

COMMENT OF [THE STATE BOARD OF ORTHOTICS, PROSTHETICS, AND PEDORTHICS](#) (OHIO)

PREPARED FOR PUBLIC COMMENT TO US DEPT of HEALTH AND HUMAN SERVICES, CENTERS FOR MEDICARE AND MEDICAID SERVICES, REGARDING A LIST THAT INITIALLY IDENTIFIES THE 2012 HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS) CODES THAT ARE CONSIDERED OTS ORTHOTICS

COMMENT PERIOD ENDING MARCH 16, 2012

The State Board of Orthotics, Prosthetics, and Pedorthics (Ohio) was established pursuant to action of the Ohio General Assembly and has been issuing licenses and governing the practice of Orthotist care in Ohio since late 2001. The Practice Act is codified at [Ohio Revised Code Chapter 4779](#); administrative rules implementing the statute are found at [Ohio Administrative Code Rule Series 4779](#). The Orthotic, Prosthetic and Pedorthic services that are subject to regulatory jurisdiction of the Board include the care involved in providing custom **fabricated** AND custom **fitted** orthotic devices. The Board is comprised of four (4) O&P practitioners, one (1) Pedorthist, one (1) MD, DO, or DPM, and one (1) consumer member.

We note that CMS is proposing to classify a certain selection of frequently-utilized orthotic devices as OTC/OTS (over the counter/off the shelf) prefabricated devices. Such classification would indicate these devices can be appropriately applied with ease, utility and without adverse consequence by the consumer with minimal instruction. We understand that equipment providers and sales representatives with little or no healthcare-specific training sometimes assert that they can help 'fit' these devices to consumers, but that does not seem compatible with our understanding of the normal meaning of the CMS term 'minimal self-adjustment.'

We appreciate this opportunity to comment on the current proposal. While developed more fully below, we would note two executive summary-type points in particular:

1. Guided in no small part by current and prior CMS Quality Standards language when crafting definition language in its rule series, the Ohio Board of Orthotics, Prosthetics, and Pedorthics developed what may be viewed as a more objective, less subjective, definition of "minimal fitting" (the Ohio statutory term), which might also be applicable to the CMS term "minimal self-adjustment."

[Ohio Administrative Code Rule 4779-3-02](#) (G):

"Minimal fitting" ... 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.

2. It is this Board's understanding that the Facility Accreditation model of DMEPOS service delivery sought and seeks to encourage localized dispensation of reimbursement-limited items that carry warranty period protection, fostering a culture of more effective continuing and cooperative interdisciplinary care by a team of rehabilitation professionals. That model stands in contrast to practices we see as making something of a comeback in the market and which this classification effort may unintentionally encourage: healthcare "services" performed or promoted from a remote out-of-state location, and often actualized through boiler-room telephone sales and mail-order delivery, unaccountable to the local regulatory, caregiver or consumer community.

Discussion

A major challenge in administering the Ohio licensing provisions has been to clarify and define the difference between prefabricated devices that are considered to require custom fitting, and those that may be dispensed basically as a point-of-sale transaction. In seeking to perform its mission appropriately, conforming as much as possible Ohio regulatory standards to national standards of care, this Board has taken guidance and instruction from the [CMS DMEPOS Quality Standards](#) documents, the most recent of which bears a Final Effective Date of October 2008.

That document, to the best of our collective knowledge, sets forth CMS' current definition of custom fitted orthotic device in Appendix C as follows:

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.

Thus, the most recent revision of the Ohio definitions rule series incorporates that language within the context of the additional regulatory parameters required by the Ohio statute as follows:

Ohio Administrative Code Rule 4779-3-02 – Definitions

(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).

(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.

In addition, please note that we have developed a working definition of the Ohio statutory term “minimal fitting,” which basically corresponds to the CMS descriptor “minimal self-adjustment.” We engaged in an inclusive, transparent process involving significant comment from the stakeholder community. Rather than rely on manufacturers’ or sales personnel’s representations as to whether a device requires individualized modifications or adjustments by trained personnel, we chose to focus on characteristics of the device itself, identifying the inherent elements that may determine whether it is subject to effective and full utilization without customizing, or instead incorporates components and options that require knowledgeable custom fitting:

(G) “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.

We would respectfully suggest that the current CMS proposal may not demonstrate consistency with accepted national standards, and from a certain perspective seems logically inconsistent with its (CMS’) own definitions and standards-based approach. In this regard, please note specifically:

A. The posting at the linked web page¹ reads, in part: “CMS regulations at 42 CFR 414.402 also define the term ‘minimal self-adjustment’ to mean an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and that does not require the services of a certified orthotist (that is, an individual who is certified by the American Board for Certification in Orthotics and Prosthetics, Inc., or by the Board for Orthotist/Prosthetist Certification) or an individual who has specialized training.”

B. However, please take note that at least one of the two certification entities in Orthotics noted in the posting has published expert opinion rating most of these items based on device complexity and consumer need and presentation. Please see the Tripartite Report² published by the professional consortium comprised of the American Board for Certification in O&P, the American O&P Association, and the American Academy of O&P. By comparative analysis, only ten (10) – thirteen (13) if including the three codes that are not treated in the Report -- of the referenced list of sixty (60) L-coded items are considered to be Off-the-Shelf items that may be safely dispensed and fitted without the services of an appropriately trained, hands-on consumer care professional, according to the findings of your recognized standard-setting professional organization.

¹ http://www.cms.gov/DMEPOSFeeSched/04_OT_S_Orthotics.asp

² <http://www.aopanet.org/docs/GR/2008tripartitereport.pdf>

C. This Board also notes that at least two of the Action Items in the [HHS OIG Work Plan for FY 2012](#)³, Part I: Medicare A & B, DMEPOS agenda, seem to reference devices in this collection, with an emphasis on concerns that the devices may either indicate overutilization of high-reimbursement items, or that devices rated under the referenced code may no longer justify the reimbursement allowable that was originally determined through the PDAC process. While reimbursement issues are not among the principal jurisdictional concerns of this Board, we must still be aware, as a regulatory agency, as to how reimbursement policy drives regulatory compliance agendas and enforcement workload. Based on complaint and compliance scenarios that have come to our attention recently, we also note the OIG's finding in the Work Plan that "the qualifications of orthotic suppliers varied, with noncertified suppliers most likely to provide inappropriate devices and services."

The Board would thus note that CMS may have an opportunity to demonstrate the effectiveness of the facility accreditation model implementation in those cases where it can be partnered with state-based licensing requirements toward more effective control of reimbursement and utilization parameters. It is this Board's understanding that the development of the Facility Accreditation model of DMEPOS service delivery sought and seeks to encourage localized dispensation of reimbursement-limited items that carry warranty period protection, fostering a culture of more effective continuing and cooperative interdisciplinary care by a team of rehabilitation professionals. That model stands in contrast to practices we see as making something of a comeback in the market and which this classification effort may unintentionally encourage: healthcare "services" performed or promoted from a remote out-of-state location, and often actualized through boiler-room telephone sales and mail-order delivery, unaccountable to the local regulatory, caregiver or consumer community.

Finally, in an effort to provide guidance to Ohio DMEPOS providers and out of state companies seeking to provide services in Ohio, [we have published a document](#) that lists a limited number of L-coded items, and provides examples and illustration as to application of the Ohio regulatory rubric established by law and rule. For some of these items, we provided practitioner comment to expand upon the regulatory basis cited for the finding of either "Reserved for Licensed Dispensation" or "Not Reserved" (not custom fitted). The items on CMS' proposed OTS/OTC list for which the Ohio Board has developed substantive practice-based language underscoring the regulatory "rating" provided with the descriptive narrative include:

(Continued ...)

³ <http://oig.hhs.gov/reports-and-publications/workplan/index.asp#current>

Device Code: L0631

HCPCS Long Description: LUMBAR-SACRAL ORTHOSIS, SAGITTAL CONTROL, WITH RIGID ANTERIOR AND POSTERIOR PANELS, POSTERIOR EXTENDS FROM SACROCOCCYGEAL JUNCTION TO T-9 VERTEBRA, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISCS, INCLUDES STRAPS, CLOSURES, MAY INCLUDE PADDING, SHOULDER STRAPS, PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Ohio Rating: Reserved for Licensed Dispensation (Custom Fit)

Practitioner Comments: ***Not a soft good; Anterior and posterior panels manufactured for warm and form custom fitting. This device is considered a 'high fitting' device due to the nature of the rigid anterior and posterior panels. When fitting this device, it is imperative that the Orthotist or Fitter be cognizant of the anatomical structures being relieved as well as the anatomical boundaries required for fitting this device. The rigid panels may have to be customized, either by heat as in a 'warm and form' or trimmed and heat modified to contour to the patient's anatomy.***

Device Code: L1832

HCPCS Long Description: KNEE ORTHOSIS, ADJUSTABLE KNEE JOINTS (UNICENTRIC OR POLYCENTRIC), POSITIONAL ORTHOSIS, RIGID SUPPORT, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT.

Ohio Rating: Reserved for Licensed Dispensation (Custom Fit)

Practitioner Comments: ***Not a soft good; not minimal fit. This device has been deemed 'low fitting' as it is typically ordered by several leg circumferences. Proper knowledge of knee anatomy is required and bending of the metal uprights might be required to obtain a properly fitting device. The stops for the joints are typically easy to set, however specialized training is required to determine the settings necessary to accommodate the knee angle.***

Device Code: L1902

HCPCS Long Description: ANKLE FOOT ORTHOSIS, ANKLE GAUNTLET, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Ohio Rating: Not Reserved / no license required (OTS-OTC)

Practitioner Comments: ***Soft good, minimal fitting. This is an OTS item that is designed to provide prophylactic support to the ankle. It relies on the elasticity of the device or straps to create mild compression of the ankle. There is typically no adjustment to this item as they are sized based off of shoe size typically.***

Device Code: L1906

HCPCS Long Description: ANKLE FOOT ORTHOSIS, MULTILIGAMENTUS ANKLE SUPPORT, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Ohio Rating: Reserved for Licensed Dispensation (Custom Fit)

Practitioner Comments: ***Not soft good; not minimal fit. Requires advanced understanding of foot anatomy, with an understanding of the dynamics and indicators for dorsi-flexion and plantar-flexion. May require repeated adjustment during patient rehabilitation.***

Device Code: L3760 (compare with L3762, offered as example only)
HCPCS Long Description: ELBOW ORTHOSIS, WITH ADJUSTABLE POSITION LOCKING JOINT(S), PREFABRICATED, INCLUDES FITTING AND ADJUSTMENTS, ANY TYPE
Ohio Rating: Reserved for Licensed Dispensation (Custom Fit)
Practitioner Comments: ***Similar to L1832 analysis. Needs to make sure that the joint stop is preventing hyperextension of the elbow joint to prevent nerve damage in the actual joint. Proper knowledge of elbow anatomy is required to obtain a properly fitting device.***

Device Code: L3807
HCPCS Long Description: WRIST HAND FINGER ORTHOSIS, WITHOUT JOINT(S), PREFABRICATED, INCLUDES FITTING AND ADJUSTMENTS, ANY TYPE
Ohio Rating: Reserved for Licensed Dispensation (Custom Fit)
Practitioner Comments: ***Combo device, not just a wrist splint or finger splint. This device is designed to maintain the wrist in an extended position. There is generally a rigid stay that can be removed from the device and requires contouring to the patient's anatomy. Knowledge of forearm, wrist, and hand anatomy and internal structures are required to prevent unnecessary pressure and offloading.***

Device Code: L3908
HCPCS Long Description: WRIST HAND ORTHOSIS, WRIST EXTENSION CONTROL COCK-UP, NON MOLDED, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT
Ohio Rating: Not Reserved / no license required (OTS-OTC)
Practitioner Comments: ***This is an OTS item with a non-removable rigid stay that comes in several different sizes and lengths based off the size of the wearers wrist.***

Device Code: L4360
HCPCS Long Description: WALKING BOOT, PNEUMATIC AND/OR VACUUM, WITH OR WITHOUT JOINTS, WITH OR WITHOUT INTERFACE MATERIAL, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT
Ohio Rating: Not Reserved / no license required (OTS-OTC)
Comments: ***Nontherapeutic or therapeutic over-the-counter or off-the-shelf shoes or boots that are not manufactured or modified for a particular individual. Excepted per statutory and regulatory language.***

Device Code: L4386
HCPCS Long Description: WALKING BOOT, NON-PNEUMATIC, WITH OR WITHOUT JOINTS, WITH OR WITHOUT INTERFACE MATERIAL, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT
Ohio Rating: Not Reserved / no license required (OTS-OTC)
Comments: ***Nontherapeutic or therapeutic over-the-counter or off-the-shelf shoes or boots that are not manufactured or modified for a particular individual. Excepted per statutory and regulatory language.***

Device Code: L4396
HCPCS Long Description: STATIC OR DYNAMIC ANKLE FOOT ORTHOSIS, INCLUDING SOFT INTERFACE MATERIAL, ADJUSTABLE FOR FIT, FOR POSITIONING, MAY BE USED FOR MINIMAL AMBULATION, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT
Ohio Rating: Not Reserved / no license required (OTS-OTC)
Practitioner Comments: **Minimal Fit. Fit based on simple sizing measurements; little or no practitioner adjustment required.**

Device Code: L4398
HCPCS Long Description: FOOT DROP SPLINT, RECUMBENT POSITIONING DEVICE, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT
Ohio Rating: Not Reserved / no license required (OTS-OTC)
Practitioner Comments: **Minimal Fit. Fit based on simple sizing measurements; little or no practitioner adjustment required.**

We appreciate the open process offered by CMS regarding this matter, and offer these comments in the spirit of regulatory cooperation for effective consumer care, protection, and delivery of necessary healthcare services in a world of finite resources.

Respectfully,



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