

**RULES
OF
THE BOARD OF PODIATRIC MEDICAL EXAMINERS
DIVISION OF HEALTH RELATED BOARDS**

**CHAPTER 1155-04
GENERAL RULES GOVERNING ORTHOTISTS, PROSTHETISTS, AND PEDORTHISTS**

TABLE OF CONTENTS

1155-04-.01	Orthotists	1155-04-.14	Advertising
1155-04-.02	Prosthetists	1155-04-.15	Change of Address and/or Name
1155-04-.03	Pedorthists	1155-04-.16	“Grandfather” Provisions for Licensure
1155-04-.04	Restrictions on the Practice of Orthotists, Prosthetists, and Pedorthists	1155-04-.17	Sale of Over-the-Counter and Off-the- Shelf Devices
1155-04-.05	Necessity of Licensure and Registration of Residency	1155-04-.18	Custom Fabricated and Fitted Devices
1155-04-.06	Qualifications for Licensure	1155-04-.19	Other Licensed Health Care Practitioners
1155-04-.07	Procedures for Licensure	1155-04-.20	Pharmacists, Home Medical Equipment Providers, and Orthosis Manufacturers
1155-04-.08	Examinations	1155-04-.21	Therapeutic Footwear
1155-04-.09	Fees	1155-04-.22	Patient Records
1155-04-.10	Renewal of Licensure		
1155-04-.11	Retirement and Reactivation		
1155-04-.12	Continuing Education		
1155-04-.13	Disciplinary Actions, Subpoenas, Declaratory Orders, Screening Panels and Advisory Private Letter Rulings		

1155-04-.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, 63-3-201, and 63-3-202. **Administrative History:** Original rule filed July 13, 2006; effective September 26, 2006.

1155-04-.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.

(Rule 1155-04-.02, continued)

- (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, 63-3-201, and 63-3-202. **Administrative History:** Original rule filed July 13, 2006; effective September 26, 2006.

1155-04-.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, 63-3-201, and 63-3-202. **Administrative History:** Original rule filed July 13, 2006; effective September 26, 2006.

1155-04-.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.

(Rule 1155-04-.04, continued)

- (4) An individual holding a certification from the American Board for Certification in Orthotics, Prosthetics and Pedorthics (ABC) as an orthotic assistant, prosthetic assistant, or prosthetic-orthotic assistant may perform orthotic and/or prosthetic duties and related tasks set forth by the 2012 ABC Scope of Practice (version effective April 2012) for certified orthotic and prosthetic assistants (www.abcop.org/maintain-certification/Documents/Scope%20of%20Practice.pdf). However, a certified assistant may not deliver a definitive custom-made prosthesis or orthosis or perform an initial evaluation of a patient.
- (5) A licensed orthotist, prosthetist, or pedorthist may utilize one or more non-certified persons to assist in the performance of minor repairs of devices which have been previously dispensed to a patient.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-3-106, 63-3-201, 63-3-202, 63-3-206, 63-3-207, and 63-3-214.

Administrative History: Original rule filed July 13, 2006; effective September 26, 2006. Amendments filed July 10, 2018; effective October 8, 2018.

1155-04-.05 NECESSITY OF LICENSURE AND REGISTRATION OF RESIDENCY.

- (1) 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 or registered in accordance with the requirements of this chapter.
- (2) Pursuant to T.C.A. § 63-3-209(2)(B), persons seeking to provide services in Tennessee as a resident in an orthotics and/or prosthetics residency program shall register with the Board, on a form notice available through the Board, at least thirty (30) days before providing such services, and the notice shall include the following information:
 - (a) The full name of the resident;
 - (b) The date of birth of the resident;
 - (c) The social security number of the resident;
 - (d) The mailing and physical address of the resident;
 - (e) The home telephone or cell phone number of the resident;
 - (f) Any other health related licenses, certificates, or permits the resident holds in Tennessee or any another state;
 - (g) The name and address of the facility or facilities where the residency is to be completed;
 - (h) The name of the resident's direct supervisor who accepts responsibility for the services provided by the resident and written acknowledgment on signed letterhead from the supervisor accepting such responsibility;
 - (i) Proof of a completed orthotics and/or prosthetics education program as described in Rule 1155-04-.06;
 - (j) Proof of a baccalaureate degree (or proof of successfully completing the number of semester hours which is equivalent to four years of study at a four-year college or university), as described in Rule 1155-04-.06;

(Rule 1155-04-.05, continued)

- (k) Proof of successful completion of all examinations required by Rule 1155-04-.08; and
 - (l) Payment of the ten dollar (\$10) Orthotic/ Prosthetic Residency Registration Fee.
- (3) Orthotic and prosthetic residents already in a clinical residency when Rule 1155-04-.05(2) takes effect shall register with the Board, on a form notice available through the Board, within sixty (60) days of Rule 1155-04-.05(2) taking effect, and such notice shall include all the information listed in Rule 1155-04-.05(2).
- (4) Registration under this rule shall authorize only such practice in Tennessee as is authorized by and under the supervision of the residency program, which must be accredited by the National Commission on Orthotic and Prosthetic Education. Termination from the residency program terminates the registration and any authority to practice in Tennessee. The director of the residency program shall immediately notify the Board in writing of any registrant's termination from the program.
- (5) Registrations shall expire twenty-four (24) months from the date of issuance and may be renewed only once, for good cause and subject to Board approval. Residency registrants shall submit to the Board written confirmation of residency status once every six (6) months, containing the signature of the direct supervisor who accepts responsibility for the services provided by that resident.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-3-106, 63-3-202, 63-3-203, 63-3-205, 63-3-208, 63-3-209, and 63-3-214. **Administrative History:** Original rule filed July 13, 2006; effective September 26, 2006. Amendments filed July 10, 2018; effective October 8, 2018.

1155-04-.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; and
 - (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 1155-04-.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; and
 - (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

(Rule 1155-04-.06, continued)

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 1155-04-.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 the following standards and procedures:
 - 1. The program or internship shall be no less than sixty (60) hours of work experience.
 - 2. The program or internship shall be under the direct supervision of a currently licensed pedorthist, orthotist, or podiatrist.
 - 3. Direct supervision, as used in this subparagraph, shall mean the requirement of the supervisor to direct, coordinate, review, inspect, and approve each act or service performed, and although the continuous and actual physical presence of the supervisor in the same room and at the same time as the intern is not mandatory, the continuous and actual presence of the supervisor within the physical confines of the practice location is required.
 - 4. The program or internship shall include training in evaluating, measuring, designing, fabricating, assembling, fitting, adjusting, or servicing pedorthic devices; and
 - (d) Successfully complete all examinations required by Rule 1155-04-.08.

(Rule 1155-04-.06, continued)

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-3-106, 63-3-202, 63-3-203, and 63-3-205. **Administrative History:** Original rule filed July 13, 2006; effective September 26, 2006.

1155-04-.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 1155-04-.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 1155-02-.07.

(Rule 1155-04-.07, continued)

- (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, 63-3-202, 63-3-203, and 63-3-205. **Administrative History:** Original rule filed July 13, 2006; effective September 26, 2006.

1155-04-.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 1155-04 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:

(Rule 1155-04-.08, continued)

- (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, 63-3-202, 63-3-203, and 63-3-205. **Administrative History:** Original rule filed July 13, 2006; effective September 26, 2006.

1155-04-.09 FEES. All fees except the State Regulatory fee are non-refundable.

(1) Application	\$300.00
(2) Renewal (biennial)	\$160.00
(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
(8) Orthotic/Prosthetic Residency Registration	\$10.00

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-3-106, 63-3-106(1), 63-3-202, 63-3-203, 63-3-205, and 63-3-214. **Administrative History:** Original rule filed July 13, 2006; effective September 26, 2006. Amendment filed August 25, 2009; effective November 23, 2009. Amendment filed April 24, 2017; effective July 23, 2017. Amendments filed July 10, 2018; effective October 8, 2018.

1155-04-.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

(Rule 1155-04-.10, continued)

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

<https://apps.tn.gov/hlrs/>
 - (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 1155-04-.09.
 - (4) To be eligible for renewal an individual must have completed the continuing education requirements provided in Rule 1155-04-.12 and must attest to such completion on the renewal application. An individual who fails to obtain continuing education hours, pursuant to Rule 1155-04-.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 1200-10-01-.10.
 - (6) Reinstatement of a license that has expired as a result of failure to timely renew in accordance with Rule 1200-10-01-.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 1155-04-.09; and
 - (c) Compliance with continuing education requirements pursuant to Rule 1155-04-.12.
 - (d) An individual having a license that has been expired for at least twelve (12) months shall submit to a criminal background check and cause the results to be submitted to the Board office before the license can be reinstated.
 - (7) Renewal applications shall be treated as licensure applications, and shall be governed by Rule 1155-02-.07.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-1-116, 63-3-106, 63-3-202, 63-3-203, and 63-3-205.
Administrative History: Original rule filed July 13, 2006; effective September 26, 2006. Amendment filed January 20, 2012; effective April 19, 2012.

1155-04-.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.

(Rule 1155-04-.11, continued)

- (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 license 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 1155-04-.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 1155-04-.12.
 - (d) An individual having a license that has been retired for at least twelve (12) months shall submit to a criminal background check and cause the results to be submitted to the Board office before the license can be reinstated.
- (4) Reactivation applications shall be treated as licensure applications, and shall be governed by Rule 1155-02-.07.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-1-116, 63-3-106, 63-3-202, 63-3-203, and 63-3-205.
Administrative History: Original rule filed July 13, 2006; effective September 26, 2006. Amendment filed January 20, 2012; effective April 19, 2012.

1155-04-.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. At least six (6) hours of the continuing education each year must be obtained by each licensee from providers in the state of Tennessee. No more than five (5) hours of the annual requirement shall be completed by any of the means listed in Rule 1155-02-.12(1)(c).
 - (a) A person who is licensed in more than one (1) profession under these rules shall annually complete a total of twenty (20) hours of continuing education.
 - (b) Of the twenty (20) hours required by subparagraph (a), six (6) hours shall be subjects pertaining to each profession in which he/she is licensed. For example, a person who is licensed as a orthotist and as a prosthetist is required to complete six (6) hours pertaining to orthotics and six (6) hours pertaining to prosthetics. The remaining eight (8) hours required could pertain to either orthotics or prosthetics.
- (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;

(Rule 1155-04-.12, continued)

- (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 1155-04-.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 1155-04-.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.

(Rule 1155-04-.12, continued)

- (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, 63-3-202, 63-3-203, and 63-3-205. **Administrative History:** Original rule filed July 13, 2006; effective September 26, 2006.

1155-04-.13 DISCIPLINARY ACTIONS, SUBPOENAS, DECLARATORY ORDERS, SCREENING PANELS AND ADVISORY PRIVATE LETTER RULINGS.

- (1) Disciplinary Actions – Licensed orthotists, prosthetists and pedorthists are subject to being disciplined by the Board for the same causes, to the same extent and pursuant to the same procedures provided in Rule 1155-02-.15 as licensed podiatrists.
- (2) Subpoenas – Subpoena procedures shall be governed by Rule 1155-02-.15.
- (3) Declaratory Orders – Declaratory order procedures shall be governed by Rule 1155-02-.19.
- (4) Screening Panels – Screening panel procedures shall be governed by Rule 1155-02-.19.
- (5) Advisory Private Letter Rulings – Advisory private letter rulings shall be governed by Rule 1155-02-.19.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-3-106, 63-3-202, 63-3-203, and 63-3-205. **Administrative History:** Original rule filed July 13, 2006; effective September 26, 2006.

1155-04-.14 ADVERTISING. Advertising shall be governed by Rule 1155-02-.22.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-3-106, 63-3-202, 63-3-203, and 63-3-205. **Administrative History:** Original rule filed July 13, 2006; effective September 26, 2006.

1155-04-.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, 63-3-202, 63-3-203, and 63-3-205. **Administrative History:** Original rule filed July 13, 2006; effective September 26, 2006.

1155-04-.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

(Rule 1155-03-.16, continued)

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, 63-3-202, 63-3-203, and 63-3-205. **Administrative History:** Original rule filed July 13, 2006; effective September 26, 2006.

1155-04-.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, 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, 63-3-202, 63-3-203, and 63-3-205. **Administrative History:** Original rule filed July 13, 2006; effective September 26, 2006.

1155-04-.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, 63-3-202, 63-3-203, and 63-3-205. **Administrative History:** Original rule filed July 13, 2006; effective September 26, 2006.

1155-04-.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, 63-3-202, 63-3-203, and 63-3-205. **Administrative History:** Original rule filed July 13, 2006; effective September 26, 2006.

1155-04-.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

(Rule 1155-04-.20, continued)

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, and who examines the patient to ensure that the device has been properly measured, fitted or adjusted by the employee or representative; and
 - (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.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-3-106, 63-3-202, 63-3-203, and 63-3-205. **Administrative History:** Original rule filed July 13, 2006; effective September 26, 2006.

1155-04-.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, or imprint;
- (4) Creation of an image of a person's foot or ankle through the use of a mold, cast, scanning device, digital appliance, 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, 63-3-202, 63-3-203, and 63-3-205. **Administrative History:** Original rule filed July 13, 2006; effective September 26, 2006.

1155-04-.22 PATIENT RECORDS.

- (1) Purpose – The purpose of this rule is:
 - (a) To recognize that patient records are an integral part of the practice of orthotists, prosthetists, and pedorthists as defined in T.C.A. § 63-3-201.
 - (b) To give orthotists, prosthetists, pedorthists, their professional and non-professional staff, and the public direction about the content, transfer, retention, and destruction of those patient records.
- (2) Applicability – This rule regarding patient records shall apply only to those records, the information for which was obtained by orthotists, prosthetists, pedorthists, or their supervisees, for purposes of services provided in any clinical setting other than those

(Rule 1155-04-.22, continued)

provided in a hospital as defined by T.C.A. § 68-11-302(4), a hospital emergency room, or hospital outpatient facility.

(3) Patient Records –

(a) Duty to Create and Maintain Records – As a component of the standard of care and of minimal competency, an orthotist, prosthetist, or pedorthist must cause to be created and cause to be maintained a patient record for every encounter between a patient and the orthotist, prosthetist, or pedorthist. For purposes of this Rule, a patient is defined as a person for whom the orthotist, prosthetist, or pedorthist has undertaken to treat or for whom the orthotist, prosthetist, or pedorthist has participated in treatment.

(b) Notice – Any notice to be provided to a patient required by these rules shall be issued within thirty (30) days of the date of the event that triggers the notice requirement, and shall be accomplished by mailing to the last known address of the patient.

(c) Content – In order to meet the minimum level of competency required of orthotists, prosthetists, and pedorthists, the patient records required by this rule shall:

1. Be recorded in such a manner as to be legible to an ordinary reasonable person, including those persons who are not licensed healthcare professionals;
2. Include all information and documentation listed in T.C.A. § 63-2-101(c)(4), to the extent applicable;
3. Contain such additional information that is necessary to ensure that a subsequent reviewing or treating healthcare professional can both ascertain the basis for the treatment plan and outcomes, and provide continuity of care for the patient.

(d) Transfer –

1. Applicability of Notice Requirements – The notice requirements of this part are only required for patients who have either:
 - (i) Had three (3) or more office encounters with the orthotist, prosthetist, or pedorthist over the eighteen (18) month period that immediately precedes the event that would otherwise trigger the notice or
 - (ii) Had their initial evaluation and treatment plan developed by the orthotist, prosthetist, or pedorthist.
2. Records of Orthotist, Prosthetist, or Pedorthist upon Death or Retirement – When an orthotist, prosthetist, or pedorthist retires or dies while in practice, patients who meet the requirements of 1155-04-.22(3)(d)1. shall be notified by the orthotist, prosthetist, or pedorthist, or his authorized representative; urged to find a new orthotist, prosthetist, or pedorthist; and informed that upon patient or patient's representative's authorization copies of the patient's records will be sent to the new orthotist, prosthetist, or pedorthist.
3. Patient Records of Orthotist, Prosthetist, or Pedorthist upon Departure from a Group – The responsibility for notifying patients of an orthotist, prosthetist, or pedorthist who leaves a group practice for any reason other than death shall be governed by the employment or professional services contract of the orthotist, prosthetist, or pedorthist. If such contract does not address the notification issue,

(Rule 1155-04-.22, continued)

or if an employment or professional services contract does not exist, the group shall be responsible for notifying the patients of the orthotist, prosthetist, or pedorthist that the orthotist, prosthetist, or pedorthist has departed from the group.

- (i) Whoever is responsible for the notification referenced in the immediately preceding paragraph must notify patients of the orthotist, prosthetist, or pedorthist who meet the requirements of 1155-04-.22(3)(d)1.
 - (ii) The orthotist, prosthetist, or pedorthist who is departing from a practice group must provide the practice group with his new practice address. Failure to provide this information within two (2) weeks of the departure date from the practice group will relieve the practice group of any obligation to provide the new address of the orthotist, prosthetist, or pedorthist as set out in (iii) below.
 - (iii) These patients shall also be notified of the orthotist's, prosthetist's, or pedorthist's new address, if known and provided by the departing orthotist, prosthetist, or pedorthist, and offered the opportunity to have copies of their patient records forwarded to the departing orthotist, prosthetist, or pedorthist at his new practice. A group shall not withhold the patient records of any patient who has authorized their transfer to the departing orthotist, prosthetist, or pedorthist or any other orthotist, prosthetist, or pedorthist.
 - (iv) The choice of orthotist, prosthetist, or pedorthist in every case should be left to the patient, and the patient should be informed that, upon authorization, his patient records will be sent to the orthotist, prosthetist, or pedorthist of the patient's choice.
4. Sale of an Orthotist, Prosthetist, or Pedorthist's Practice – An orthotist, prosthetist, or pedorthist or the estate of a deceased orthotist, prosthetist, or pedorthist, may sell the elements that comprise his practice, which include the goodwill of the practice and the opportunity to take over the patients of the seller by purchasing those records; provided that nothing herein shall be deemed to preclude the ultimate decision-making rights of the patient. Therefore, the transfer of patient records upon the sale of an orthotist, prosthetist, or pedorthist's practice is subject to the following:
- (i) The orthotist, prosthetist, or pedorthist (or the estate) must ensure that all patient records are transferred to another orthotist, prosthetist, or pedorthist or entity that is held to the same standards of confidentiality as provided in these rules.
 - (ii) Patients seen by the orthotist, prosthetist, or pedorthist who meet the requirements of 1155-04-.22(3)(d)1. shall be notified that the orthotist, prosthetist, or pedorthist (or the estate) is transferring the practice to another orthotist, prosthetist, or pedorthist, or entity who will retain custody of their patient records and that, upon written authorization by the patient or the patient's representative, the copies of their patient records will be sent to another orthotist, prosthetist, or pedorthist.
5. Failure to Adequately Provide for Transfer of Patient Records or Notify Patients – It shall be a prima facie violation of T.C.A. § 63-3-204(b)(9) and (10) for a orthotist, prosthetist, or pedorthist to depart from his group, retire, or sell his

(Rule 1155-04-.22, continued)

practice without making written provisions for the security or transfer of patient records, or otherwise establish and memorialize in writing a secure method of patient access to his patient records.

- (e) Retention of Records – Patient records shall be retained for a period of not less than seven (7) years from the orthotist's, prosthetist's, or pedorthist's last professional contact with the patient except for the following:
 - 1. Patient records for incompetent patients, other than those who are incompetent solely because they are minors, shall be retained at least until one (1) year after the patient's death or alleviation of incompetency.
 - 2. Patient 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 the orthotist's, prosthetist's, or pedorthist's last professional contact with the patient, whichever is longer.
 - 3. Notwithstanding the foregoing, no patient record involving services which are currently under dispute shall be destroyed until the dispute is resolved.
 - 4. Nothing herein shall be deemed to supersede any federal or state law or regulation requiring providers to retain patient records for periods longer than the time stated above.

- (f) Destruction of Records –
 - 1. No patient record shall be singled out for destruction other than in accordance with established office operating procedures.
 - 2. Patient records shall be destroyed only in the ordinary course of business according to established office operating procedures that are consistent with these rules.
 - 3. Physical copies of patient records may be destroyed by burning, shredding, or other method that safeguards patient protected health information from any use or disclosure that is in violation of any state or federal laws or regulations.
 - 4. Any recordable and erasable media device upon which electronic patient records have been stored must be rendered inaccessible, cleaned, or scrubbed by overwriting the data, degaussing the media (using magnetic field to neutralize the data stored on magnetic media), or other method that safeguards patient protected health information from any use or disclosure that is in violation of any state or federal laws or regulations. Simply discarding a data storage device without rendering the data stored upon it inaccessible, cleaned, or scrubbed does not constitute compliance with this rule.
 - 5. When patient 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 records that were destroyed but shall be sufficient to identify which group of destroyed patient records contained a particular patient's records.

- (4) In addition to the requirements of this rule, orthotists, prosthetists, and pedorthists must also comply with the Health Insurance Portability and Accountability Act (HIPAA) and the regulations promulgated thereto if such entity is considered a Covered Entity as defined by

(Rule 1155-04-.22, continued)

HIPAA. Failure to comply with HIPAA shall constitute violation of this rule unless the provider proves to the satisfaction of the Board that he is not required to comply with HIPAA.

- (5) Mandatory Release of Patient Records –
 - (a) Pursuant to T.C.A. § 63-2-102 and upon request from a patient or the patient's authorized representative, an individual registered with this Board shall provide a complete copy of the patient's records or a summary of such records which were maintained by the provider. The provider may charge a reasonable fee for production of such records as authorized in T.C.A. § 63-2-102.
 - (b) It shall be the provider's option as to whether copies of the patient records or a summary will be given to the patient, in accordance with T.C.A. § 63-2-101(a)(1).
 - (c) Requests for patient records shall be honored by the provider in accordance with timelines identified in T.C.A. § 63-2-101.
 - (d) Nothing herein shall be deemed to supersede any federal or state law or regulation.
- (6) Violations – Violation of any provision of these rules is grounds for disciplinary action pursuant to T.C.A. §§ 63-3-204(b)(9) and 63-3-204(b)(10).
- (7) This rule shall be applied prospectively. An orthotist, prosthetist, or pedorthist shall not be found to be in violation of this rule if the violation occurred before the effective date of this rule.

Authority: T.C.A. §§ 63-3-201, 63-3-202, and 68-11-302. **Administrative History:** New rule filed May 7, 2021; effective August 5, 2021.