As used in this chapter:

(A) "Accommodative" means designed with the primary goal of conforming to the anatomy of a particular individual.

(B) "Full-time" means not less than one thousand six hundred hours per year.

(C) "Inlay" means any removable material on which the foot rests inside a shoe and that may be an integral design component of the shoe.

(D) "Orthotics" means the evaluation, measurement, design, fabrication, assembly, fitting, adjusting, servicing, or training in the use of an orthotic or pedorthic device, or the repair, replacement, adjustment, or service of an existing orthotic or pedorthic device. It does not include upper extremity adaptive equipment used to facilitate the activities of daily living, finger splints, wrist splints, prefabricated elastic or fabric abdominal supports with or without metal or plastic reinforcing stays and other prefabricated soft goods requiring minimal fitting, nontherapeutic accommodative inlays, shoes that are not manufactured or modified for a particular individual, prefabricated foot care products, durable medical equipment, dental appliances, pedorthic devices, or devices implanted into the body by a physician.

(E) "Orthotic device" means a custom fabricated or fitted medical device used to support, correct, or alleviate neuromuscular or musculoskeletal dysfunction, disease, injury, or deformity.

(F) "Pedorthics" means the evaluation, measurement, design, fabrication, assembly, fitting, adjusting, servicing, or training in the use of a pedorthic device, or the repair, replacement, adjustment, or servicing of a pedorthic device.

(G) "Pedorthics device" means a custom fabricated or fitted therapeutic shoe, shoe modification for therapeutic purposes, prosthetic filler of the forefoot, or foot orthosis for use from the apex of the medial malleolus and below. It does not include an arch support, a nontherapeutic accommodative inlay, nontherapeutic accommodative footwear, prefabricated footcare products, or unmodified, over-the-counter shoes.

(H) "Prosthetics" means the evaluation, measurement, design, fabrication, assembly, fitting, adjusting, servicing, or training in the use of a prosthesis or pedorthic device, or the repair, replacement, adjustment, or service of a prosthesis or pedorthic device.

(I) "Prosthesis" means a custom fabricated or fitted medical device used to replace a missing appendage or other external body part. It includes an artificial limb, hand, or foot, but does not include devices implanted into the body by a physician, artificial eyes, intraocular lenses, dental appliances, ostomy products, cosmetic devices such as breast prostheses, eyelashes, wigs, or other devices that do not have a significant impact on the musculoskeletal functions of the body.

Effective Date: 06-06-2001
4779-3-02 Device-related and scope of practice definitions.

The following definitions shall apply to the language of Chapter 4779 of the Revised Code:

(A) "Accommodative" as defined at division (A) of section 4779.01 of the Revised Code means in addition that the item is designed to conform to the anatomy of the particular individual who purchases and wears the item. "Accommodative" may describe an item sold on a strictly retail basis, but may also describe an item requiring custom fitting or custom fabricating as required by patient presentation and medical order.

(B) "Arch support" as used in division (G) of section 4779.01 of the Revised Code means an item sold off-the-shelf on a retail basis to be accommodative to the anatomy of the foot for the person who uses it; and which is not custom fitted or custom fabricated, and is not provided to fill a doctor's order or healthcare prescription.

(C) "Nontherapeutic" as used in divisions (D) and (G) of section 4779.01 of the Revised Code means an item sold off-the-shelf on a retail basis, which is not custom fitted or custom fabricated, and is not delivered to fill a doctor's order or healthcare prescription.

(D) "Therapeutic" as used in division (A) of section 4779.01 of the Revised Code refers to an item delivered to fill a patient-specific doctor's order or healthcare prescription.

(E) "Custom fabricated or fitted medical device" as referenced in division (E), (G), or (I) of section 4779.01 of the Revised Code means an orthotic, prosthetic or pedorthic device that is individually made (custom fabricated) or fitted (custom fitted) for a specific patient. Further, it is a device the provision of which requires access to a facility with the equipment necessary to fulfill the ongoing consumer-care responsibility to provide follow-up treatment, including modification, adjustment, maintenance and repair of the item(s).

(1) A custom fabricated item is defined as a device which is individually made for a specific patient. No other patient would be able to use this item. A custom fabricated item is a device which is fabricated based on clinically derived and rectified castings, tracings, measurements, and/or other images (such as x-rays or digital scans) of the body part. The fabrication may involve using calculations, templates and components. This process requires the use of basic materials including, but not limited to plastic, metal, leather or cloth in the form of uncut or unshaped sheets, bars, or other basic forms and involves substantial work such as vacuum forming, cutting, bending, molding, sewing, drilling and finishing prior to fitting on the patient.

A molded-to-patient-model item is a particular type of custom fabricated device in which either:

(a) An impression (usually by means of a plaster or fiberglass cast) of the specific body part is made directly on the patient, and this impression is then used to make a positive model of the body part from which the final product is crafted; or

(b) A digital image of the patient's body part is made using computer-aided design-computer aided manufacture (CAD-CAM) systems software. This technology includes specialized probe/digitizers and scanners that create a computerized positive model and then direct milling equipment to carve a positive model. The device is then individually fabricated and molded over the positive model of the patient. The use of CAD/CAM software or digital software packages and hardware to generate a
negative model (3D printing) can be used for direct fabrication of intermediate stages of the device up to and including the final or definitive device itself.

(2) A custom fitted item is defined as a prefabricated device which is manufactured in quantity without a specific patient in mind. The device may or may not be supplied as a kit that requires some assembly and/or fitting and adjustment, or a device that may be trimmed, bent, molded (with or without heat), or otherwise modified by an individual with expertise in customizing the item to fit and be used by a specific patient.

A custom fitted item/device as referenced in division (E), (G), or (I) of section 4779.01 of the Revised Code does not include:

(a) Upper extremity adaptive equipment used to facilitate the activities of daily living;
(b) Finger splints or wrist splints;
(c) Prefabricated elastic or fabric abdominal supports with or without metal or plastic reinforcing stays requiring minimal fitting;
(d) Other prefabricated soft goods requiring minimal fitting;
(e) Nontherapeutic accommodative inlays;
(f) Nontherapeutic or therapeutic over-the-counter or off-the-shelf shoes or boots that are not manufactured or modified for a particular individual;
(g) Prefabricated foot care products;
(h) Other durable medical equipment that is not categorized as an orthotic, prosthetic, or pedorthic device; dental appliances; or devices implanted into the body by a physician.

(F) "For use from the apex of the medial malleolus and below" as used in division (G) of section 4779.01 of the Revised Code means that the pedorthic device does not physically extend proximal to the apex of the medial malleolus, meaning not extending higher than the middle of the ankle bone.

(G) "Minimal fitting" as used in section 4779.01 of the Revised Code and rule 4779-3-02 of the Administrative Code means the prefabricated device is classified as an off the shelf (OTS) device by the U.S. department of health and human services center for medicare/medicaid services.

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