Department of Health
Notice of Rulemaking Hearing
Board of Podiatric Medical Examiners
Division of Health Related Boards

There will be a hearing before the Tennessee Board of Podiatric Medical Examiners to consider the promulgation of new rules pursuant to T.C.A. §§ 4-5-202, 4-5-204, and 63-3-106. The hearing will be conducted in the manner prescribed by the Uniform Administrative Procedures Act, Tennessee Code Annotated, Section 4-5-204 and will take place in the Cumberland Room of the Cordell Hull Building located at 425 Fifth Avenue North, Nashville, TN at 3:30 p.m. (CST) on the 28th day of December, 2005.

Any individuals with disabilities who wish to participate in these proceedings (review these filings) should contact the Department of Health, Division of Health Related Boards to discuss any auxiliary aids or services needed to facilitate such participation or review. Such initial contact may be made no less than ten (10) days prior to the scheduled meeting date (the date such party intends to review such filings), to allow time for the Division to determine how it may reasonably provide such aid or service. Initial contact may be made with the ADA Coordinator at the Division of Health Related Boards, First Floor, Cordell Hull Building, 425 Fifth Avenue North, Nashville, TN 37247-1010, (615) 532-4397.

For a copy of the entire text of this notice of rulemaking hearing contact:

Jerry Kosten, Regulations Manager, Division of Health Related Boards, 425 Fifth Avenue North, First Floor, Cordell Hull Building, Nashville, TN 37247-1010, (615) 532-4397.

Substance of Proposed Rules

New Rules

Chapter 1155-4
General Rules Governing Orthotists, Prosthetists, and Pedorthists

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1155-4-.01 Orthotists.

(1) An "orthotist" is an allied health professional who is specifically trained and educated to provide or manage the provision of a custom-designed, fabricated, modified and fitted external orthosis to an orthotics patient, based on a clinical assessment and a prescription from a health care practitioner authorized by law to write such prescriptions, to restore physiological function or cosmesis.

(2) An "orthosis" is a custom-designed, fabricated, fitted or modified device to correct, support or compensate for a neuro-musculoskeletal disorder or acquired condition. "Orthosis" does not include fabric or elastic supports, corsets, arch supports, low-temperature plastic splints, trusses, elastic hoses, canes, crutches, soft cervical collars, dental appliances, or other similar devices that are carried in stock and sold without modification as "over-the-counter" items by a drug store, department store, corset shop, or surgical supply facility.

(3) "Orthotics" is the science and practice of evaluating, measuring, designing, fabricating, assembling, fitting, adjusting, or servicing an orthosis under an order from a licensed health care practitioner authorized by law to issue such an order for the correction or alleviation of neuromuscular or musculoskeletal dysfunction, disease, injury, or deformity.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-3-106, and Public Chapter 380 of the Public Acts of 2005.

1155-4-.02 Prosthetists.

(1) A "prosthetist" is an allied health professional who is specifically trained and educated to provide or manage the provision of a custom designed, fabricated, modified, and fitted external limb prosthesis to a prosthetic patient, based on a clinical assessment and a prescription from a health care practitioner authorized to write such prescriptions, to restore physiological function or cosmesis.

(2) A "prosthesis" is a custom designed, fabricated, fitted, or modified device to replace an absent external limb for purposes of restoring physiological function or cosmesis. "Prosthesis" does not include artificial eyes, ears, or dental appliances, cosmetic devices or other devices that do not have a significant impact on the musculoskeletal functions of the body.

(3) "Prosthetics" is the science and practice of evaluating, measuring, designing, fabricating, assembling, fitting, adjusting, or servicing a prosthesis under an order from a licensed health care practitioner authorized by law to issue such order.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-3-106, and Public Chapter 380 of the Public Acts of 2005.

1155-4-.03 Pedorthists.

(1) A "pedorthist" is an allied health professional who is specifically trained and educated to measure, design, fabricate, fit or service a pedorthic device, based on a clinical assessment and a prescription from a health care practitioner authorized to write such prescriptions, for the support or correction of disabilities caused by neuro-musculoskeletal diseases, injuries, or deformities.

(2) The term "pedorthic device" includes therapeutic footwear, foot orthoses for use at the ankle or below, and modified footwear made for therapeutic purposes, as prescribed by a licensed health care practitioner authorized by law to issue such prescription. "Pedorthic device" does not include non-therapeutic accommodative inlays or non-therapeutic accommodative footwear, shoe modifications made for non-therapeutic purposes, unmodified, over-the-counter shoes, or prefabricated foot care products.

(3) "Pedorthics" is the science and practice of evaluating, measuring, designing, fabricating, assembling, fitting, adjusting, or servicing a pedorthic device under an order from a licensed health care practitioner authorized by law to issue such order for the correction or alleviation of neuromuscular or musculoskeletal dysfunction, disease, injury, or deformity.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-3-106, and Public Chapter 380 of the Public Acts of 2005.

1155-4-.04 Restrictions on the Practice of Orthotists, Prosthetists and Pedorthists.

(1) A licensed orthotist, prosthetist or pedorthist may provide care or services only if the care or services are provided pursuant to an order from a licensed health care practitioner authorized to issue such an order.

(2) A licensed orthotist, prosthetist, or pedorthist must provide services at a facility which has appropriate clinical and laboratory space and equipment to allow that licensee to provide comprehensive orthotic, prosthetic, or pedorthic care.

(3) The scope of practice of a licensed orthotist, prosthetist, or pedorthist does not include the right to diagnose a medical problem or condition or the right to give medical advice as to the nature, cause, or treatment for the problem or condition for which the orthosis, prosthesis, or pedorthic device is being dispensed. However, the scope of practice of a licensed orthotist, prosthetist, or pedorthist does include the right to provide information or demonstration regarding the proper use and care of the device and to make adjustments to the device as needed.

(4) A licensed orthotist, prosthetist, or pedorthist may utilize one or more non-licensed persons to assist in the provision of services, but the non-licensed person shall be limited to the performance of minor repairs on devices which have been previously dispensed to a patient.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-3-106, and Public Chapter 380 of the Public Acts of 2005.

1155-4-.05 Necessity of Licensure. On and after January 1, 2008, except as provided in Tennessee Code Annotated, Title 63, Chapter 3, Sections 205, 208 and 209, no person shall practice orthotics, prosthetics, or pedorthics in Tennessee, or hold himself or herself out as being able to practice such professions, or dispense an orthosis, prosthesis, or pedorthic device, unless such person is licensed in accordance with the requirements of this chapter.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-3-106, and Public Chapter 380 of the Public Acts of 2005.

1155-4-.06 Qualifications for Licensure.

(1) Orthotist – To qualify for a license to practice orthotics, a person shall:

(a) Complete an orthotics education program which is accredited by the Commission on Accreditation of Allied Health Education Programs or its successor organization; or

(b) Possess a baccalaureate degree (or have successfully completed the number of semester hours which is equivalent to four [4] years of study at a four-year college or university). The curriculum of the program of study completed by such person must include mathematics, physics, biology, chemistry, anatomy, biomechanics, pathology and psychology courses; and

(c) Successfully complete a clinical residency in orthotics. The majority of training must be devoted to services performed under the supervision of an orthotist licensed in Tennessee or a person in another state who has obtained certification from the American Board for Certification in Orthotics and Prosthetics, Inc. or the Board for Orthotist/Prosthetist Certification; and

(d) Successfully complete all examinations required by Rule 1155-4-.08.

(2) Prosthetist – To qualify for a license to practice prosthetics, a person shall:

(a) Complete a prosthetic education program which is accredited by the Commission on Accreditation of Allied Health Education Programs or its successor organization; or

(b) Possess a baccalaureate degree (or have successfully completed the number of semester hours which is equivalent to four (4) years of study at a four-year college or university). The curriculum of the program of study completed by such person must include math, physics, biology, chemistry, anatomy, biomechanics, pathology and psychology courses; and

(c) Successfully complete a clinical residency in prosthetics. The majority of training must be devoted to services performed under the supervision of a prosthetist licensed in Tennessee or a person in another state who has obtained certification from the American Board for Certification in Orthotics and Prosthetics, Inc. or the Board for Orthotist/Prosthetist Certification; and

(d) Successfully complete all examinations required by Rule 1155-4-.08.

(3) Pedorthist – To qualify for a license to practice pedorthics, a person shall:

(a) Possess a high school diploma or comparable credential approved by the Board; and

(b) Successfully complete a pedorthics education program accredited by the Board for Certification in Pedorthics, or a pedorthics education program approved by the board, which includes:

1. A basic curriculum of instruction in foot-related pathology of diseases, anatomy, and biomechanics;

2. A specific curriculum in pedorthics courses, including but not limited to lectures covering shoes, foot orthoses, and shoe modifications, pedorthics components and materials, training and functional capabilities, pedorthics performance evaluation, prescription considerations, etiology of disease processes necessitating use of pedorthics devices, medical management, and subject matter related to pediatric and geriatric problems; and

3. Lectures, demonstrations, and laboratory experiences related to the entire process of measuring and casting, fitting, fabricating, aligning, and completing pedorthic devices; and

(c) Successfully complete a qualified work experience program or internship in pedorthics in accordance with standards and procedures established by the Board; and

(d) Successfully complete all examinations required by Rule 1155-4-.08.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-3-106, and Public Chapter 380 of the Public Acts of 2005.

1155-4-.07 Procedures for Licensure.

(1) An applicant shall download a current application from the Board's Internet Web page or shall obtain a current application packet from the Board's Administrative Office, respond truthfully and completely to every question or request for information contained in the application form, and submit it, along with all documentation and fees required, to the Board's Administrative Office. It is the intent of this rule that all steps necessary to accomplish the filing of the required documentation be completed prior to filing an application and that all materials be filed simultaneously.

(2) An applicant shall submit with his application a "passport" style photograph taken within the preceding twelve (12) months and attach it to the appropriate page of the application.

(3) An applicant shall have successfully completed the requirements of Rule 1155-4-.06 and cause the supporting documentation to be sent from the document's issuer directly to the Board's Administrative Office. If the applicant has an active license in good standing as an orthotist, prosthetist, or pedorthist in another state which has licensure requirements substantially similar to those set forth in these rules, the Board may choose to waive the submission of the documentation required by this chapter.

(4) An applicant shall disclose the circumstances surrounding any of the following:

(a) Conviction of a crime in any country, state, or municipality, except minor traffic violations;

(b) The denial of certification or licensure application by any other state or country, or the discipline of the certificate holder or licensee in any state or country;

(c) Loss, restriction, or voluntary surrender of certification or licensure privileges; and

(d) Any judgment or settlement in a civil suit in which the applicant was a party defendant, including malpractice, unethical conduct, breach of contract, or any other civil action remedy recognized by the country's or state's statutory, common law, or case law.

(5) 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.

(6) When necessary, all required documents shall be translated into English and such translation, together with the original document, shall be certified as to authenticity by the issuing source. Both versions must be submitted simultaneously.

(7) If the applicant is licensed or was ever licensed as a health care professional in another state, the applicant shall cause the appropriate licensing Board in each state in which he holds or has held a license to send directly to the Board an official statement which indicates the condition of his license in such other state, including the date on which he

was so licensed and under what provision such license was granted (i.e. certificate of clinical competence, examination, reciprocity, grandfathering, etc.).

(8) Application review, approval, denial, and interview decisions shall be made pursuant to Rule 1155-2-.07.

(9) The requirement for licensure under these rules shall not apply to:

(a) A person who is employed by any bureau, division, or agency of the federal government while in the discharge of the employee's official duties;

(b) A student enrolled in an educational program at a college or university which will enable that student to obtain a license to practice orthotics, prosthetics, or pedorthics upon graduation from the program;

(c) A resident continuing such resident's clinical education in a residency accredited by the National Commission on Orthotic and Prosthetic Education; and

(d) A student in a qualified work experience program or internship in pedorthics.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-3-106, and Public Chapter 380 of the Public Acts of 2005.

1155-4-.08 Examinations.

(1) In addition to the jurisprudence examination required by paragraph (4), an applicant for licensure as an orthotist, prosthetist, or pedorthist must successfully complete and make a passing score on the examination(s) approved and offered by the American Board for Certification in Orthotics and Prosthetics, Inc., the Board for Certification in Pedorthics, or other examination(s) approved by the board.

(2) Passing scores shall be determined by the testing agencies and/or exam providers.

(3) Examination fees shall be sent from the applicant directly to the testing agencies and/or exam providers.

(4) Jurisprudence Examination. All applicants for licensure must successfully complete the Board's jurisprudence examination as a prerequisite to licensure.

(a) The Board shall include a jurisprudence examination with all applications for licensure that are mailed from the Board's administrative office, or the applicant may obtain the jurisprudence examination from the Board's Internet web page that can be accessed at www.Tennessee.gov/health.

(b) The applicant shall include a completed jurisprudence examination when his/her completed application for licensure is returned to the Board's administrative office.

(c) There is no fee for the jurisprudence examination.

(d) The scope and content of the examination shall be determined by the Board but limited to:

1. statutes and regulations governing the practice of orthotics, prosthetics, or pedorthics (T.C.A. §§ 63-3-201 et seq., and Chapter 1155-4 of the Official Compilation, Rules and Regulations of the State of Tennessee); and

2. the following ethics documents, as applicable for the type licensure being sought:

(i) The Canons of Ethics of the American Board for Certification in Orthotics and Prosthetics Inc.

(ii) The Code of Ethics of the Board for Orthotist/Prosthetist Certification.

(iii) The Code of Ethical Conduct of the Board for Certification in Pedorthics, Inc.

(e) Information regarding how to acquire copies of the applicable statutes, regulations and ethics documents is available upon request from the Board's administrative office.

(f) The format of the examination shall be "open-book."

(g) Correctly answering ninety percent (90%) of the examination questions shall constitute successful completion of the jurisprudence exam.

(h) Applicants who fail to successfully complete the jurisprudence examination must continue to retake the examination until it has been successfully completed before the application will be deemed complete and presented to the Board for consideration.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-3-106, and Public Chapter 380 of the Public Acts of 2005.

1155-4-.09 Fees. All fees except the State Regulatory fee are non-refundable.

(1)	Application	$300.00
(2)	Renewal (biennial)	$300.00
(3)	Late Renewal	$100.00
(4)	Reinstatement	$300.00
(5)	Duplicate or Replacement License	$ 25.00
(6)	Continuing Education Course Accreditation	$ 50.00
(7)	State Regulatory (biennial)	$ 10.00

Authority: T.C.A. §§ 4-3-1011, 4-5-202, 4-5-204, 63-3-106, and Public Chapter 380 of the Public Acts of 2005.

1155-4-.10 Renewal of Licensure.

(1) The due date for renewal is the last day of the month in which a licensee's birthday falls pursuant to the Division of Health Related Board's biennial birthdate renewal system, which is the expiration date shown on the licensee's renewal certificate.

(2) Methods of Renewal

(a) Internet Renewals - Individuals may apply for renewal and pay the necessary fees via the Internet. The application to renew can be accessed at:

www.tennessee.gov

(b) Paper Renewals - For individuals who have not renewed their license online via the Internet, a renewal application form will be mailed to each individual licensed by the Board to the last address

provided to the Board. Failure to receive such notification does not relieve the licensee from the responsibility of meeting all requirements for renewal.

(3) A license issued pursuant to these rules is renewable by the expiration date. To be eligible for renewal an individual must submit to the Division of Health Related Boards on or before the expiration date the following:

(a) A completed renewal application form; and

(b) The renewal and state regulatory fees as provided in Rule 1155-4-.09.

(4) To be eligible for renewal an individual must have completed the continuing education requirements provided in Rule 1155-4-.12 and must attest to such completion on the renewal application. An individual who fails to obtain continuing education hours, pursuant to Rule 1155-4-.12, may be subject to disciplinary action by the Board.

(5) Licensees who fail to comply with the renewal rules or notification received by them concerning failure to timely renew shall have their license processed pursuant to Rule 1200-10-1-.10.

(6) Reinstatement of a license that has expired as a result of failure to timely renew in accordance with Rule 1200-10-1-.10 may be accomplished upon meeting the following conditions:

(a) Payment of all past due renewal and state regulatory fees;

(b) Payment of the late renewal fee provided in Rule 1155-4-.09; and

(c) Compliance with continuing education requirements pursuant to Rule 1155-4-.12.

(7) Renewal applications shall be treated as licensure applications, and shall be governed by Rule 1155-2-.07.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-3-106, and Public Chapter 380 of the Public Acts of 2005.

1155-4-.11 Retirement And Reactivation.

(1) A person who holds a current license and does not intend to practice as an orthotist, prosthetist or pedorthist may apply to convert an active license to

retired ("inactive") status. An individual who holds a retired license will not be required to pay the renewal fee.

(2) A person who holds an active license may apply for retired status in the following manner:

(a) Obtain, complete, and submit to the Board's administrative office an affidavit of retirement form; and

(b) Submit any other documentation which may be required to the Board's administrative office.

(3) A licensee whose certificate has been retired may re-enter active status by doing the following:

(a) Obtain complete and submit to the Board's administrative office a reactivation application; and

(b) Pay the renewal fees and state regulatory fees as provided in Rule 1155-4-.09. If reactivation is requested prior to the expiration of one (1) year from the date of retirement, the Board will require payment of the late renewal fee and past due renewal fees; and

(c) Submit verification of successful completion of continuing education hours for the period of retirement, pursuant to Rule 1155-4-.12.

(4) Reactivation applications shall be treated as licensure applications, and shall be governed by Rule 1155-2-.07.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-3-106, and Public Chapter 380 of the Public Acts of 2005.

1155-4-.12 Continuing Education.

(1) Each licensed orthotist, prosthetist and pedorthist must annually complete fifteen (15) hours of continuing education in courses applicable to his/ her profession. No more than five (5) hours of the annual requirement shall be completed by any of the means listed in Rule 1155-2-.12 (1) (c). A person who is licensed in more than one (1) profession under these rules shall annually complete twenty (20) hours of continuing education in courses applicable to the professions in which he/she is licensed. At least six (6) hours of the continuing education each year must be obtained by each licensee from providers in the state of Tennessee.

(2) Acceptable continuing education shall consist of courses provided, approved, or sponsored by:

(a) The American Board for Certification in Orthotics and Prosthetics, Inc.;

(b) The Board for Orthotist/Prosthetist Certification;

(c) The Board for Certification in Pedorthics;

(d) The Pedorthic Footwear Association;

(e) Tennessee Orthotic and Prosthetic Facilities, Inc.;

(f) The Tennessee Podiatric Medical Association; and

(g) any other entity whose education programs have been approved by the Board.

(3) Course Approval

(a) Courses to be offered for credit toward the required continuing education hours must, unless provided, approved or sponsored by an entity listed in paragraph (2), receive prior approval from the Board.

(b) Prior approval of a course may be obtained by submitting the following information to the Board's administrative office at least forty-five (45) days prior to the scheduled date of the course:

1. A course description or outline;

2. Names of all lecturers;

3. Brief resume of all lecturers;

4. Number of hours of educational credit requested;

5. Date and location of course or how to access the course electronically;

6. How certification of attendance is to be documented; and

7. The Continuing Education Course Accreditation Fee required to be paid pursuant to Rule 1155-4-.09.

(4) Each licensee must retain proof of attendance and completion of all continuing education requirements. This documentation must be retained for a period of four (4) years from the end of the calendar year in which the continuing education was required. This documentation must be produced for inspection and verification, if requested in writing by the Board during its verification process. The Board will not maintain continuing education files.

(5) Each licensee must, within thirty (30) days of a request from the Board, provide evidence of continuing education activities. Certificates verifying the individual's attendance or original letters from course providers are such evidence.

(6) Licensees are exempt from the continuing education requirements for the calendar year that the requirements of Rule 1155-4-.06 were completed.

(7) Violations

(a) Any person who falsely attests to attendance and completion of the required hours of continuing education may be subject to disciplinary action.

(b) Any person who fails to obtain the required continuing education hours may be subject to disciplinary action.

(8) Education hours obtained as a result of compliance with the terms of a Board order in any disciplinary action shall not be counted toward the continuing education hours required to be obtained by paragraph (1) of this rule.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-3-106, and Public Chapter 380 of the Public Acts of 2005.

1155-4-.13 Disciplinary Actions, Subpoenas, Declaratory Orders, Screening Panels and Advisory Private Letter Rulings.

(1) Disciplinary Actions – Licensed orthotists, prosthetist and pedorthists issued by the Board are subject to being disciplined for the same causes, to the same extent and pursuant to the same procedures provided in Rule 1155-2-.15 as licensed podiatrists.

(2) Subpoenas – Subpoena procedures shall be governed by Rule 1155-2-.15.

(3) Declaratory Orders – Declaratory order procedures shall be governed by Rule 1155-2-.19.

(4) Screening Panels – Screening panel procedures shall be governed by Rule 1155-2-.19.

(5) Advisory Private Letter Rulings – Advisory private letter rulings shall be governed by Rule 1155-2-.19.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-3-106, and Public Chapter 380 of the Public Acts of 2005.

1155-4-.14 Advertising. Advertising shall be governed by Rule 1155-2-.22.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-3-106, and Public Chapter 380 of the Public Acts of 2005.

1155-4-.15 Change of Address and/or Name.

(1) Change of Name - Licensees shall notify the Board in writing within thirty (30) days of a name change and shall provide both the old and new names. A request for name change must also include a copy of the official document involved and reference the individual's profession and license number.

(2) Change of Address – A licensee who has had a change of address or place of employment shall file in writing with the Board his/her current address, giving both old and new addresses. Such requests shall be received in the Board's administrative office no later than thirty (30) days after such change is effective and must reference the licensee's name, profession, and license number.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-3-106, and Public Chapter 380 of the Public Acts of 2005.

1155-4-.16 "Grandfather" Provisions for Licensure.

(1) Until January 1, 2008, a person certified by the American Board for Certification in Orthotics and Prosthetics, Inc., with the title of Certified Orthotist (CO), Certified Prosthetist (CP), or Certified Orthotist-Prosthetist (CPO) or The Board for Orthotist/Prosthetist Certification with the title of Board of Orthotic Certification - Orthotist (BOCO) or Board of Certification - Prosthetist (BOCP) or holding similar certifications from other accrediting bodies with equivalent educational requirements and examination standards may apply for and may be granted orthotic or prosthetic licensure upon payment of the required fee. After that date, any applicant for initial licensure as an orthotist or a prosthetist shall meet the requirements of these rules regarding

licensure.

(2) Until January 1, 2008, a person certified as a Certified Pedorthist (CPED) by the Board of Certification in Pedorthics, Inc., or a person certified as a CO, CP or CPO by the American Board for Certification in Orthotics and Prosthetics, Inc. or certified as a BOCO or BOCP by the Board for Orthotist/Prosthetist Certification or holding similar certifications from other accrediting bodies with equivalent educational requirements and examination standards may apply for and may be granted pedorthic licensure upon payment of the required fee. After that date, any applicant for initial licensure as a pedorthist shall meet the requirements of these rules regarding licensure.

(3) Until January 1, 2007, a person who has practiced full-time for a minimum of the past five (5) years in a prosthetic/orthotics facility as an orthotist or prosthetist or in a pedorthics facility as a pedorthist may file an application with the Board and may be issued a license to practice orthotics, prosthetics, or pedorthics without examination, upon payment of the required fee and after the Board has completed an investigation of the applicant's work history. The investigation may include, but is not limited to, completion by the applicant of a questionnaire regarding the applicant's work history and scope of practice. A "facility" is the business location where orthotics, prosthetic, or pedorthic care is provided and which has the appropriate clinical and laboratory space and equipment to provide such care.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-3-106, and Public Chapter 380 of the Public Acts of 2005.

1155-4-.17 Sale of Over-the-Counter and Off-the-Shelf Devices.

(1) "Over-the-counter device" means a prefabricated, mass-produced device that is prepackaged and requires no professional advice or judgment in either size selection or use, including fabric or elastic supports, corsets, generic arch supports and elastic hoses.

(2) "Off-the-shelf device" means a prefabricated prosthesis or orthosis sized or modified for use by the patient in accordance with a prescription from a health care practitioner authorized by law to write such prescriptions and which does not require substantial clinical judgment and substantive alteration for appropriate use.

(3) The sale of over-the-counter and off-the-shelf devices by non-licensed persons is not prohibited by these rules.

(4) No person shall dispense or sell an over-the-counter device or an off-the-

shelf device based upon an image of the customer's limb captured by the person through a mold, cast, tracing, scanning device, digital appliance, or pressure sensitive device, unless the customer has first presented to that person a written prescription for that device from a health care practitioner authorized by law to write such a prescription.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-3-106, and Public Chapter 380 of the Public Acts of 2005.

1155-4-.18 Custom Fabricated and Fitted Devices.

(1) "Custom fabricated and fitted device" means an orthosis, prosthesis, or pedorthic device which is fabricated to original measurements or a mold for use by a patient in accordance with a prescription from a health care practitioner authorized by law to write such prescriptions and which requires substantial clinical and technical judgment in its design and fitting.

(2) "Custom fitted device" means a prefabricated orthosis, prosthesis, or pedorthic device sized or modified for use by the patient in accordance with a prescription from a health care practitioner authorized by law to write such prescriptions and which requires substantial clinical judgment and substantive alteration for appropriate use.

(3) Custom fabricated devices and custom fabricated and fitted devices must be dispensed by a licensed health care practitioner or by a person licensed under these rules in accordance with a prescription from a licensed health care practitioner.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-3-106, and Public Chapter 380 of the Public Acts of 2005.

1155-4-.19 Other Licensed Health Care Practitioners. Nothing in these rules shall be interpreted as limiting or restricting a health care practitioner licensed under any chapter of Title 63, Tennessee Code Annotated, from engaging in the full scope of practice allowed by such person's license.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-3-106, and Public Chapter 380 of the Public Acts of 2005.

1155-4-.20 Pharmacists, Home Medical Equipment Providers, and Orthosis Manufacturers.

(1) Nothing in these rules shall be interpreted as limiting or restricting individuals acting under the supervision and control of a pharmacist or

pharmacy licensed under Title 63, or home medical equipment provider licensed under Title 68, from measuring, fitting or adjusting any non-custom fabricated and fitted device, including but not limited to over-the-counter devices or off-the-shelf devices, so long as such individual does not create a cast, mold or scan of a part of the human body for the purpose of constructing a medical device to treat a patient's medical condition and so long as such individual meets one of the following criteria for such device:

(a) Documented training from a manufacturer; or training from a licensed or certified orthotist, prosthetist, or pedorthist; or

(b) Certification or registration as a fitter of orthotics, prosthetics, or pedorthics, from a nationally recognized board or association such as the Board for Orthotist/Prosthetist Certification (BOC), the Board of Certification for Pedorthists, the National Community Pharmacists Association (NCPA), or the American Board for Certification in Orthotics and Prosthetics (ABC); or

(c) Direct supervision by a trained and experienced, or certified, or registered, fitter of orthotic, prosthetic, or pedorthic devices.

(2) Nothing in these rules shall be interpreted as limiting or restricting individuals acting under the supervision and control of a pharmacist or pharmacy licensed under Title 63, or home medical equipment provider licensed under Title 68, from measuring, fitting or adjusting any non-custom fabricated and fitted pedorthic devices, including but not limited to diabetic shoes, provided such individual meets the criteria of either subparagraph (1) (b) or (1) (c) and so long as the individual does not create a cast, mold or scan of a part of the human body for the purpose of constructing a medical device to treat a patient's medical problem.

(3) Nothing in these rules shall be interpreted as limiting or restricting the measuring, fitting or adjusting of an orthotic device by an employee or authorized representative of an orthosis manufacturer registered with the federal Food and Drug Administration, provided:

(a) such employee or representative is supervised by a licensed health care professional authorized by law to prescribe, measure or fit such device;

(b) the measuring, fitting or adjusting of such device occurs in the office of such licensed health care professional or in a health care facility; and

(c) the licensed health care professional examines the patient to ensure

that the device has been properly measured, fitted or adjusted by the employee or authorized representative.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-3-106, and Public Chapter 380 of the Public Acts of 2005.

1155-4-.21 Therapeutic Footwear. The following actions with respect to therapeutic footwear and medical devices for the foot and ankle must be performed by a health care practitioner licensed under Title 63 who is acting within his or her lawful scope of practice:

(1) Modifications or additions to the interior or exterior of footwear for therapeutic purposes, including but not limited to heel lifts, outflare heels, Thomas heels, full sole lifts, wedged soles, rocker bottom soles, metatarsal bars, metatarsal raises or inserts that have fillers as part of their construction, toe fillers, and partial foot fillers;

(2) Permanent or temporary attachment of an orthosis to the footwear;

(3) Addition or modification of a removable or attached therapeutic foot device inside the shoe which was fabricated based on a cast, impression, mold, scan, imprint or tracing;

(4) Creation of an image of a person's foot or ankle through the use of a mold, cast, scanning device, digital appliance, tracing, pressure sensitive device or other similar device; and

(5) Analysis, evaluation, measurement, assessment, or screening of a foot for the purpose of making a therapeutic recommendation.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-3-106, and Public Chapter 380 of the Public Acts of 2005.

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Contact who can answer questions concerning this notice of rulemaking hearing, technical contact for disk acquisition, and person who will approve final copy for publication: Jerry Kosten, Regulations Manager, Division of Health Related Boards, First Floor, Cordell Hull Building, 425 Fifth Avenue North, Nashville, TN 37247-1010 615-532-4397.

I certify that this is an accurate and complete representation of the intent and scope of rulemaking proposed by the Tennessee Board of Podiatric Medical Examiners.

Robbie H. Bell, Director
Health Related Boards

Subscribed and sworn to before me this the 6th day of October, 2005.

Notary Public

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

The notice of rulemaking set out herein was properly filed in the Department of State on the 6 day of Oct., 2005.

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Secretary of State

By: