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, but does not have the added value of the capacity to be custom fitted or custom fabricated for use by a particular individual, and is sold off-the-shelf on a retail basis.

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

(i) 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

(ii) 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.

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

(i) Upper extremity adaptive equipment used to facilitate the activities of daily living;

(ii) Finger splints or wrist splints;

(iii) Prefabricated elastic or fabric abdominal supports with or without metal or plastic reinforcing stays requiring minimal fitting;

(iv) Other prefabricated soft goods requiring minimal fitting;

(v) Nontherapeutic accommodative inlays;

(vi) Nontherapeutic shoes that are not manufactured or modified for a particular individual;

(vii) Prefabricated foot care products;

(viii) 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.

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