

# State Board of Orthotics, Prosthetics, and Pedorthics



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## STATEMENT REGARDING CMS' RE-WRITE OF ORTHOTICS HCPCS CODES AND DIFFERENTIATION BETWEEN CUSTOM FIT AND OTS

The State Board of Orthotics, Prosthetics, and Pedorthics is aware of the recent issuance of a "final" list of OTS orthotics by CMS, and the CMS decision to "explode" a number of devices into dual codes, so as to create a two-track system of device accounting for those devices CMS has determined may be dispensed as either custom fit or OTS.

We are also aware of the confusing language and analysis that accompanies the list.

Ohio regulatory language does not align exactly with federal language, and the Ohio Board has determined that devices marketed and reimbursed under many of the HCPCS codes referenced in CMS' action meet the requirements of custom fit devices and do not meet the Ohio definition of a device requiring "minimal fitting."

Ohio Revised Code Section 4779.01(D) provides the following limiting language indicating device types that are beyond the Board's regulatory interest:

*"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."*

None of the LSO or TLSO bracing items on the revised HCPCS schedule can be considered to fit the definition of "soft good".

In addition, Ohio Administrative Code Agency Rule 4779-3-02 provides a definition of a device requiring minimal fitting which is based on the device characteristics, not a subjective determination as to whether a particular device for a particular patient requires certain qualifications:

"Minimal fitting" as used in section [4779.01](#) of the Revised Code and rule 4779-3-02 of the Administrative Code means a prefabricated device which is fit for size by use of not more than two simple body size measurements; which is sized as small, medium, large, extra large, 2xl, 3xl; which is fastened or fit to the body or body part by use of elastic or self-fastening straps, buttons or strips; which is not molded by the consumer-care provider to fit the consumer; **and which is not provided by the manufacturer with items or component parts which are intended or designed to be custom molded, heat moldable or custom fitted.**' (emphasis supplied)

Thus, it appears that CMS's OTS list finalization acknowledges that all of the "exploded" codes represent devices which are manufactured according to specifications which anticipate and allow for custom fitting of the device.

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The Board would remind DME suppliers of the following baseline language of the Social Security Act which requires a default to state licensing standards where they exist:

(c) Application certification standards. The supplier must meet and must certify in its application for billing privileges that it meets and will continue to meet the following standards:

(1) Operates its business and furnishes Medicare-covered items in compliance with the following applicable laws:

...

(ii) State licensure and regulatory requirements. If a State requires licensure to furnish certain items or services, a DMEPOS supplier—

(A) Must be licensed to provide the item or service;

(B) Must employ the licensed professional on a full-time or part-time basis, except for DMEPOS suppliers who are—

(1) Awarded competitive bid contracts using subcontractors to meet this standard; or

(2) Allowed by the State to contract licensed services as described in paragraph (c)(1)(ii)(C) of this section.

In addition, we note the cautionary language carried on the National Supplier Clearinghouse’s webpage gateway to its state licensure directory:

***“This licensure directory is only a guide. The various state boards or regulating agencies have the final determination as to what license is or is not required. It is the supplier’s responsibility to ensure they are in compliance with all state and federal laws and regulations.”(emphasis supplied)***

**While the Board acknowledges that the guidance document presently posted on its website, last revised in 2011, requires updating, the determinations regarding appropriate device dispensation reflected on that document remain valid for compliance with State of Ohio regulatory language.** New codes assigned to the same devices do not alter the Board’s determination or the regulatory language scope.

For further information:

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