below, except when the licensee has applied for and received from the Board of Osteopathic Examination a written approval for the clinical investigation of such drugs under a protocol satisfactory to the Board. Any such approval by the Board of Osteopathic Examination will be filed with the Board of Pharmacy and disseminated by the Board of Pharmacy to any pharmacy which would fill prescriptions written during the research.

1. The list of amphetamine-like substances governed by this rule are the following controlled substances:
 - (i) Phenmetrazine and its salts; (an example is Preludin)
 - (ii) Benzphetamine; (an example is Didrex)
 - (iii) Chlorphentermine; (an example is Pre Sate)
 - (iv) Phendimetrazine; (examples are Plegine, Bontril, Meltiat, Prelu-2, dipost, Wehles, and others)
 - (v) Diethylpropion; (examples are Tenuate and Tepanil)
 - (vi) Mazindol; (examples are Mazandor and Sanorex)
 - (vii) Phentermine; (examples Ionamin, Fastin, Adipex and others), except as authorized pursuant to T.C.A. § 63-6-214;
 - (viii) Fenfluramine HS; (an example Pondimin), except as authorized pursuant to T.C.A. § 63-6-214.
 2. Any salt, any type of isomer and salts of such isomers, or any chemical element or any mixture, compound, material or preparation, containing any quantity of any of the substances listed above or their salts, any type of isomers and salts of such isomers, or chemical elements, except as authorized pursuant to T.C.A. § 63-6-214, are also governed by this rule.
- (d) It shall be a prima facie violation of T.C.A. §§ 63-9-111 (b)(1) and 63-9-111 (b)(11) to prescribe, order, administer, sell or otherwise distribute any central nervous system stimulant listed below except:
1. For treatment of any of the following:
 - (i) attention deficit disorder;
 - (ii) drug-induced brain dysfunction;
 - (iii) narcolepsy;
 - (iv) dementia or organic brain syndrome with severe psychomotor retardation;
 - (v) Chronic depression refractory to other drugs. Such diagnosis must be included on the prescription.
 2. When the licensee has applied for and received from the Board of Osteopathic Examination a written approval for the clinical investigation of such drugs under a protocol satisfactory to the Board. Any such approval by the Board of

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Osteopathic Examination will be filed with the Board of Pharmacy and disseminated by the Board of Pharmacy to any pharmacy which would fill prescriptions written during the research.

- (e) The list of central nervous system stimulants governed by this rule are the following controlled substances:
 - 1. methylphenidate; (an example is Ritalin);
 - 2. pemoline (including organometallic complexes and chelates thereof; an example is Cylert);
 - 3. Any salt, any type of isomer and salts of such isomers, or any chemical element or any mixture, compound, material or preparation, containing any quantity of any of the substances listed above or their salts, any type of isomers and salts of such isomers, or chemical elements are also governed by this rule.

- (8) Code of Ethics - The Board adopts, as if fully set out herein and to the extent that it does not conflict with state law, rules or Board Position Statements, as its code of medical ethics the "Code of Ethics" published by the A.O.A. as it may, from time to time, be amended.
 - (a) In the case of a conflict the state law, rules or position statements shall govern. Violation of the Board's code of ethics shall be grounds for disciplinary action pursuant to T.C.A. § 63-9-111 (b) (1).
 - (b) A copy of the A.O.A. "Code of Ethics" may be obtained from the American Osteopathic Association, 142 E. Ontario Street, Chicago, IL 60611 or by phone at (312) 202-8138.

- (9) Treatment of Chlamydia trachomatis
 - (a) Purpose - This rule provides an acceptable deviation from the normal standard of care in the treatment of Chlamydia trachomatis (hereafter Ct) and provides a means for physicians to help reduce Tennessee's rate of Ct infection which currently exceeds the national rate by over ten percent (10%), and which, if left untreated, can cause serious health problems including pelvic inflammatory disease, ectopic pregnancies, infertility, cervical cancer and an increased risk of HIV infection. This rule will allow physicians and those over whom they exercise responsibility and control to provide an effective and safe treatment to the partners of patients infected with Ct who for various reasons may not otherwise receive appropriate treatment.
 - (b) For purpose of this rule "partner(s)" shall mean any person who comes into sexual contact with the infected patient during the sixty (60) days prior to the onset of patient's symptoms or positive diagnostic test results.
 - (c) Prerequisites - Physicians and those who provide medical services under their responsibility and control who have first documented all of the following in the medical records for patients may provide partner treatment pursuant to subparagraph (d) of this rule:
 - 1. A laboratory-confirmed Ct infection without evidence of co-infection with gonorrhea or other complications suggestive of a relationship to Ct infection; and
 - 2. Provision of treatment of the patient for Ct; and

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3. An attempt to persuade the infected patient to have all partners evaluated and treated and the patient indicated that partners would not comply; and
 4. Provision of a copy of reproducible, department-provided Ct educational fact sheet or substantially similar Ct-related literature available from other professional sources to the patient with copies for all partners; and
 5. Counseling the patient on sexual abstinence until seven (7) days after treatment and until seven (7) days after partners have been treated; and
- (d) Partner Treatment - Upon documentation in the patient's medical records of all prerequisites in subparagraph (c) physicians or those who provide medical services under their responsibility and control may either:
1. Provide to the treated patient non-named signed prescriptions for, or dispense to the patient, the appropriate quantity and strength of azithromycin sufficient to provide curative treatment for the total number of unnamed "partners" as defined in subparagraph (b) and indicated by the patient.
 2. Provide to the treated patient signed, name-specific prescriptions for, or dispense to the patient, the appropriate quantity and strength of azithromycin sufficient to provide curative treatment for the total number of known partners as defined in subparagraph (b) and named by the patient.
- (10) Use of Laser Equipment - Any procedure encompassed within the definition of the practice of osteopathic medicine contained in T.C.A. § 63-9-106 that is to be performed by use of a laser shall be considered, except as provided in T.C.A. §§ 63-26-102 (5) and 63-6-204, to be the practice of osteopathic medicine.
- (11) Use of Titles - Any person who possesses a valid, current and active license issued by the Board that has not been suspended or revoked has the right to use the titles "Osteopathic Physician," "Osteopathic Physician and Surgeon," "Doctor of Osteopathic Medicine," "Doctor of Osteopathy," or "D.O." and to practice osteopathic medicine, as defined in T.C.A. §§ 63-9-106. Any person licensed by the Board to whom this rule applies must use one of the titles authorized by this rule in every "advertisement" [as that term is defined in rule 1050-02-.11 (2) (a)] he or she publishes or the failure to do so will constitute an omission of a material fact which makes the advertisement misleading and deceptive and subjects the physician to disciplinary action pursuant to T.C.A. § 63-9-111(b) (1), (b) (3), (b) (10) and (b) (19).

Authority: T.C.A. §§ 4-5-202, 4-5-204, 53-10-201, et seq., 63-1-145, 63-1-146, 63-9-101, 63-9-106, 63-9-109, 63-9-111, and 63-9-116. **Administrative History:** Original rule filed April 10, 2000; effective June 24, 2000. Amendment filed April 10, 2000; effective June 24, 2000. Amendment filed January 28, 2002; effective April 13, 2002. Amendment filed October 2, 2002; effective December 16, 2002. Amendment filed October 23, 2002; effective January 6, 2003. Amendment filed May 28, 2003; effective August 11, 2003. Amendment filed October 6, 2005; effective December 20, 2005. Amendment filed March 22, 2007; effective June 5, 2007. Amendment filed October 21, 2008; effective January 4, 2009.

1050-02-.14 UNIVERSAL PRECAUTIONS FOR THE PREVENTION OF HIV TRANSMISSION. The Board adopts, as if fully set out herein, rules 1200-14-03-.01 through 1200-14-03-.03 inclusive, of the Department of Health and as they may from time to time be amended, as its rule governing the process for implementing universal precautions for the prevention of HIV transmission for health care workers under its jurisdiction.

Authority: T.C.A. §§ 4-5-202, 4-5-204, and 68-11-222. **Administrative History:** Original rule filed April 10, 2000; effective June 24, 2000.

1050-02-.15 THE UTILIZATION AND SUPERVISION OF A CERTIFIED NURSE PRACTITIONER OR LICENSED PHYSICIAN ASSISTANT.

- (1) Physician Assistants - The Tennessee Board of Osteopathic Examination adopts, as if fully set out herein, paragraph (30) of rule 0880-03-.01, rule 0880-03-.02 and rule 0880-03-.10 of the Board of Medical Examiners, and as they may from time to time be amended, as its rules governing an osteopathic physician's supervision of a licensed physician assistant.
- (2) Nurse Practitioners - The Tennessee Board of Osteopathic Examination adopts, as if fully set out herein, rule 0880-06-.01 and rule 0880-06-.02 of the Board of Medical Examiners, and as they may from time to time be amended, as its rules governing an osteopathic physician's supervision of a certified nurse practitioner.
- (3) Penalties - Any licensed osteopathic physician subject to the jurisdiction of the Board of Osteopathic Examination who supervises a certified nurse practitioner or licensed physician assistant inconsistent with the provisions of the Tennessee Osteopathic Practice Act and/or any of the other rules and regulations promulgated pursuant thereto shall be deemed guilty of "unprofessional conduct" and subject to disciplinary action by the Board in accordance with the provisions of T.C.A. § 63-9-101, *et seq.* Such disciplinary action includes, but is not limited to, the suspension of privileges to utilize a certified nurse practitioner or licensed physician assistant pursuant to T.C.A. §§ 63-9-106 and 63-9-111 and the provisions of this chapter, or the suspension, or revocation of an osteopathic physician's license to practice in Tennessee.

Authority: T.C.A. §§4-5-202, 4-5-204, 63-7-123, 63-9-101, 63-9-106, 63-9-111, 63-9-113, 63-19-106, and 63-19-107. **Administrative History:** Original rule filed April 10, 2000; effective June 24, 2000.

1050-02-.16 CONSUMER RIGHT-TO-KNOW REQUIREMENTS.

- (1) Malpractice Reporting Requirements - The threshold amount below which medical malpractice judgments, awards or settlements in which payments are awarded to complaining parties need not be reported pursuant to the "Health Care Consumer Right-To-Know Act of 1998" shall be seventy-five thousand dollars (\$75,000).
- (2) Criminal Conviction Reporting Requirements - For purposes of the "Health Care Consumer Right-To-Know Act of 1998," the following criminal convictions must be reported:
 - (a) Conviction of any felony; and
 - (b) Conviction or adjudication of guilt of any misdemeanor, regardless of its classification, in which any element of the misdemeanor involves any one or more of the following:
 1. Sexual Misconduct.
 2. Alcohol or drugs.
 3. Physical injury or threat of injury to any person.
 4. Abuse or neglect of any minor, spouse or the elderly.
 5. Fraud or theft.
 6. Practicing medicine without a license.

(Rule 1050-02-.16, continued)

- (c) If any misdemeanor conviction reported under this rule is ordered expunged, a copy of the order of expungement signed by the judge must be submitted to the Department before the conviction will be expunged from any profile.

Authority: T.C.A. §§4-5-202, 4-5-204, 63-9-101, 63-9-111, 63-51-102, and 63-51-105. **Administrative History:** Original rule filed April 10, 2000; effective June 24, 2000.

1050-02-.17 TELEMEDICINE LICENSURE. No person shall engage in the practice of osteopathic medicine across state lines in this State, hold himself out as qualified to do the same, or use any title, word, or abbreviation to indicate to or induce others to believe that he is licensed to practice osteopathic medicine across state lines in this State unless he is actually so licensed in accordance with the provisions of this rule.

- (1) Definitions - As used in this rule, the practice of osteopathic medicine across state lines (telemedicine) means:
 - (a) The rendering of a written or otherwise documented medical opinion concerning diagnosis or treatment of a patient within this State by an osteopathic physician located outside this State as a result of transmission of individual patient data by electronic or other means from within this State to such osteopathic physician or his agent; or
 - (b) The rendering of treatment to a patient within this State by an osteopathic physician located outside this State as a result of transmission of individual patient data by electronic or other means from within this State to such osteopathic physician or his agent.
- (2) Issuance of License - An applicant who has an unrestricted license in good standing in another state and maintains an unencumbered certification in a recognized specialty area; or is eligible for such certification and indicates a residence and a practice outside the State of Tennessee but proposes to practice osteopathic medicine across state lines on patients within the physical boundaries of the State of Tennessee, shall in the discretion of the Board be issued a telemedicine license.
 - (a) To obtain a license, an applicant shall compile the following and when completed, submit them to the Board Administrative Office:
 - 1. A Board approved application form; and
 - 2. All documentation required by rule 1050-02-.03 subparagraphs (1) (b), (1) (f), (1) (g), (1) (i), (1) (j) and (2) (a).
 - (b) The practice of any person issued a telemedicine license shall be restricted to the specialty area of osteopathic medicine in which that person is certified or in which the person is eligible for certification.
 - (c) All telemedicine licenses must be renewed, inactivated or retired according to the same procedure as active unrestricted licenses governed by rules 1050-02-.07 and 1050-02-.08.
 - (d) All telemedicine licenses are subject to discipline for the same causes and pursuant to the same procedures as active unrestricted licenses.
 - (e) In the event of previous disciplinary or other action against the applicant, the Board may, in its discretion, issue a license to practice osteopathic medicine across state

(Rule 1050-02-.17, continued)

lines if it finds that the previous disciplinary or other action does not indicate that the osteopathic physician is a potential threat to the public.

- (3) Effect of License - The issuance by the Board of a special purpose license to practice osteopathic medicine across state lines subjects the licensee to the jurisdiction of the Board in all matters set forth in the Osteopathic Practice Act and implementing rules and regulations, including all matters related to discipline. The licensee agrees by acceptance of such license to do the following:
 - (a) Produce patient medical records and/or materials as requested by the Board and/or to appear before the Board upon receipt of notice commanding appearance issued by the Board. Failure of the licensee to appear and/or to produce records or materials as requested, after appropriate notice, shall constitute grounds to suspend or revoke the licensee's telemedicine license at the Board's discretion.
 - (b) Designate on the licensure application the name, address and telephone number of a physician residing in Tennessee upon whom service of process for any disciplinary action filed against the licensee can be legally made in the event that personal service upon the licensee has been shown to be unsuccessful. Service of process on that named individual, for acts or omissions that occurred during or as a result of the treatments provided or ordered by the licensee for patients physically located in Tennessee, is legally equivalent to personal service on the licensee.
- (4) Patient Medical Records - Any licensee licensed under the provision of this rule shall comply with all laws, rules, and regulations governing the maintenance of patient medical records, including patient confidentiality requirements, regardless of the state where the medical records of any patient within this State are maintained.
- (5) Any person who violates the provisions of this Act is subject to criminal prosecution for the unlicensed practice of osteopathic medicine pursuant to T.C.A. § 63-9-109, and/or injunctive or other action authorized in this State to prohibit or penalize continued practice without a license. Nothing in this rule shall be interpreted to limit or restrict the Board's authority to discipline any osteopathic physician licensed to practice in this State who violates the Osteopathic Practice Act while engaging in the practice of osteopathic medicine within this or any other State.
- (6) Exempted from the provisions of this rule are the following:
 - (a) An osteopathic physician who practice osteopathic medicine across state lines in an emergency; or
 - (b) Licensed / registered osteopathic physicians or surgeons of other states when called in consultation by a Tennessee licensed / registered osteopathic physician.
- (7) Not exempted from these rules is the practice of osteopathic medicine across state lines conducted within the parameters of a contractual relationship.
- (8) At the Board's discretion, submission of any document or set of documents required by this rule or submission of verification of the authenticity, validity and accuracy of the content of any document or set of documents required by this rule directly from the FCVS or other Board approved credentialing service to the Board Administrative Office shall be deemed to be submission of originals of those documents or sets of documents by the issuing institution(s).

(Rule 1050-02-.17, continued)

Authority: T.C.A. §§4-5-202, 4-5-204, 63-9-101, 63-9-104, and 63-9-111. **Administrative History:** Original rule filed April 10, 2000; effective June 24, 2000. Amendment filed March 14, 2006; effective May 28, 2006.

1050-02-.18 MEDICAL RECORDS.

- (1) Purposes - The purposes of these rules are:
 - (a) To recognize that medical records are an integral part of the practice of osteopathic medicine as defined in T.C.A. § 63-9-106.
 - (b) To give physicians, their professional and non-professional staff, and the public direction about the content, transfer, retention, and destruction of those records.
 - (c) To recognize that a distinction exists between a physician's medical records for a patient receiving services in the physician's office and those records created by the physician for that patient for purposes of services provided in a hospital as defined by T.C.A. § 68-11-302 (4) and that the distinction exists regardless of the fact that the physician may also be an employee of the hospital or of a medical group employed or owned by the hospital.
- (2) Conflicts - As to medical records, these rules should be read in conjunction with the provisions of T.C.A. §§ 63-2-101 and 102, and are not intended to conflict with those statutes in any way. Those statutes, along with these rules, govern the subjects that they cover in the absence of other controlling state or federal statutes or rules to the contrary.
- (3) Applicability - These rules regarding medical records shall apply only to those records, the information for which was obtained by physicians or their professionally licensed employees, or those over whom they exercise supervision, for purposes of services provided in any clinical setting other than those provided in a hospital as defined by T.C.A. § 68-11-302 (4), a hospital emergency room or hospital outpatient facility.
- (4) Medical Records -
 - (a) Duty to Create and Maintain Medical Records - As a component of the standard of care and of minimal competency a physician must cause to be created and cause to be maintained a medical record for every patient for whom he or she, and/or any of his or her professionally licensed supervisees, performs services or provides professional consultation.
 - (b) Notice - Anywhere in these rules where notice is required to be given to patients of any physician that notice shall be required to be issued within thirty (30) days of the date of the event that triggers the notice requirement, and may be accomplished by public notice.
 - (c) Distinguished from Hospital Medical Records - The medical records covered by these rules are separate and distinct from those records generated for the patient by the physician during the course of providing medical services for the patient in a hospital as defined by T.C.A. § 68-11-302 (4) regardless of the fact that the physician may also be an employee of the hospital or of a medical group employed or owned by the hospital.
 1. The provisions of T.C.A. Title 68, Part 11, Chapter 3 govern medical records generated in a hospital as defined by T.C.A. § 68-11-302 (4).
 2. The medical records covered by these rules are those:

(Rule 1050-02-.18, continued)

- (i) That are created prior to the time of the patient's admission to or confinement and/or receipt of services in a hospital as defined by T.C.A. § 68-11-302 (4), hospital emergency room and/or hospital outpatient facility, and/or
 - (ii) That are created after the patient's discharge from a hospital as defined by T.C.A. § 68-11-302 (4), hospital emergency room or hospital outpatient facility.
 - (iii) That are created during the practice of medicine as defined by T.C.A. § 63-6-204 outside of a hospital as defined by T.C.A. § 68-11-302 (4), hospital emergency room or hospital outpatient facility.
3. Even though the records covered by these rules may, of necessity, reference provision of services in the hospital setting and the necessary initial work-up and/or follow-up to those services, that does not make them "hospital records" that are regulated by or obtainable pursuant to T.C.A. Title 68, Part 11, Chapter 3.
- (d) Content - All medical records, or summaries thereof, produced in the course of the practice of medicine for all patients shall include all information and documentation listed in T.C.A. § 63-2-101 (c) (2) and such additional information that is necessary to insure that a subsequent reviewing or treating physician can both ascertain the basis for the diagnosis, treatment plan and outcomes, and provide continuity of care for the patient.
- (e) Transfer -
 1. Records of Physicians upon Death or Retirement - When a physician retires or dies while in practice, patients seen by the physician in his/her office during the immediately preceding thirty-six (36) months shall be notified by the physician, or his/her authorized representative and urged to find a new physician and be informed that upon authorization, copies of the records will be sent to the new physician. This notification requirement shall not apply to a patient when there have been fewer than two (2) office patient encounters within the immediately preceding eighteen (18) months.
 2. Records of Physicians upon Departure from a Group - The responsibility for notifying patients of a physician who leaves a group practice whether by death, retirement or departure shall be governed by the physician's employment contract.
 - (i) Whomever is responsible for that notification must notify patients seen by the physician in his/her office during the immediately preceding thirty-six (36) months of his/her departure, except that this notification requirement shall not apply to a patient when there have been fewer than two (2) office patient encounters within the immediately preceding eighteen (18) months.
 - (ii) Except where otherwise governed by provisions of the physician's contract, those patients shall also be notified of the physician's new address and offered the opportunity to have copies of their medical records forwarded to the departing physician at his or her new practice. Provided however, a group shall not withhold the medical records of any patient who has authorized their transfer to the departing physician or any other physician.

(Rule 1050-02-.18, continued)

- (iii) The choice of physicians in every case should be left to the patient, and the patient should be informed that upon authorization his/her records will be sent to the physician of the patient's choice.
- 3. Sale of a Medical Practice - A physician or the estate of a deceased physician may sell the elements that comprise his/her practice, one of which is its goodwill, i.e., the opportunity to take over the patients of the seller by purchasing the physician's medical records. Therefore, the transfer of records of patients is subject to the following:
 - (i) The physician (or the estate) must ensure that all medical records are transferred to another physician or entity that is held to the same standards of confidentiality as provided in these rules.
 - (ii) Patients seen by the physician in his/her office during the immediately preceding thirty-six (36) months shall be notified that the physician (or the estate) is transferring the practice to another physician or entity who will retain custody of their records and that at their written request the copies of their records will be sent to another physician or entity of their choice. This notification requirement shall not apply to a patient when there have been fewer than two (2) office patient encounters within the immediately preceding eighteen (18) months.
- 4. Abandonment of Records - For purposes of this section of the rules death of a physician shall not be considered as abandonment.
 - (i) It shall be a prima facie violation of T.C.A. § 63-9-111 (b) (1) for a physician to abandon his practice without making provision for the security, or transfer, or otherwise establish a secure method of patient access to their records.
 - (ii) Upon notification that a physician in a practice has abandoned his practice and not made provision for the security, or transfer, or otherwise established a secure method of patient access to their records patients should take all reasonable steps to obtain their medical records by whatever lawful means available and should immediately seek the services of another physician.
- (f) Retention of Medical Records - Medical records shall be retained for a period of not less than ten (10) years from the physician's or his supervisees' last professional contact with the patient except for the following:
 - 1. Immunization records shall be retained indefinitely.
 - 2. Medical records for incompetent patients shall be retained indefinitely.
 - 3. Mammography records shall be retained for at least twenty (20) years.
 - 4. X-rays, radiographs and other imaging products shall be retained for at least four (4) years after which if there exist separate interpretive records thereof they may be destroyed.
 - 5. Medical records of minors shall be retained for a period of not less than one (1) year after the minor reaches the age of majority or ten (10) years from the date of

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the physician's or his supervisees' last professional contact with the patient, whichever is longer.

6. Notwithstanding the foregoing, no medical record involving services which are currently under dispute shall be destroyed until the dispute is resolved.

(g) Destruction of Medical Records -

1. No medical record shall be singled out for destruction other than in accordance with established office operating procedures.
2. Records shall be destroyed only in the ordinary course of business according to established office operating procedures that are consistent with these rules.
3. Records may be destroyed by burning, shredding, or other effective methods in keeping with the confidential nature of the records.
4. When records are destroyed, the time, date and circumstances of the destruction shall be recorded and maintained for future reference. The record of destruction need not list the individual patient medical records that were destroyed but shall be sufficient to identify which group of destroyed records contained a particular patient's medical records.

- (5) Violations - Violation of any provision of these rules is grounds for disciplinary action pursuant to T.C.A. §§ 63-9-111 (b) (1), and/or (2).

Authority: T.C.A. §§4-5-202, 4-5-204, 63-2-101, 63-2-102, 63-9-101, 63-9-106, and 63-9-111.
Administrative History: Original rule filed July 27, 2000; effective October 10, 2000. Repeal and new rule filed April 29, 2003; effective July 13, 2003. Amendment filed October 18, 2004; effective January 1, 2005.

1050-02-.19 MEDICAL PROFESSIONAL CORPORATIONS AND MEDICAL PROFESSIONAL LIMITED LIABILITY COMPANIES.

- (1) Medical Professional Corporations (MPC) – Except as provided in this rule Medical Professional Corporations shall be governed by the provisions of Tennessee Code Annotated, Title 48, Chapter 101, Part 6.
 - (a) Filings – A MPC need not file its Charter or its Annual Statement of Qualifications with the Board.
 - (b) Ownership of Stock – With the exception of the health care professional combinations specifically enumerated in Tennessee Code Annotated, Section 48-101-610 only the following may form and own shares of stock in a foreign or domestic MPC doing business in Tennessee:
 1. Physicians licensed pursuant to Tennessee Code Annotated Title 63, Chapter 6 and/or Chapter 9 or licensed in another state; and/or
 2. A foreign or domestic general partnership, MPC or M PLLC in which all partners, shareholders, members or holders of financial rights are either:
 - (i) Physicians licensed pursuant to Tennessee Code Annotated Title 63, Chapter 6 and/or Chapter 9 to practice medicine in Tennessee or

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physicians licensed by other states, or composed of entities which are directly or indirectly owned by such licensed physicians; and/or

- (ii) Professionals authorized by Tennessee Code Annotated 48-101-610 or 48-248-401 or part 1109 of Section 1 of Public Chapter 286 of the Public Acts of 2005 to either own shares of stock in an MPC or be a member or holder of financial rights in an MPLLC; and/or
- (iii) A combination of professionals authorized by subparts (i) and (ii).

(c) Officers and Directors of Medical Professional Corporations

1. All, except the following officers, must be persons who are eligible to form or own shares of stock in a medical professional corporation as limited by T.C.A. § 48-101-610 (d) and subparagraph (1) (b) of this rule:
 - (i) Secretary;
 - (ii) Assistant Secretary;
 - (iii) Treasurer; and
 - (iv) Assistant Treasurer.
2. With respect to members of the Board of Directors, only persons who are eligible to form or own shares of stock in a medical professional corporation as limited by T.C.A. § 48-101-610 (d) and subparagraph (1) (b) of this rule shall be directors of a MPC.

(d) Practice Limitations

1. Physician incorporators, shareholders, officers, or directors of a MPC, acting individually or on behalf of, or collectively as the MPC, shall exercise only such authority as an "employing entity" may exercise pursuant to Tennessee Code Annotated, Section 63-6-204 (f)(1)(A), (B) and (C) regarding diagnosis, treatment and/or referral decisions made by any physician employed by or contracting with or otherwise providing medical services within the scope of their practice within the MPC.
2. A physician shall not enter into an employment, compensation, or other contractual arrangement with a MPC that may violate the code of ethics or which gives the MPC more authority over the physician's diagnosis, treatment and/or referral decisions than an "employing entity" may exercise pursuant to Tennessee Code Annotated, Section 63-6-204 (f)(1)(A), (B) and (C) regarding those decisions.
3. Engaging in, or allowing another physician incorporator, shareholder, officer, or director, while acting on behalf of the MPC, to engage in, medical practice in any area of practice or specialty beyond that which is specifically set forth in the charter may be a violation of the code of ethics and/or either Tennessee Code Annotated, Sections 63-6-214 (b)(1) or 63-9-111 (b)(1).

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4. Nothing in these rules shall be construed as prohibiting any health care professional licensed pursuant to Tennessee Code Annotated, Title 63 from being an employee of or a contractor to a MPC.
 5. Nothing in these rules shall be construed as prohibiting a MPC from electing to incorporate for the purposes of rendering professional services within two (2) or more professions or for any lawful business authorized by the Tennessee Business Corporations Act so long as those purposes do not interfere with the exercise of independent medical judgment by the physician incorporators, directors, officers, shareholders, employees or contractors of the MPC who are practicing medicine as defined by Tennessee Code Annotated, Sections 63-6-204 and 63-9-106.
 6. Nothing in these rules shall be construed as prohibiting a physician from owning shares of stock in any type of professional corporation other than a MPC so long as such ownership interests do not interfere with the exercise of independent medical judgment by the physician while practicing medicine as defined by Tennessee Code Annotated, Sections 63-6-204 and 63-9-106.
- (2) Medical Professional Limited Liability Companies (MPLLC) – Except as provided in this rule Medical Professional Limited Liability Companies shall be governed by either the provisions of Tennessee Code Annotated, Title 48, Chapter 248 or Public Chapter 286 of the Public Acts of 2005.
- (a) Filings – Articles filed with the Secretary of State shall be deemed to be filed with the Board and no Annual Statement of Qualifications need be filed with the Board.
 - (b) Membership – With the exception of the health care professional combinations specifically enumerated in Tennessee Code Annotated, Section 48-248-401 or part 1109 of Section 1 of Public Chapter 286 of the Public Acts of 2005 only the following may be members or holders of financial rights of a foreign or domestic MPLLC doing business in Tennessee:
 1. Physicians licensed pursuant to Tennessee Code Annotated Title 63, Chapter 6 and/or Chapter 9 or licensed in other states; and/or
 2. A foreign or domestic general partnership, MPC or MPLLC in which all partners, shareholders, members or holders of financial rights are either:
 - (i) Physicians licensed pursuant to Tennessee Code Annotated Title 63, Chapter 6 and/or Chapter 9 to practice medicine in Tennessee or physicians licensed by other states or composed of entities which are directly or indirectly owned by such licensed physicians; and/or
 - (ii) Professionals authorized by Tennessee Code Annotated 48-101-610 or 48-248-401 or part 1109 of Section 1 of Public Chapter 286 of the Public Acts of 2005 to either own shares of stock in an MPC or be a member or holder of financial rights in an MPLLC; and/or
 - (iii) A combination of professionals authorized by subparts (i) and (ii).
 - (c) Managers, Directors or Governors of a MPLLC

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1. All, except the following managers, must be persons who are eligible to form or become members or holders of financial rights of a medical professional limited liability company as limited by T.C.A. § 48-248-401 and subparagraph (2) (b) of this rule:
 - (i) Secretary
 - (ii) Treasurer
2. Only persons who are eligible to form or become members or holders of financial rights of a medical professional limited liability company as limited by T.C.A. § 48-248-401 and subparagraph (2) (b) of this rule shall be allowed to serve as a director, or serve on the Board of Governors of a M PLLC.

(d) Practice Limitations

1. Physician members or holders of financial rights, managers, directors, or governors of a M PLLC, acting individually or on behalf of, or collectively as the M PLLC, shall exercise only such authority as an "employing entity" may exercise pursuant to T.C.A. § 63-6-204 (f)(1)(A), (B) and (C) regarding diagnosis, treatment and/or referral decisions made by any physician employed by or contracting with or otherwise providing medical services within the scope of their practice within the M PLLC.
2. A physician shall not enter into an employment, compensation, or other contractual arrangement with a M PLLC that may violate the code of ethics or which gives the M PLLC more authority over the physician's diagnosis, treatment and/or referral decisions than an "employing entity" may exercise pursuant to T.C.A. § 63-6-204 (f)(1)(A), (B) and (C) regarding those decisions.
3. Engaging in, or allowing another physician member, officer, manager, director, or governor, while acting on behalf of the M PLLC, to engage in, medical practice in any area of practice or specialty beyond that which is specifically set forth in the articles of organization may be a violation of the code of ethics and/or either Tennessee Code Annotated, Sections 63-6- 214 (b) (1) or 63-9-111 (b) (1).
4. Nothing in these rules shall be construed as prohibiting any health care professional licensed pursuant to Tennessee Code Annotated, Title 63 from being an employee of or a contractor to a M PLLC.
5. Nothing in these rules shall be construed as prohibiting a M PLLC from electing to form for the purposes of rendering professional services within two (2) or more professions or for any lawful business authorized by the Tennessee Limited Liability Company Act or the Tennessee Revised Limited Liability Company Act so long as those purposes do not interfere with the exercise of independent medical judgment by the physician members or holders of financial rights, governors, officers, managers, employees or contractors of the M PLLC who are practicing medicine as defined by Tennessee Code Annotated, Sections 63-6-204 and 63-9-106.
6. Nothing in these rules shall be construed as prohibiting a physician from being a member of any type of professional limited liability company other than a M PLLC so long as such membership interests do not interfere with the exercise of

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independent medical judgment by the physician while practicing medicine as defined by Tennessee Code Annotated, Sections 63-6-204 and 63-9-106.

7. All M PLLCs formed in Tennessee pursuant to Tennessee Code Annotated, Section 48-248-104 or Public Chapter 286 of the Public Acts of 2005, to provide services only in states other than Tennessee shall annually file with the Board a notarized statement that they are not providing services in Tennessee.
- (3) Dissolution - The procedure that the Board shall follow to notify the attorney general that a MPC or a M PLLC has violated or is violating any provision of Title 48, Chapters 101 and/or 248 or Public Chapter 286 of the Public Acts of 2005, shall be as follows but shall not terminate or interfere with the secretary of state's authority regarding dissolution pursuant to Tennessee Code Annotated, Sections 48-101-624 or 48-248-409.
 - (a) Service of a written notice of violation by the Board on the registered agent of the MPC and/or M PLLC or the secretary of state if a violation of the provisions of Tennessee Code Annotated, Title 48, Chapters 101 and/or 248 or Public Chapter 286 of the Public Acts of 2005 occurs.
 - (b) The notice of violation shall state with reasonable specificity the nature of the alleged violation(s).
 - (c) The notice of violation shall state that the MPC and/or M PLLC must, within sixty (60) days after service of the notice of violation, correct each alleged violation or show to the Board's satisfaction that the alleged violation(s) did not occur.
 - (d) The notice of violation shall state that, if the Board finds that the MPC and/or M PLLC is in violation, the attorney general will be notified and judicial dissolution proceedings may be instituted pursuant to Tennessee Code Annotated, Title 48.
 - (e) The notice of violation shall state that proceedings pursuant to this section shall not be conducted in accordance with the contested case provisions of the Uniform Administrative Procedures Act, compiled in Title 4, Chapter 5 but that the MPC and/or M PLLC, through its agent(s), shall appear before the Board at the time, date, and place as set by the Board and show cause why the Board should not notify the attorney general and reporter that the organization is in violation of the Act or these rules. The Board shall enter an order that states with reasonable particularity the facts describing each violation and the statutory or rule reference of each violation. These proceedings shall constitute the conduct of administrative rather than disciplinary business.
 - (f) If, after the proceeding the Board finds that a MPC and/or M PLLC did violate any provision of Title 48, Chapters 101 and/or 248 or these rules, and failed to correct said violation or demonstrate to the Board's satisfaction that the violation did not occur, the Board shall certify to the attorney general and reporter that it has met all requirements of either Tennessee Code Annotated, Sections 48-101-624 (1) - (3) and/or 48-248-409 (1)-(3) and/or Public Chapter 286 of the Public Acts of 2005.
 - (4) Violation of this rule by any physician individually or collectively while acting as an MPC or as an M PLLC may subject the physician(s) to disciplinary action pursuant to Tennessee Code Annotated, Sections 63-6-214 (b) (1), or 63-9-111 (b) (1).
 - (5) The authority to own shares of stock or be members or holders of financial rights in an MPC or an M PLLC granted by statute or these rules to professionals not licensed in this state shall

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in no way be construed as authorizing the practice of any profession in this state by such unlicensed professionals.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 48-101-605, 48-101-608, 48-101-610, 48-101-618, 48-101-624, 48-101-628, 48-101-629, 48-101-630, 48-248-104, 48-248-202, 48-248-401, 48-248-404, 48-248-409, 48-248-501, 48-248-601, 48-248-602, 48-248-603, 63-6-204, 63-9-101, 63-9-104, 63-9-111, and Public Chapter 286 of the Public Acts of 2005. **Administrative History:** Original rule filed August 29, 2003; effective November 12, 2003. Amendment filed March 22, 2007; effective June 5, 2007.

1050-02-.20 FREE HEALTH CLINIC AND VOLUNTEER PRACTICE REQUIREMENTS.

- (1) Free Health Clinic Practice Pursuant to T.C.A. § 63-1-201
 - (a) Any osteopathic physician licensed to practice osteopathy in this state or any other state who has not been disciplined by any osteopathic and/or medical licensure board may have their license converted to or receive a Tennessee “Special Volunteer License,” as defined in T.C.A. § 63-1-201, which will entitle the licensee to practice without remuneration solely within a “free health clinic,” as defined by T.C.A. § 63-1-201, at a specified site or setting by doing the following:
 1. Obtaining from the Board’s administrative office a “Special Volunteer License” application, completing it and submitting it along with any required documentation to the Board’s administrative office; and
 2. Have the licensing authority of every state in which the osteopathic physician holds or ever held a license to practice osteopathy submit directly to the Board’s administrative office the equivalent of a “certificate of fitness” as described in T.C.A. § 63-1-118 which shows that the license has never been subjected to any disciplinary action and is free and clear of all encumbrances; and
 3. For osteopathic physicians who have not been licensed in Tennessee, comply with all provisions of subparagraphs (1) (b), (1) (e), (1) (f) and (1) (i) of rule 1050-02-.03 and the Health Care Consumer-Right-To-Know Act compiled at T.C.A. §§ 63-51-101, et seq.; and
 4. Submitting the specific location of the site or setting of the free health clinic in which the licensee intends to practice along with proof of the clinic’s private, and not-for-profit status.
 - (b) An osteopathic physician holding a Special Volunteer License is not required to pay any fee for its issuance or the required biennial renewal pursuant to the Division of Health Related Board’s biennial birthdate renewal system
 - (c) An osteopathic physician holding a Special Volunteer License may not do any of the following:
 1. Practice osteopathy anywhere other than in the free health clinic site or setting specified in the application; and
 2. Charge any fee or receive compensation or remuneration of any kind from any person or third party payor including insurance companies, health plans and state or federal benefit programs for the provision of osteopathic or any other services; and

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3. Practice for any free health clinic that imposes any charge on any individual to whom health care services are rendered or submits charges to any third party payor including insurance companies, health plans and state or federal benefit programs for the provision of any services.
- (d) Special Volunteer Licenses are subject to all of the following
1. All rules governing renewal, retirement, reinstatement and reactivation as provided by rules 1050-02-.07 and .08, except those requiring the payment of any fees; and
 2. The rules governing continuing osteopathic education as provided by rule 1050-02-.12; and
 3. Disciplinary action for the same causes and pursuant to the same procedures as all other licenses issued by the Board.
- (2) Practice Pursuant to the "Volunteer Health Care Services Act" T.C.A. §§ 63-6-701, et seq.
- (a) Any osteopathic physician licensed in this or any other state, territory, district or possession of the United States whose license is not under a disciplinary order of suspension or revocation may practice osteopathy in this state but only under the auspices of an organization that has complied with the provisions of this rule and T.C.A. §§ 63-6-701 through 63-6-707 and rule 1200-10-1-.12 of the Division of Health Related Boards.
 - (b) Any person who may lawfully practice osteopathy in this or any other state, territory, district or possession of the United States under an exemption from licensure and who is not under a disciplinary order of suspension or revocation and who is not and will not "regularly practice," as defined by T.C.A. § 63-6-703 (3) may practice osteopathy in this state but only under the auspices of an organization that has complied with the provisions of this rule and T.C.A. §§ 63-6-701 through 63-6-707 and rule 1200-10-01-.12 of the Division of Health Related Boards.
 - (c) An osteopathic physician or anyone who practices under an exemption from osteopathic licensure pursuant to this rule may not charge any fee or receive compensation or remuneration of any kind from any person or third party payor including insurance companies, health plans and state or federal benefit programs for the provision of osteopathic or any other services; and may not practice for any organization that imposes any charge on any individual to whom health care services are rendered or submits charges to any third party payor including insurance companies, health plans and state or federal benefit programs for the provision of any services.
 - (d) Any organization that organizes or arranges for the voluntary provision of health care services on residents of Tennessee may utilize persons described in subparagraphs (a) and (b) to practice osteopathy only when it has complied with the provisions of T.C.A. §§ 63-6-701 through 63-6-707 and rule 1200-10-01-.12 of the Division of Health Related Boards.
- (3) At the Board's discretion, submission of any document or set of documents required by this rule or submission of verification of the authenticity, validity and accuracy of the content of any document or set of documents required by this rule directly from the FCVS or other Board approved credentialing service to the Board Administrative Office shall be deemed to

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be submission of originals of those documents or sets of documents by the issuing institution(s).

- (4) Application review and licensure decisions for these types of osteopathic licensure or organization registration shall be governed by rule 1050-02-.05.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-1-201, 63-6-701 through 63-6-707, 63-9-101, and 63-9-115.

Administrative History: Original rule filed October 6, 2005; effective December 20, 2005.

1050-02-.21 OFFICE BASED SURGERY. A license to practice osteopathic medicine issued pursuant to T.C.A. § 63-9-106 authorizes the holder to perform surgery. To the extent that any licensee performs surgery in his or her office rather than a hospital, abortion clinic, or ASTC, that licensee, or the governing body of the entity lawfully authorized to practice medicine wherein the surgery is to be performed, shall comply with these rules.

- (1) General Statement and Precaution - The Board will always judge the decision to perform surgery in the office setting based upon what was in the patient's best interest and through strict application of these rules.

- (2) Intent and Application

- (a) Intent – It is not the intent of these rules to circumvent the law and rules and regulations governing ambulatory surgical treatment centers. The intent of these rules is to provide osteopathic physicians, who perform Level I, II, IIA, and III surgeries as part of a medical practice whose focus is on provision of medical services and procedures that are not related to surgery (and procedures and services incidental thereto), an option to provide on-site surgical and surgical related services that are within the scope of the physician's specialty and training and in the best interest of the patient.

- (b) Application – These rules do not apply to physicians or the governing body of entities lawfully authorized to practice medicine whose practice location(s) has as its primary purpose the provision of Level I, II, IIA and III surgical or surgical preparatory services and/or procedures. Those types of practice locations must comply with all laws, rules and regulations applicable to ambulatory surgical treatment centers including rules 0720-10, 11 and 12.

- (3) Definitions

- (a) Acceptable Plan of Correction. The Board of Osteopathic Examination approves an Office Based Surgical Suite's plan to correct deficiencies identified during an on-site survey conducted by the Division. The plan of correction shall be a written document and shall provide, but not be limited to, the following information:

1. How the deficiency will be corrected.
2. Who will be responsible for correcting the deficiency.
3. The date the deficiency will be corrected.
4. How the facility will prevent the same deficiency from re-occurring.

- (b) ACLS (Advanced cardiac life support) - A certification that means a person has successfully completed an advanced cardiac life support course offered by a

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recognized accrediting organization in accordance with American Heart Association (AHA) guidelines.

- (c) ASA - American Society of Anesthesiologists.
- (d) ASTC - An ambulatory surgical treatment center licensed by the Department of Health Division of Health Care Facilities.
- (e) Block -
 - 1. Digital Block - The injection of a local anesthetic to stop or prevent painful sensation in a digit (i.e., finger or toe).
 - 2. Minor Regional Block or Minor Regional Anesthesia - The administration of local anesthetics to interrupt nerve impulses in an extremity, or other minor region of the body, including but not limited to upper and lower extremity plexus blocks.
 - 3. Major Regional Block or Major Regional Anesthesia - The administration of local anesthetic agents to interrupt nerve impulses in a major region of the body, including but not limited to spinal blocks, epidural blocks, caudal blocks, and intravenous regional anesthetic.
- (f) Board - The Tennessee Board of Osteopathic Examination.
- (g) BCLS (Basic Cardiac Life Support) - A certification that means a person has successfully completed a basic cardiac life support course offered by a recognized accrediting organization in accordance with AHA guidelines.
- (h) Conscious Sedation/Moderate Sedation/Sedation-Analgesia - A drug induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are usually required to maintain a patient airway, and spontaneous ventilation is usually adequate. Cardiovascular function is usually maintained.
- (i) Deep Sedation - A drug induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients often require assistance in maintaining a patient airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.
- (j) General Anesthesia - A drug induced loss of consciousness during which patients are not arousable even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patient airway, and positive-pressure ventilation may be required because of depressed spontaneous ventilation or drug induced depression of neuromuscular function. Cardiovascular function may be impaired.
- (k) Hospital - A hospital licensed by the Department of Health Division of Health Care Facilities.
- (l) Local Anesthetic - The administration of an agent which produces a transient and reversible loss of sensation in a circumscribed portion of the body.

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- (m) PALS (Pediatric Advanced Life Support) - A certification that means a person has successfully completed a pediatric advanced life support course offered by a recognized accrediting organization in accordance with AHA guidelines.
 - (n) Osteopathic Physician - A person licensed to practice osteopathic medicine and surgery pursuant to Tennessee Code Annotated Title 63, Chapter 9.
 - (o) Surgery - The excision or resection, partial or complete, destruction, incision or other structural alteration of human tissue by any means (including through the use of lasers) performed upon the body of a living human for purposes of preserving health, diagnosing or curing disease, repairing injury, correcting deformity or defects, prolonging life, relieving suffering, or for aesthetic, reconstructive or cosmetic purposes, to include, but not limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or organ, including a closed or an open reduction of a fracture; extraction of tissue, including premature extraction of products of conception from the uterus; and insertion of natural or artificial implants. For the purpose of this rule, certain diagnostic and therapeutic procedures requiring medication to immobilize the patient are contained within the definition of surgery.
 - (p) Surgical Suite - The operating room and recovery room(s) located in a physician's office where surgery is to be performed.
- (4) Surgery on Infants and Children
- (a) Infants - Infants shall include only those persons in the neonatal age group. For such infants, only those procedures that can be reasonably performed under local anesthetic, such as neonatal circumcisions, may be performed in a physician's office.
 - (b) Children -
 1. Level I surgeries may be performed in a physician's office on a patient under the age of fourteen (14).
 2. No Level II, Level IIA or Level III surgeries or any surgery requiring any level of sedation may be performed on patients under the age of (2) years in a physician's office.
 3. Most Level II and IIA surgeries are not allowed to be performed in a physician's office on any patient under the age of fourteen (14) years. Provided however, it is recognized that in the pediatric population, certain types of surgeries may be performed under mild sedation in a physician's office. Those Level II and IIA surgeries are limited to the following conditions and circumstances all of which must be met before the surgery is allowed:
 - (i) The child is at least two (2) years of age but younger than fourteen (14) years of age and is healthy according to ASA risk classification criteria; and
 - (ii) The surgery is anticipated to be brief and superficial and is of such a nature that it is more safely performed while the patient is not agitated; and
 - (iii) Sedative or anxiolytic medications are not to be administered at home as part of a pre-procedural sedating plan; and
 - (iv) Only minimal sedation is to be used which shall include only one (1) sedating drug that is administered only one (1) time, in a low dose in

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addition to a local anesthetic or appropriate block such that at all times the child is awake and interactive. An antagonist to the sedating drug used must be immediately available; and

- (v) A pediatric equipped emergency cart is available and a person who has a current certification in PALS is assigned with the task of staying in close proximity to the child at all times to observe the child throughout the pre-operative and surgical procedures and until such time as the child is declared fit to be released from the office.
4. No Level III surgeries may be performed in a physician's office on a patient under the age of fourteen (14).
- (c) If the patient has not recovered sufficiently to be safely discharged within twelve (12) hours after the initial administration of anesthesia, the patient must be transferred to a hospital for continued postoperative care.
- (5) Level I Office Based Surgery
- (a) Level of Anesthesia - Level I Office Surgery is the type of surgery in which pre-operative medications are not required or used other than minimal pre-operative tranquilization/antiolysis of the patient. There is no anesthesia or it is a local, topical, or appropriate block. No drug-induced alteration of consciousness other than minimal pre-operative tranquilization of the patient is permitted and the chances of complication requiring hospitalization are remote.
 - (b) Level I Surgical Procedures - Procedures authorized to be performed under Level I anesthesia include, but are not limited to, the following:
 - 1. Minor procedures including, but not limited to, the following:
 - (i) Excision of skin lesions, moles, warts, cysts, lipomas; and
 - (ii) Repair of lacerations or surgery limited to the skin and subcutaneous tissue.
 - 2. Liposuction involving the removal of less than 250 cc supernatant fat,
 - 3. Incision and drainage of superficial abscesses,
 - 4. Limited endoscopies such as proctoscopies,
 - 5. Skin biopsies, arthrocentesis, thoracentesis, paracentesis, endometrial biopsy,
 - 6. IUD's, colposcopy,
 - 7. Dilation of urethra, cysto-scope procedures, and
 - 8. Closed reduction of simple fractures or small joint dislocations (i.e., finger and toe joints).
 - (c) Standards for Level I Office Based Surgery.
 - 1. Training required of personnel involved in Level I Surgical Procedures. The physician's continuing medical education should include instruction in proper

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dosages of regional anesthetic drugs and management of toxicity or hypersensitivity to those drugs. It is required that either the physician or someone in the operating room at the time of the surgery has a current BCLS certification.

2. Equipment and Supplies Required - Basic medications and equipment to manage toxic or hypersensitivity reactions which shall be age and procedure appropriate.
3. Assistance of Other Personnel Required - No assistance from other personnel is required unless the specific surgical procedure being performed should reasonably involve an assistant.

(d) If the patient has not recovered sufficiently to be safely discharged within twelve (12) hours after the initial administration of anesthesia, the patient must be transferred to a hospital for continued postoperative care.

(6) Levels II and IIA Office Surgery

1. Pre-operative medication and sedation introduced intravenously, intramuscularly, inhalation, orally, or rectally, thus making intra and postoperative monitoring necessary; and/or
2. Local or peripheral major nerve block, including Bier Block; and/or
3. Intravenous, oral, rectal or intramuscular sedation that preserve vital reflexes. However, the use of nitrous oxide in conjunction with other types of sedatives is not allowed for Level II or IIA surgical procedures; and/or
4. Any level or type of anesthesia in which the patient is placed in a state that allows the patient to tolerate unpleasant procedures while maintaining adequate cardio respiratory function and the ability to respond purposefully to verbal command and/or light tactile stimulation. Patients whose only response is reflex withdrawal from a painful stimulus are sedated to a greater degree than is authorized for Level II and/or IIA surgeries.

(b) Level II Surgical Procedures - Procedures authorized to be performed under Level II anesthesia include, but are not limited to, the following:

1. Hemorrhoidectomy,
2. Hernia repair,
3. Reduction of closed, uncomplicated fractures,
4. Large joint dislocations,
5. Breast biopsies,
6. Colonoscopy and other endoscopic procedures,
7. Diagnostic radiologic procedures requiring sedation,
8. Liposuction involving the removal of up to 4000 cc supernatant fat, and
9. Diagnostic cardiac procedures which usually require sedation.

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- (c) Level IIA Surgical Procedures - are those Level II office surgical procedures with a maximum planned duration of thirty (30) minutes or less and in which chances of complications requiring hospitalization are remote. This category includes procedures requiring sedation for diagnostic purposes including, but not limited to, endoscopic procedures and radiologic procedures.
- (d) Standards for Level II and IIA Office Based Surgery.
 - 1. Transfers – The physician performing the surgery must have staff privileges at a licensed hospital within reasonable proximity or a written transfer protocol to a licensed hospital within reasonable proximity.
 - 2. Training required of personnel involved in Level II and IIA Surgical Procedures.
 - (i) The physician must be able to document satisfactory completion of training such as Board certification or Board eligibility by a Board approved by the American Osteopathic Association or the American Board of Medical Specialties or comparable background, training, or experience.
 - (ii) The physician or one (1) assistant must have current certification in ACLS or there must be a qualified anesthetic provider practicing within the scope of the provider's license present to manage the anesthetic.
 - (iii) Individuals responsible for patients receiving sedation/analgesia should understand the pharmacology of the agents that are administered, as well as the role of pharmacologic antagonists for opioids and benzodiazepines.
 - (iv) Individuals monitoring patients receiving these agents shall be able to recognize the associated complications.
 - (v) At least one (1) individual with current ACLS certification who is capable of establishing a patient airway and positive pressure ventilation shall be continuously present whenever sedation/analgesia are administered. There must also be a means immediately available for summoning additional assistance.
 - 3. Equipment and Supplies: All of the following which shall be age and procedure appropriate are required:
 - (i) Suction devices, endotracheal tubes, laryngoscopes, etc.
 - (ii) Positive pressure ventilation device (e.g., Ambu) plus oxygen supply.
 - (iii) Double tourniquet for the Bier block procedure.
 - (iv) Monitors for blood pressure, EKG, Oxygen saturation, and temperature.
 - (v) Emergency intubation equipment.
 - (vi) Adequate operating room lighting.
 - (vii) Appropriate sterilization equipment.
 - (viii) IV solution and IV equipment.

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- (ix) Reversal or antagonist agents for medications used.
 - (x) A standard and emergency ACLS equipped cart and other such equipment as is necessary for the procedure being performed.
4. Assistance of Other Personnel Required.
- (i) During the procedure
 - (I) Level II Surgical Procedures - The physician must be assisted by a professional licensed pursuant to Tennessee Code Annotated Title 63, Chapters 6, 7, 9, or 19 and practicing within the lawful scope of their licensure functioning as an assisting anesthesia provider who cannot function in any other capacity during the procedure.
 - (II) Level IIA Surgical Procedures - A certified nurse practitioner, physician assistant, registered nurse, advanced practice nurse or licensed practical nurse must assist the physician. Additional assistance may be required by specific procedure or patient circumstances and if so, it must be provided by a person licensed pursuant to either Tennessee Code Annotated, Title 63, Chapters 6, 7, 9 or 19, or a nationally certified operating room technician.
 - (ii) Following the procedure
 - (I) There must be a person with current ACLS certification present at all times with the patient while in the recovery area; and
 - (II) An additional professional who has post-anesthesia care unit experience or its equivalent and a current ACLS certification and who is licensed pursuant to either Tennessee Code Annotated, Title 63 Chapter 6, 9 or 19 or a registered or advanced practice nurse licensed pursuant to Tennessee Code Annotated, Title 63 Chapter 7 must also be immediately available on the premises to assist in monitoring the patient in the recovery room until the patient has recovered from anesthesia.
5. Pre, Intra, Postoperative Services In General.
- (i) An operative/procedure note shall be created for each surgery describing the procedure performed, the techniques used, participating personnel and their titles, postoperative diagnosis, type of anesthesia, and complications. Where similar procedures are performed at an office routinely, partially pre-printed forms may be utilized as a guide, provided that original data and conclusions applicable to the specific patient are contemporaneously entered to create a complete report.
 - (ii) A post-procedure note shall be created for each surgery and completed prior to discharge of a patient from the office, which shall include such post-procedure data as the patient's general condition, vital signs, treatments ordered, and all drugs prescribed, administered or dispensed including dosages and quantities.

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- (iii) All patients, except those who receive minor regional blocks and/or local anesthetic only, shall receive appropriate postoperative management. A patient may be excused from a stay in the recovery area only by a specific order of the anesthesia personnel or the operating physician.
 - (iv) The patient shall be transported to the recovery area accompanied by a member of the anesthesia care team who is knowledgeable about the patient's condition. The patient shall be continually evaluated and treated during transport appropriate to the patient's condition.
 - (v) An oral report on the patient's condition shall be given to the health care personnel responsible for the patient in the recovery area who were not present in the anesthetizing location.
 - (vi) The patient's recovery area condition shall be evaluated and recorded in the medical record. The blood pressure, pulse rate, respiratory rate, blood oxygen saturation, level of consciousness, and when appropriate temperature shall be assessed at least every fifteen (15) minutes (five [5] minutes for pediatric patients) until they are stable and returned to pre-operative baseline values and/or normal values consistent with the patient's age and medical condition.
 - (vii) Objective criteria (for example a scoring system such as PARR or Aldrete Score) shall be established to determine when a patient is medically ready or "fit" to be discharged.
 - (viii) Before discharge, the patient shall be given written and verbal instructions for follow-up care and advice concerning complications. Emergency phone number shall be provided to the patient.
 - (ix) If sedation or regional blocks have been used, a responsible adult must be available to accompany the patient and be instructed with regard to the patient care and follow-up.
 - (x) If a patient has not recovered sufficiently to be safely discharged within twelve (12) hours after the initial administration of anesthesia, the patient must be transferred to a hospital for continued postoperative care.
6. Sufficient space in the room in which the surgical procedure is being performed shall be available to accommodate all necessary equipment and personnel and to allow for expeditious access to the patient and all resuscitation and monitoring equipment.
 7. Pharmaceutical Services - The office shall maintain and provide drugs and biologicals in a safe and effective manner in accordance with accepted standards of practice. Such drugs and biologicals must be stored in a separate room or cabinet which shall be kept locked at all times and a log of all such drugs and biologicals dispensed shall be maintained.
 8. Ancillary Services - All ancillary or supportive health medical services, including but not limited to, radiological, pharmaceutical, or medical laboratory services shall be provided in accordance with all applicable state and federal laws and regulations.

(Rule 1050-02-.21, continued)

- (e) ASA Risk Classifications - Level II and IIA surgeries are limited to patients who fall within ASA Class 1 and 2 risk classification criteria.

(7) Level III Office Based Surgery

- (a) Levels of Anesthesia - Includes all levels of anesthesia which sedate a patient beyond the levels described in subparagraph (6)(a) of this rule which includes:

1. Deep sedation as defined by subparagraph (3)(i) of this rule; and/or
2. Major Conduction Anesthesia (epidural, spinal, caudal); and/or
3. Major conduction anesthesia and pre-operative sedation; and/or
4. General Anesthesia as defined in subparagraph (3)(j) of this rule; and/or
5. The use of nitrous oxide in conjunction with other types of sedatives.

- (b) Level III Surgical Procedures - Procedures authorized to be performed under Level III anesthesia are those contained on the Centers for Medicare & Medicaid Services (CMS) list of procedures published in Volume 71, Number 226 of the Federal Register dated November 24, 2006 as it may from time to time be amended that are authorized for reimbursement at the Ambulatory Surgical Center (ASC) level and only those cosmetic surgical procedures that, based upon reasonable medical judgment, would require Level III sedation. The surgical procedures authorized pursuant to this subparagraph are limited to those that also have all the following characteristics:

1. Have a planned duration of less than four (4) hours. This includes multiple surgeries regardless of the level of surgery; the combined planned duration of all planned procedures shall be less than four (4) hours; and
2. Generally result in blood loss of less than ten percent (10%) of estimated blood volume in a patient with normal hemoglobin; and
3. Will not require major or prolonged intracranial or intrathoracic procedures; and
4. Will not require major or prolonged abdominal or major hip replacement procedures (this criteria does not apply to laparoscopic procedures); and
5. Will not be generally emergent or life threatening in nature.

- (c) Application for Certification and Renewal-

1. Application for Certification - A physician office which contains operating and recovery rooms wherein Level III office based surgeries are to be performed, which shall be referred to as "surgical suites" for purposes of this rule, must obtain certification from the Board before any Level III surgical procedures may be performed therein. The process for obtaining that certification is as follows:

- (i) Obtain the Board's Level III Office Based Surgery Certification application (which shall also serve as the official request for a site survey) and provide all the information requested thereon which shall include the following:

- (l) The name of a responsible physician in whose name the surgical suite certification shall be issued who shall also arrange to have

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provided, for each physician in the office who will be performing Level III procedures, the following information and/or documentation:

- (II) A statement identifying all Level III procedures expected to be performed by each such physician; and
 - (III) A copy of what, if any, specialty board certification or board eligibility has been obtained by each such physician; and
 - (IV) Written verification of medical malpractice coverage from each physician's malpractice insurance carrier; and
 - (V) Written verification of hospital staff privileges from at least one hospital at which each of the physicians has been granted staff privileges that is within thirty (30) miles or thirty (30) minutes from the surgical suite.
- (ii) Submit copies of both the office's by-laws and its documentation of the management system that will insure that no more than three (3) patients that are in surgery or recovery are incapable of self-preservation at the same time.
 - (iii) Submit the Surgical Suite Certification fee in the amount of one thousand eighty dollars (\$1,080.00) and the state regulatory fee of five dollars (\$5.00).
 - (iv) Obtain a surgical suite site survey performed by the Board's authorized agents to determine compliance with the standards set forth in this rule. Those authorized agents shall have the authority to:
 - (I) Require plans of correction from the physician office for any deficiencies they may find in compliance with the standards set forth in this rule and to make a determination of the acceptability of the submitted plans of correction, and verify that the plans of correction have been implemented.
 - (II) Initiate subsequent, unannounced site surveys during regular business hours as long as the physician office continues to be used to perform Level III office-based surgeries but no more frequently than once every twelve (12) months.
 - (III) Respond to any complaints made by patients or the public against a physician who performs office based surgery or a physician's office at which Level III office-based surgery is being performed at the request of the Department's office of investigations.
 - (v) Receive approval from the Board on the result of the surgical suite site survey.
2. Renewal of Certification - A physician office which obtains Level III Office Based Surgery Certification for its surgical suites, must renew that certification every year by submitting to the Board the annual renewal fee in the amount of one thousand eighty dollars (\$1,080.00) and the state regulatory fee of five dollars (\$5.00), on or before its anniversary date.

(Rule 1050-02-.21, continued)

3. The information required to be included on and/or with the application form as itemized in subparagraph (c) 1 (i) and (ii) of this rule must be updated within thirty (30) days of the date on which any of the provided information or documentation has changed or additions need to be made.
4. Transition Provisions -
 - (i) In order for a physician office at which Level III office-based surgeries have been performed prior to October 1, 2007, (pursuant to certifications/accreditations received pursuant to prior Board rules) to continue doing so, the office must submit an application and a request for a site survey and remit payment of the Surgical Suite Certification fee and the state regulatory fee to the board by October 1, 2007. If such office makes a timely filing in accordance with this provision, the physician's office may continue to be a site for office-based surgeries pending completion of a survey confirming compliance with board rules and subsequent issuance of a certification of the surgical suite(s).
 - (ii) A physician office at which office-based surgeries have not been performed as of October 1, 2007, (pursuant to certifications/accreditations received pursuant to prior Board rules) shall not perform any such procedures until an application form and payment of the Surgical Suite Certification fee and the state regulatory fee are submitted to the board and a site survey is completed and a certification of the surgical suite is issued by the board.
- (d) Level III Surgery Standards - All physician offices for which certification for performance of Level III surgeries is to be sought and obtained shall meet the following standards:
 1. Infection Control
 - (i) The surgical suite(s) must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active performance improvement program for the prevention, control, and investigation of infections and communicable diseases.
 - (ii) The physical environment of the surgical suite(s) shall be maintained in a safe, clean and sanitary manner.
 - (I) Any condition on the surgical suite(s) site conducive to the harboring or breeding of insects, rodents or other vermin shall be prohibited. Chemical substances of a poisonous nature used to control or eliminate vermin shall be properly identified. Such substances shall not be stored with or near food or medications.
 - (II) Cats, dogs or other animals shall not be allowed in any part of the surgical suite except for specially trained animals for the handicapped and except as addressed by physician office policy for pet therapy programs. The physician's office shall designate in its policies and procedures those areas where animals will be excluded. The areas designated shall be determined based upon an assessment of the surgical suite performed by medically trained personnel.

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- (III) A bed complete with mattress and pillow shall be provided. In addition, patient units shall be provided with at least one chair, a bedside table, an over bed tray and adequate storage space for toilet articles, clothing and personal belongings.
 - (IV) Individual wash cloths, towels and bed linens must be provided for each patient. Linen shall not be interchanged from patient to patient until it has been properly laundered.
 - (V) Bath basin water service, emesis basin, bedpan and urinal shall be individually provided.
 - (VI) Water pitchers, glasses, thermometers, emesis basins, douche apparatus, enema apparatus, urinals, mouthwash cups, bedpans and similar items of equipment coming into intimate contact with patients shall be disinfected or sterilized after each use unless individual equipment for each use is provided and then sterilized or disinfected between patients and as often as necessary to maintain them in a clean and sanitary condition. Single use, patient disposable items are acceptable but shall not be reused.
- (iii) The physician office shall assure that an infection control committee including members of the medical, nursing and administrative staff develops guidelines and techniques for the prevention, surveillance, control and reporting of surgical suite infections. Duties of the committee shall include the establishment of:
- (I) Written infection control policies;
 - (II) Techniques and systems for identifying, reporting, investigating and controlling infections in the facility;
 - (III) Written procedures governing the use of aseptic techniques and procedures in all areas of the facility;
 - (IV) Written procedures concerning food handling, laundry practices, disposal of environmental and patient wastes, traffic control and visiting rules in high risk areas, sources of air pollution, and routine culturing of autoclaves and sterilizers;
 - (V) A log of incidents related to infectious and communicable diseases;
 - (VI) A method of control used in relation to the sterilization of supplies and water, and a written policy addressing reprocessing of sterile supplies;
 - (VII) Formal provisions to educate and orient all appropriate personnel in the practice of aseptic techniques such as hand washing and scrubbing practices, proper grooming, masking and dressing care techniques, disinfecting and sterilizing techniques, and the handling and storage of patient care equipment and supplies; and
 - (VIII) Continuing education provided for all office personnel on the cause, effect, transmission, prevention, and elimination of infections, as

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evidenced by front line employees verbalizing understanding of basic techniques.

- (iv) The physician office must ensure that the facility-wide performance improvement program and training programs address problems identified by the infection control committee and must be responsible for the implementation of successful corrective action plans in affected problem areas.
- (v) The physician office shall develop policies and procedures for testing a patient's blood for the presence of the hepatitis B virus and the HIV (AIDS) virus in the event that any person, employee or other health care provider rendering services at the facility is exposed to a patient's blood or other body fluid. The testing shall be performed at no charge to the patient, and the test results shall be confidential.
- (vi) The physician office and its employees shall adopt and utilize standard precautions (per CDC) for preventing transmission of infections, HIV, and communicable diseases.
- (vii) The physician office shall adopt appropriate policies regarding the testing of patients and staff for human immunodeficiency virus (HIV) and any other identified causative agent of acquired immune deficiency syndrome

2. Life Safety

- (i) All surgical suites shall conform to the current addition of the Standard Building Code, the National Fire Protection Code (NFPA), the National Electrical Code, the AIA Guidelines for Design and Construction of Hospital and Health Care Facilities (if applicable), and the U.S Public Health Service Food Code as adopted by the Board for Licensing Health Care Facilities. When referring to height, area or construction type, the Standard Building Code shall prevail. All new and existing surgical suites are subject to the requirements of the Americans with Disabilities Act (A.D.A.). Where there are conflicts between requirements in the above listed codes and regulations and provisions of this chapter, the most restrictive shall apply.
- (ii) Any surgical suite(s) which complies with the required applicable building and fire safety regulations at the time the board adopts new codes or regulations will, so long as such compliance is maintained (either with or without waivers of specific provisions), be considered to be in compliance with the requirements of the new codes or regulations.
- (iii) A surgical suite(s) shall be provided fire protection by the elimination of fire hazards, by the installation of necessary fire fighting equipment and by the adoption of a written fire control plan. All fires which result in a response by the local fire department shall be reported to the Board within seven (7) days. The report shall contain sufficient information to ascertain the nature and location of the fire, its probable cause and any injuries incurred by any person or persons as a result of the fire. Initial reports by the facility may omit the name(s) of patient(s) and parties involved, however, should the department find the identities of such persons to be necessary to an investigation, the facility shall provide such information.

(Rule 1050-02-.21, continued)

- (iv) The following alarms are required and shall be monitored twenty-four (24) hours per day:
 - (I) Fire alarms; and
 - (II) Generators (if applicable).
- (v) A negative air pressure shall be maintained in the soiled utility area, toilet room, janitor's closet, dishwashing and other such soiled spaces, and a positive air pressure shall be maintained in all clean areas including, but not limited to, clean linen rooms and clean utility rooms.
- (vi) The emergency power system shall:
 - (I) Use either propane, gasoline or diesel fuel. The generator shall be designed to meet the facility's HVAC and essential needs and shall have a minimum of twenty-four (24) hours of fuel designed to operate at its rated load. The fuel quantity shall be based on its expected or known connected load consumption during power interruptions.
 - (II) Automatically transfer within ten (10) seconds in surgical suites conducting invasive surgical procedures.
 - (III) Be inspected monthly and exercised at the actual load and operating temperature conditions and not on dual power for at least thirty (30) minutes each month, including automatic and manual transfer of equipment. A log shall be maintained for all inspections and tests and kept on file for a minimum of three (3) years. The facility shall have trained staff familiar with the generator's operation.
 - (IV) Emergency generators are not required if the surgical suite does not utilize anesthesia that renders the patient incapable of self preservation. However, the facility shall have an emergency power source able to produce adequate power to run required equipment for a minimum of two (2) hours.
- (vii) Emergency electrical power connections shall be through a switch which shall automatically transfer the circuits to the emergency power source in case of power failure. (It is recognized that some equipment may not sustain automatic transfer and provisions will have to be made to manually change these items from a non-emergency powered outlet to an emergency powered outlet or other power source.)

3. Patient Rights

- (i) Each patient has at least the following rights:
 - (I) To privacy in treatment and personal care;
 - (II) To be free from mental and physical abuse. Should this right be violated, the physician office must notify the department within five (5) business days and the Tennessee Department of Human Services, Adult Protective Services immediately as required by T.C.A. §§ 71-6-101 et seq;

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- (III) To refuse treatment. The patient must be informed of the consequences of that decision; the refusal and its reason must be reported to the physician and documented in the medical record;
 - (IV) To refuse experimental treatment and drugs. The patient's or health care decision maker's written consent for participation in research must be obtained and retained in his or her medical record;
 - (V) To have their records kept confidential and private. Written consent by the patient must be obtained prior to release of information except to persons authorized by law. If the patient lacks capacity, written consent is required from the patient's health care decision maker. The physician office must have policies to govern access and duplication of the patient's record;
 - (VI) To have appropriate assessment and management of pain; and
 - (VII) To be involved in the decision making of all aspects of their care.
- (ii) Each patient has a right to self-determination, which encompasses the right to make choices regarding life-sustaining treatment (including resuscitative services). This right of self-determination may be effectuated by an advance directive.
4. Hazardous Waste
- (i) Each physician office must develop, maintain and implement written policies and procedures for the definition and handling of its infectious and hazardous wastes. These policies and procedures must comply with the standards of this section and all other applicable state and federal regulations.
 - (ii) The following waste shall be considered to be infectious waste:
 - (I) Waste contaminated by patients who are isolated due to communicable disease, as provided in the U.S. Centers for Disease Control "Guidelines for Isolation Precautions in Hospitals;"
 - (II) Cultures and stocks of infectious agents including specimen cultures collected from medical and pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, wastes from the production of biologicals, discarded live and attenuated vaccines, and culture dishes and devices used to transfer, inoculate, and mix cultures;
 - (III) Waste human blood and blood products such as serum, plasma, and other blood components;
 - (IV) Pathological waste, such as tissues, organs, body parts, and body fluids that are removed during surgery and autopsy;
 - (V) All discarded sharps (including but not limited to, hypodermic needles, syringes, Pasteur pipettes, broken glass, scalpel blades)

(Rule 1050-02-.21, continued)

- used in patient care or which have come into contact with infectious agents during use in medical, research, or industrial laboratories;
- (VI) Contaminated carcasses, body parts, and bedding of animals that were exposed to pathogens in research, in the production of biologicals, or in the in vivo testing of pharmaceuticals;
 - (VII) Other waste determined to be infectious by the physician office in its written policy.
- (iii) Infectious and hazardous waste must be segregated from other waste at the point of generation (i.e., the point at which the material becomes a waste) within the physician office.
- (iv) Waste must be packaged in a manner that will protect waste handlers and the public from possible injury and disease that may result from exposure to the waste. Such packaging must provide for containment of the waste from the point of generation up to the point of proper treatment or disposal. Packaging must be selected and utilized for the type of waste the package will contain, how the waste will be treated and disposed, and how it will be handled and transported, prior to treatment and disposal.
- (I) Contaminated sharps must be directly placed in leakproof, rigid, and puncture-resistant containers which must then be tightly sealed;
 - (II) Whether disposable or reusable, all containers, bags, and boxes used for containment and disposal of infectious waste must be conspicuously identified. Packages containing infectious waste which pose additional hazards (e.g., chemical, radiological) must also be conspicuously identified to clearly indicate those additional hazards;
 - (III) Reusable containers for infectious waste must be thoroughly sanitized each time they are emptied, unless the surfaces of the containers have been completely protected from contamination by disposable liners or other devices removed with the waste;
 - (IV) Opaque packaging must be used for pathological waste.
- (v) After packaging, waste must be handled and transported by methods ensuring containment and preserving the integrity of the packaging, including the use of secondary containment where necessary.
- (I) Waste must not be compacted or ground (i.e., in a mechanical grinder) prior to treatment, except that pathological waste may be ground prior to disposal;
 - (II) Plastic bags of infectious waste must be transported by hand.
- (vi) Waste must be stored in a manner which preserves the integrity of the packaging, inhibits rapid microbial growth and putrefaction, and minimizes the potential of exposure or access by unknowing persons.
- (I) Waste must be stored in a manner and location which affords protection from animals, precipitation, wind, and direct sunlight, does

(Rule 1050-02-.21, continued)

not present a safety hazard, does not provide a breeding place or food source for insects or rodents and does not create a nuisance.

- (II) Pathological waste must be promptly treated, disposed of, or placed into refrigerated storage.
- (vii) In the event of spills, ruptured packaging, or other incidents where there is a loss of containment of waste, the physician office must ensure that proper actions are immediately taken to:
- (I) Isolate the area from the public and all except essential personnel;
 - (II) To the extent practicable, repackage all spilled waste and contaminated debris in accordance with the requirements of subpart (iv) of this part;
 - (III) Sanitize all contaminated equipment and surfaces appropriately. Written policies and procedures must specify how this will be done; and
 - (IV) Complete incident report and maintain copy on file.
- (viii) Except as provided otherwise in this section a physician office must treat or dispose of infectious waste by one or more of the methods specified in this part.
- (I) A physician office may treat infectious waste in an on-site sterilization or disinfection device, or in an incinerator or a steam sterilizer, which has been designed, constructed, operated and maintained so that infectious wastes treated in such a device are rendered non-infectious and is, if applicable, authorized for that purpose pursuant to current rules of the Department of Environment and Conservation. A valid permit or other written evidence of having complied with the Tennessee Air Pollution Control Regulations shall be available for review, if required. Each sterilizing or disinfection cycle must contain appropriate indicators to assure conditions were met for proper sterilization or disinfection of materials included in the cycle, and records kept. Proper operation of such devices must be verified at least monthly, and records of these monthly checks shall be available for review. Waste that contains toxic chemicals that would be volatilized by steam must not be treated in steam sterilizers. Infectious waste that has been rendered to a carbonized or mineralized ash shall be deemed non-infectious. Unless otherwise hazardous and subject to the hazardous waste management requirements of the current rules of the Department of Environment and Conservation, such ash shall be disposable as a (nonhazardous) solid waste under current rules of the Department of Environment and Conservation.
 - (II) The physician may discharge liquid or semi-liquid infectious waste to the collection sewerage system of a wastewater treatment facility which is subject to a permit pursuant to T.C.A. §§ 69-3-101, et seq., provided that such discharge is in accordance with any applicable terms of that permit and/or any applicable municipal sewer use requirements.

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- (III) Any physician office accepting waste from another state must promptly notify the Department of Environment and Conservation, county and city public health agencies, and must strictly comply with all applicable local, state and federal regulations.
 - (ix) The physician office may have waste transported off-site for storage, treatment, or disposal. Such arrangements must be detailed in a written contract, available for review. If such off-site location is located within Tennessee, the physician office must ensure that it has all necessary State and local approvals, and such approvals shall be available for review. If the off-site location is within another state, the physician office must notify in writing all public health agencies with jurisdiction that the location is being used for management of the facility's waste. Waste shipped off-site must be packaged in accordance with applicable Federal and State requirements. Waste transported to a sanitary landfill in this state must meet the requirements of current rules of the Department of Environment and Conservation.
 - (x) Human anatomical remains which are transferred to a mortician for cremation or burial shall be exempt from the requirements of this subpart. Any other human limbs and recognizable organs must be incinerated or discharged (following grinding) to the sewer.
 - (xi) All garbage, trash and other non-infectious wastes shall be stored and disposed of in a manner that must not permit the transmission of disease, create a nuisance, provide a breeding place for insects and rodents, or constitute a safety hazard. All containers for waste shall be water tight, be constructed of easily cleanable material and be kept on elevated platforms.
5. Equipment and Supplies
- (i) Adequate equipment and supplies must be available to the operating room suites and to the postoperative care area which, when applicable shall be age and procedure appropriate and shall include but not be limited to the following;
 - (I) Call-in system (OR)
 - (II) Cardiac monitor
 - (III) Pulse Oximeter
 - (IV) Resuscitator
 - (V) Defibrillator
 - (VI) Aspirator
 - (VII) Tracheotomy set
 - (ii) A crash cart must be available and include at a minimum all the medication and supplies recommended by the current ACLS guidelines of the American Heart Association and:

(Rule 1050-02-.21, continued)

(l) Dantrolene

6. Administration

- (i) Physician offices that perform office-based surgery must adopt bylaws that put in place a management system and documentation that will insure that no more than three (3) patients that are in surgery or recovery are incapable of self-preservation at the same time.
- (ii) Except for emergencies, a surgical suite certified for office based surgery may be utilized only by physician employees of the practice in which the surgical suite is located. Surgical suites may not be shared with other practices or other physicians.
- (iii) When licensure is applicable for a particular job within the surgery suite, a copy of the current license must be included as a part of the personnel file. Each personnel file shall contain accurate information as to the education, training, experience, and personnel background of the employee.
- (iv) The surgical suite shall have available a plan for emergency transportation to a licensed local hospital.
- (v) As needed, the patient and family members or interested persons must be taught and/or counseled to prepare them for post-operative care.
- (vi) There must be a complete history and physical work-up in the chart of every patient prior to surgery. If the history has been dictated, but not yet recorded in the patient's chart, there must be a statement to that effect and an admission note in the chart by the practitioner who admitted the patient.
- (vii) Properly executed informed consent forms must be in the patient's chart before surgery, except in emergencies.
- (viii) The physician office shall report information contained in the medical records of patients who have cancer or pre-cancerous or tumorous diseases as provided by existing regulations. These reports shall be sent to the Cancer Reporting System of the department on a quarterly schedule no later than six (6) months after the date of the diagnosis or treatment.
- (ix) The physician office shall report to the Department of Health each case of communicable disease detected in the office. Repeated failure to report communicable diseases shall be cause for revocation of a surgical suite's certification.
- (x) Any claim required to be reported under T.C.A. §56-54-101 (Reports on Medical Malpractice Claims) shall be reported to the Department of Health in a format designed by the Department within seven (7) business days of the date of the payment of the claim.
- (xi) Unusual events shall be reported by the physician office to the Department of Health in a format designed by the Department within seven (7) business days of the date of the identification of the abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient.

(Rule 1050-02-.21, continued)

- (I) The following represent circumstances that could result in an unusual event that is an unexpected occurrence or accident resulting in death, life threatening or serious injury to a patient, not related to a natural course of the patient's illness or underlying condition. The circumstances that could result in an unusual event include, but are not limited to:
- I. medication errors;
 - II. aspiration in a non-intubated patient related to conscious/moderate sedation;
 - III. intravascular catheter related events including necrosis or infection requiring repair or intravascular catheter related pneumothorax;
 - IV. volume overload leading to pulmonary edema;
 - V. blood transfusion reactions, use of wrong type of blood and/or delivery of blood to the wrong patient;
 - VI. perioperative/periprocedural related complication(s) that occur within 48 hours of the operation or the procedure, including a procedure which results in any new central neurological deficit or any new peripheral neurological deficit with motor weakness;
 - VII. burns of a second or third degree;
 - VIII. falls resulting in radiologically proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma, but does not include fractures resulting from pathological conditions;
 - IX. procedure related incidents, regardless of setting and within thirty (30) days of the procedure and includes readmissions, which include:
 - A. procedure related injury requiring repair or removal of an organ;
 - B. hemorrhage;
 - C. displacement, migration or breakage of an implant, device, graft or drain;
 - D. post operative wound infection following clean or clean/contaminated case;
 - E. any unexpected operation or reoperation related to the primary procedure;
 - F. hysterectomy in a pregnant woman;
 - G. ruptured uterus;

(Rule 1050-02-.21, continued)

- H. circumcision;
 - I. incorrect procedure or incorrect treatment that is invasive;
 - J. wrong patient/wrong site surgical procedure;
 - K. unintentionally retained foreign body;
 - L. loss of limb or organ, or impairment of limb if the impairment is present at discharge or for at least two (2) weeks after occurrence;
 - M. criminal acts;
 - N. suicide or attempted suicide;
 - O. elopement from the facility;
 - P. infant abduction, or infant discharged to the wrong family;
 - Q. adult abduction;
 - R. rape;
 - S. patient altercation;
 - T. patient abuse, patient neglect, or misappropriation of resident/patient funds;
 - U. restraint related incidents; or
 - V. poisoning occurring within the facility.
7. Hospital Staff Privileges required - The physician performing the surgery must have staff privileges to perform the same procedure as that being performed in the office setting at a licensed hospital within reasonable proximity.
8. Training Required – The physician performing the surgery must have documentation of training to perform the particular surgical procedures and must have knowledge of the principles of general anesthesia. The physician performing the surgery and at least one (1) assistant must be currently certified in ACLS.
9. Assistance of Other Personnel Required.
- (i) An anesthesiologist or certified registered nurse anesthetist licensed pursuant to Tennessee Code Annotated, Title 63, Chapter 7 and practicing within the lawful scope of that license, must administer the general or regional anesthesia. The anesthesia provider cannot function in any other capacity during the procedure and shall be physically present with the patient at all times during the intra-operative period.

(Rule 1050-02-.21, continued)

- (ii) When general anesthesia using volatile anesthetic gases, succinylcholine or other agents known to trigger malignant hyperthermia are administered, the surgical suite shall maintain or have immediate access to thirty-six (36) ampoules of dantrolene and its diluent for injection. If dantrolene is administered, appropriate monitoring must be provided postoperatively.
 - (iii) Following the procedure –
 - (I) There must be a person with current ACLS certification present at all times with the patient while in the recovery area; and
 - (II) An additional professional who has post-anesthesia care unit experience or its equivalent and a current ACLS certification and who is licensed pursuant to either Tennessee Code Annotated, Title 63 Chapter 6, 9 or 19 or a registered or advanced practice nurse licensed pursuant to Tennessee Code Annotated, Title 63 Chapter 7 must also be immediately available on the premises to assist in monitoring the patient in the recovery room until the patient has recovered from anesthesia.
 - (III) If the patient has not recovered sufficiently to be safely discharged within twelve (12) hours after the initial administration of anesthesia, the patient must be transferred to a hospital for continued postoperative care.
10. Level III surgical suites shall be used exclusively for surgery and recovery, respectively and for no other purpose.
11. Physicians performing Level III surgery in an office setting shall obtain written informed consent prior to the procedure from the patient or the patient's representative which shall be documented in the patient's health record. The consent shall explain to the patient the risks and benefits of the procedure; the alternative treatments to the surgical procedure; the type of anesthesia to be used and its risks; and the qualifications of the professional who is expected to administer the anesthesia during the procedure.
12. A physician performing Level III surgery in an office setting must inform the patient, in writing, that the medical office is not a licensed facility and that the patient may elect to have the surgery performed at a licensed ASTC or hospital. The patient or the patient's representative must consent in writing to have the surgery performed in a medical office.
- (e) ASA Risk Classifications - Only patients classified under the ASA risk classification criteria as Class 1 or 2 are appropriate candidates for Level III office based surgical procedures.
 - (f) The Board shall post on its web site a list, including the names and locations of physician offices that have qualified as sites for Level III surgeries and have been issued certification by the Board. Information on the list shall be updated at least quarterly.
- (8) Procedure Specific Restrictions
- (a) Liposuction - Liposuction procedures performed pursuant to these rules shall be performed only by physicians with appropriate training following prescribed national

(Rule 1050-02-.21, continued)

professional guidelines. These procedures shall be within the scope of practices of the physician and capabilities of the office. Provided however, no such procedures may be performed if the anticipated supernatant fat removal is to be greater than 4000 cc. In addition the following shall also apply:

1. When combined with other surgical procedures, liposuction may not exceed 2000 cc of supernatant fat.
 2. A maximum of 50mg/kg of Lidocaine can be injected for tumescent liposuction in the office setting. A maximum of 35mg/kg of Lidocaine can be injected for non-tumescent liposuction in the office setting.
- (b) Laser surgery - Laser surgeries performed pursuant to these rules require written policies and procedures that include, but are not limited to, laser safety, education, training, and the supervision of other licensed health care practitioners who are performing laser treatments. A safe environment shall be maintained for laser surgery.
- (9) The Board shall appoint a standing Office Based Surgery Committee comprised of three (3) members of the Board who shall meet twice a year to review and make whatever recommendations for revision of these rules as circumstances require. All comments and suggestions for revision and improvement of these rules should be addressed to that committee and sent to the Board's Administrative Office.
- (10) Any violation of these rules shall be grounds for disciplinary actions before the board pursuant to T.C.A. § 63-9-111(b) (1), (2) or (4) or Public Chapter 373 of the Public Acts of 2007.
- (a) When a physician office is found by the department to have committed a violation of this chapter, the department will issue a statement of deficiencies. Within ten (10) days of the receipt of the statement of deficiencies the physician office must return a plan of correction indicating the following:
1. How the deficiency will be corrected.
 2. Who will be responsible for correcting the deficiency.
 3. The date the deficiency will be corrected.
 4. How the facility will prevent the same deficiency from re-occurring.
- (b) Either failure to submit a plan of correction in a timely manner or a finding by the department that the plan of correction is unacceptable shall subject a surgical suite's certification to possible disciplinary action.

Authority: T.C.A. § 63-6-211, 63-9-101, 63-9-106, 63-9-111 and 63-9-117. **Administrative History:** Public necessity new rule filed October 5, 2007; expired March 18, 2008. Public necessity rule filed October 5, 2007 expired effective March 19, 2007, and reverted to its previous status. Original rule filed January 25, 2008; effective April 8, 2008. Amendment filed April 30, 2010; effective July 29, 2010.

1050-02-.22 TAMPER-RESISTANT PRESCRIPTIONS.

- (1) Purpose.

(Rule 1050-02-.22, continued)

This rule is designed to implement the law requiring that licensed osteopathic physicians have all written, typed, or computer-generated prescriptions issued on tamper-resistant prescription paper.

(2) Definitions.

The following definitions are applicable to this rule:

- (a) "Drug" shall have the same meaning as set forth in T.C.A. §63-10-204(16).
- (b) "Prescriber" means an individual licensed in Tennessee as a medical doctor, podiatrist, advanced practice nurse with a certificate of fitness to prescribe, dentist, optometrist, osteopathic physician, or physician's assistant.
- (c) "Prescription order" shall have the same meaning as set forth in T.C.A. §63-10-204(38).
- (d) "Tamper-resistant prescription" means a written prescription order with features that are designed to prevent unauthorized copying, erasure, modification, and use of counterfeit prescription forms.

(3) Tamper-Resistant Prescription Requirements.

- (a) A prescriber shall ensure that all handwritten, typed, or computer-generated prescription orders are issued on tamper-resistant prescriptions. Tamper-resistant prescriptions shall contain the following features:
 - 1. Either a void or illegal pantograph or a watermark designed to prevent copying;
 - 2. Either quantity check-off boxes with refill indicators or a uniform, non-white background color designed to prevent erasure or modification; and
 - 3. Security features and descriptions listed on the prescriptions designed to prevent use of counterfeit forms.

(4) Security Measures and Recordkeeping.

- (a) Each prescriber shall undertake adequate safeguards and security measures to ensure against loss, improper destruction, theft, or unauthorized use of the tamper-resistant prescriptions in the prescriber's possession.

(5) Use of Tamper-Resistant Prescriptions.

- (a) Facsimile Prescription Transmission.
 - 1. Prescriptions sent by facsimile transmission are not required to be placed on tamper-resistant prescription paper.
 - 2. If a prescriber transmits a prescription order to a pharmacy by facsimile transmission, the prescriber or someone designated by the prescriber shall document in the patient's medical record the name of the drug, strength, and quantity prescribed. The prescriber may, but is not required to, document the means by which the prescription was transmitted.
- (b) Electronic Prescription Transmission.

(Rule 1050-02-.22, continued)

1. Prescriptions sent by electronic transmission are not required to be placed on tamper-resistant prescription paper.
2. If a prescriber transmits a prescription order to a pharmacy by electronic transmission, the prescriber shall document the prescription in the patient's file and in accordance with the applicable laws and rules for each of the prescribers' respective professions as well as applicable federal laws and rules. The prescriber may, but is not required to, document the means by which the prescription was transmitted.

Authority: Chapter 1035 of the Public Acts of 2008 and T.C.A. §§53-10-401 and 63-9-116. [effective October 1, 2008 for TennCare prescriptions and July 1, 2009 for non-TennCare prescriptions].

Administrative History: Public necessity rule filed June 25, 2009; effective through December 7, 2009. Public necessity rule filed June 25, 2009 expired; on December 8, 2009, the rule reverted to its prior status. Emergency rule filed December 21, 2009; effective through June 19, 2010. Original rule filed March 22, 2010; effective June 20, 2010.