

PUBLIC HEARING NOTICE
OHIO DEPARTMENT OF MEDICAID

DATE: May 29, 2018
TIME: 11:00 a.m.
LOCATION: Room A401, Lazarus Government Center
50 West Town Street, Columbus, OH 43215

Pursuant to section 5164.02 and Chapter 119. of the Ohio Revised Code, the director of the Ohio Department of Medicaid gives notice of the Department's intent to consider the adoption of the rules identified below and to hold a public hearing on these rules.

With the exception of rules 5160-10-16 (wheelchairs) and 5160-10-26 (enteral nutrition products), all of the existing rules in Chapter 5160-10 of the Ohio Administrative Code concerning durable medical equipment, prostheses, orthoses, and supplies (DMEPOS) are being considered for rescission and replacement by new rules.

The content of the rules has been reorganized, streamlined, and clarified. Unnecessary definitions and superfluous provisions have been removed. Associated certificates of medical necessity (CMNs) have been completely reworked; references to these forms in the body of the rules have been retained (and, in one case, added), but the practice of including forms themselves as appendices has been discontinued. References to the Ohio Department of Medicaid or to other Medicaid rules have been modified to comport with the new agency name and designation in the Ohio Administrative Code. The new rules are consistent with the provision in Section 5002 of the Twenty-First Century Cures Act that limits aggregate Medicaid DMEPOS payment to Medicare levels.

Existing rules 5160-4-27, 5160-10-01, 5160-10-02, 5160-10-03, 5160-10-05, 5160-10-06, and 5160-10-20 have been consolidated into a single new rule 5160-10-01, "Durable medical equipment, prostheses, orthoses, and supplies (DMEPOS): general provisions." New rule 5160-10-01 incorporates provisions that are common to many of the other existing rules in Chapter 5160-10, such as the statement that payment for a particular durable medical equipment item or medical supply furnished to a resident of a long-term care facility (LTCF) is the responsibility of the LTCF or the obligation placed on a supplier to ensure proper instruction on equipment use and procedures (which has been expanded to include, when appropriate, instruction for someone assisting the individual recipient). The default maximum length of time from the date of a prescription to the first date of service is specified as sixty days.

The existing payment schedules that have been published previously as appendices to rules 5160-10-03 and 5160-10-20 have been combined into a single schedule, which is published as an appendix to new rule 5160-10-01.

Certain changes apply to specific rules:

Existing rule 5160-4-27, "Physician reimbursement of medical supplies and durable medical equipment," sets forth provisions under which payment may be made to a physician for dispensing medical supplies or durable medical equipment. This rule has been incorporated into new rule 5160-10-01, titled "Durable medical equipment, prostheses, orthoses, and supplies (DMEPOS): general provisions."

Existing rule 5160-10-01, "Eligible providers," describes those eligible providers that may receive payment for dispensing durable medical equipment, prostheses, orthoses, or medical supplies. This rule has been incorporated into new rule 5160-10-01.

Existing rule 5160-10-02, "Coverage and limitations for medical supplier services," sets forth definitions, coverage and payment policies, and limitations pertaining to medical supplier services. This rule has been incorporated into new rule 5160-10-01.

Existing rule 5160-10-03, "Medical supplies and the medicaid supply list," sets forth definitions, coverage and payment policies, and limitations pertaining to medical supplier services. Information about individual items is listed in the rule appendix. The body of this rule has been incorporated into new rule 5160-10-01, and the information in the appendix has been incorporated into the appendix to new rule 5160-10-01.

Existing rule 5160-10-04, "Pneumatic compression devices and accessories," sets forth coverage and payment policies for pneumatic compression devices and accessories. The new rule is titled "DMEPOS: pneumatic compression devices and accessories" and has been renumbered 5160-10-17. The associated CMN is form ODM 02929. The requirement for prior authorization (PA) of payment has been removed. Implied coverage statements concerning segmented and non-segmented devices have been omitted.

Existing rule 5160-10-05, "Reimbursement for covered services," sets forth prescription and payment policies for DMEPOS items and services. This rule has been incorporated into new rule 5160-10-01. A reference to a published list of DMEPOS items that require a face-to-face encounter has been replaced by a reference to the website of the Centers for Medicare and Medicaid Services (CMS), where the information may be found. The delivery confirmation requirement has been relaxed to allow the provider or shipper to collect only a signature if other identifying information for a particular person is kept on file.

Existing rule 5160-10-06, "Prior authorization," sets forth prior authorization policies for DMEPOS items and services. This rule has been incorporated into new rule 5160-10-01. Use of the prior authorization (PA) process has been discontinued for requests that exceed the specified maximum for an item but do not otherwise require PA. The explicit twelve-month minimum limit on the frequency of PA requests has been removed.

Existing rule 5160-10-08, "Repair of medical equipment," sets forth coverage and payment policies for the repair of medical equipment. (The repair of wheelchairs is addressed separately in rule 5160-10-16.) The new rule is titled "DMEPOS: repair" and has been renumbered 5160-10-02. The associated form, ODM 01904, has been converted from a CMN to a request for need verification. The threshold amount for a "major repair" of an orthotic or prosthetic device has been increased from one hundred dollars to one hundred twenty dollars. The process of "need verification" is defined, by which a determination is made whether to make payment for an item or service that exceeds the established cost threshold or frequency guideline. The requirement for a practitioner's signature on the ODM 01904 (in effect, a prescription for repair) has been eliminated.

Existing rule 5160-10-09, "Apnea monitors," sets forth coverage and payment policies for apnea monitors used in the home. The new rule is titled "DMEPOS: apnea monitors." The associated CMN is form ODM 02900.

Existing rule 5160-10-10, "Dialysis equipment," sets forth coverage and payment policies for dialysis equipment used in the home. The new rule is titled "DMEPOS: home dialysis equipment and supplies."

Existing rule 5160-10-11, "Hearing aids," sets forth coverage and payment policies for hearing aids. The new rule is titled "DMEPOS: hearing aids." The associated CMN is form ODM 01915. The age limit on programmable hearing aids has been removed, but the requirement for prior authorization has not.

Existing rule 5160-10-12, "Orthopedic shoes and foot orthoses," sets forth coverage and payment policies for orthopedic shoes and foot orthoses. This rule has been incorporated along with rule 5160-10-31 into new rule 5160-10-31, titled "DMEPOS: footwear and foot orthoses." A payment restriction has been removed for a depth inlay shoe that is not an integral part of a brace. Payment for a foot orthosis now includes not only the casting process specifically but the acquisition (by casting or other means) of the model on which the orthosis is constructed. A new provision has been added to clarify coverage of a specialized non-orthopedic shoe for a child when commercially available shoes do not fit properly over an orthotic device. A limitation specifying that only an individual who performs an actual casting may submit a claim for a foot orthosis has been replaced by a more general statement about the acquisition of the model on which an orthosis is constructed.

Existing rule 5160-10-13, "Oxygen services," sets forth coverage and payment policies for oxygen. The amended rule is titled "DMEPOS: oxygen." The associated CMN is form ODM 01909. Terminology has been updated and clarified, and unnecessary wording has been removed. A correction has been made in the specification of which blood gas study is to be used in connection with an individual's discharge from a hospital or long-term care facility (LTCF). A provision has been added to make it clear that a need for oxygen originally established in connection with the use of a positive airway pressure device is presumed to last as long as the need for the device, and no further sleep study is required for recertification. A provision allowing increased payment for concerning high-volume oxygen flow has been discontinued. A longstanding but informal policy that payment for a transfill unit includes the associated oxygen concentrator has been discontinued.

Existing rule 5160-10-14, "Compression garments," sets forth coverage and payment policies for compression garments. The new rule is titled "DMEPOS: compression garments." The associated CMN is form ODM 01905. A requirement predicating payment to a supplier of custom-made garments on an employment or contract relationship with a certified fitter has been removed. Specification of a particular, limited purpose for using a burn compression garment (i.e., to reduce hypertrophic scarring and joint contractures) has been discontinued.

Existing rule 5160-10-15, "Transcutaneous electrical nerve stimulators (TENS)," sets forth coverage and payment policies for transcutaneous electrical nerve stimulation (TENS) units. The new rule is titled "DMEPOS: transcutaneous electrical nerve

stimulation (TENS) units." The associated CMN is form ODM 03402. The current list of specific acceptable diagnoses (which is incomplete) has been replaced by a simple requirement that an appropriate diagnosis be specified. Criteria for rental during the initial month have been brought in line with criteria for rental during the subsequent three months. The prohibition against payment for a TENS unit used in conjunction with acupuncture has been lifted. The statement that the department does not allow the sharing of TENS units has been removed. The payment provision for rental or purchase of a used TENS unit has been clarified. A provision has been added to clarify that payment for a TENS unit does not indicate or imply coverage of a conductive TENS garment. For a TENS unit owned by an individual, distinctions based on payer source have been eliminated. The collective term "supplies" is defined.

Existing rule 5160-10-18, "Hospital beds, pressure reducing support surfaces and accessories," sets forth coverage and payment policies for hospital beds, bed accessories, and pressure-reducing support surfaces. The new rule is titled "DMEPOS: hospital beds, bed accessories, and pressure-reducing support surfaces and accessories." The associated CMNs are, respectively, forms ODM 02910 and ODM 02904. Information about the stages of tissue breakdown that is currently presented in Appendix A has been incorporated into the body of the rule, and Appendix A itself has been rescinded. The blanket exclusion of coverage for completely power-operated hospital beds has been lifted.

Existing rule 5160-10-19, "Definition of terms associated with orthotic and prosthetic services," consists of a list of definitions. This rule has been rescinded.

Existing rule 5160-10-20, "Orthotic devices, prostheses, and related services," sets forth coverage and payment policies pertaining to orthotic devices, prostheses, and related services. Information about individual items is listed in the rule appendix. The body of this rule has been incorporated into new rule 5160-10-01, and the information in the appendix has been incorporated into the appendix to new rule 5160-10-01.

Existing rule 5160-10-21, "Incontinence garments and related supplies," sets forth coverage and payment policies for incontinence garments and related supplies. The new rule is titled "DMEPOS: incontinence garments and related supplies." The associated CMN is form ODM 02912. The current policy on payment for incontinence items used because of stress incontinence has been rephrased in the negative: No payment is made if no specific physiological, psychological, or physiopsychological cause can be attributed to the stress incontinence. The quantity of items the Medicaid-eligible individual currently has on hand has been added to the list of information the supplier must verify before dispensing additional items.

Existing rule 5160-10-22, "Volume ventilators, positive and negative pressure ventilators, continuous positive airway pressure (CPAP), alternating positive airway pressure (APAP), and intermittent positive pressure ventilation (IPPV)," sets forth coverage and payment policies for ventilators and positive airway pressure devices. This single rule has been replaced by two rules: New rule 5160-10-19 is titled "DMEPOS: positive airway pressure devices," and new rule 5160-10-22 is titled "DMEPOS: ventilators." The associated CMNs are forms ODM 01903 and ODM 01902 respectively; form ODM 01903 can now be used for all positive airway pressure devices, not just devices

prescribed in lieu of a ventilator. Redundant provisions have been struck. Correct use has been removed from the list of prescription attestations for a positive airway pressure device; instead, a provision has been added stating that prior authorization may be withheld if a device is not being used appropriately and may not be subsequently granted without the support of a prescriber. The restriction that sleep studies involving a positive airway pressure device must be performed in a fixed facility (laboratory) rather than in the home or in a mobile facility has been eliminated. To prevent any misapprehension that having a wheelchair is a prerequisite for ventilator use outside the home, mention of a mobility device has been removed from the criteria for a second ventilator.

Existing rule 5160-10-23, "Pulse Oximeters," sets forth coverage and payment policies for pulse oximeters. The new rule is titled "DMEPOS: pulse oximeters." The associated CMN is form ODM 03401. Because they imply an age restriction, references to children have been omitted. An overly broad requirement concerning printouts of pulse oximeter data has been removed. Unnecessary limits on the duration and frequency of diagnostic monitoring have been removed. Payment for pulse oximeter probes is no longer included in monthly rental; separate payment may be made for probes during the rental period.

Existing rule 5160-10-24, "Speech generating devices," sets forth coverage and payment policies for speech-generating devices (SGDs). The new rule is titled "DMEPOS: speech-generating devices." The associated CMNs are forms ODM 02924, ODM 02925, and ODM 02926, which have been consolidated into a single form, designated ODM 02924. The range of covered SGDs has been expanded to include software applications that are suitable for use with a portable or tablet computer.

Existing rule 5160-10-25, "Lactation Pumps," sets forth coverage and payment policies for lactation pumps. The new rule is titled "DMEPOS: lactation pumps." The associated CMN is form ODM 01901. The term '*hospital-grade lactation pump*' has been replaced by '*multiple-user lactation pump*', and the capabilities of such a pump have been listed as characteristics rather than specifications. Revisions have been made to the information to be listed in a prior authorization request for additional rental of a multiple-user lactation pump; the rule body now includes the length of the additional rental period, and the specification of "other documentation as required or requested" has been removed. A provision that requires suppliers to document the use of a lactation pump but does not specify the nature of the documentation has been removed.

Existing rule 5160-10-27, "Continuous Passive Motion (CPM) Devices," sets forth coverage and payment policies for continuous passive motion (CPM) devices. The new rule is titled "DMEPOS: continuous passive motion (CPM) devices." Wording has been added for consistency with other rules. A statement that could be interpreted as a directive for medical practitioners to take a particular course of action has been removed.

Existing rule 5160-10-28, "Noninvasive Bone (Osteogenesis) Stimulators," sets forth coverage and payment policies for osteogenesis stimulators applied externally. The new rule is titled "DMEPOS: osteogenesis stimulators." The associated CMN is form ODM 07134. The term '*physician*' has been replaced by '*qualified practitioner*'.

Existing rule 5160-10-29, "External Insulin Infusion Pump," sets forth coverage and payment policies for portable external insulin infusion pumps. The new rule is titled "DMEPOS: insulin pumps." The associated CMN is form ODM 07136. Definitions

have been added to clarify that coverage provisions apply to insulin infusion pumps equipped with a continuous glucose monitoring (CGM) sensor. An unnecessary and misleading indicator of type 1 diabetes mellitus has been removed. The time period for glucose self-testing needed to demonstrate medical necessity has been reduced from two months to one month. A statement that could be interpreted as a directive for medical practitioners to take a particular course of action has been removed.

Existing rule 5160-10-30, "Canes, Crutches and Walkers," sets forth coverage and payment policies for canes, crutches, and walkers. The new rule is titled "DMEPOS: ambulation aids." The weight guideline for heavy-duty walkers has been changed from 'more than three hundred pounds' to 'at least three hundred pounds.'

Existing rule 5160-10-31, "Therapeutic Footwear for Consumers with Diabetes," sets forth coverage and payment policies for therapeutic footwear for individuals who have diabetes. This rule has been incorporated along with rule 5160-10-12 into new rule 5160-10-31. The associated CMN is form ODM 01912. A provision allowing payment to a prescriber for dispensing therapeutic footwear only if the prescriber practices in a defined rural area or a defined health professional shortage area has been removed. A provision has been added allowing payment for specialized non-orthopedic shoes for children, designed to be worn over an orthotic device, if no commercially available shoe fits properly.

Existing rule 5160-10-32, "Ostomy and Urological Supplies," sets forth coverage and payment policies for stoma maintenance supplies and urination aids. The new rule is titled "DMEPOS: ostomy supplies and urological supplies." Payment policies have been clarified for irrigation solutions containing acetic acid or hydrogen peroxide and for irrigation solutions containing antibiotics or chemotherapeutic agents. In one coverage criterion for sterile intermittent catheters and related supplies, spinal cord defect has been included, along with spinal cord injury, as a cause of neurogenic bladder dysfunction. A lengthy listing of symptoms associated with urinary tract infection has been removed. A sharper distinction has been drawn between an external urinary collection device (e.g., a condom-style catheter for males, a cup or pouch for females) and a urinary drainage system (e.g., a leg bag with tubing). A coverage limit on leg bags and leg bag straps that is stated in the "Medicaid supply list" (the appendix to rule 5160-10-03) has been incorporated into the body of this rule.

Existing rule 5160-10-33, "Commodes," sets forth coverage and payment policies for commodes (toilet chairs). The new rule is titled "DMEPOS: commodes."

Existing rule 5160-10-34, "Surgical Dressings and Related Supplies," sets forth coverage and payment policies for wound dressings (covers and fillers) and related supplies (e.g., tape, elastic bandages). The new rule is titled "DMEPOS: wound dressings and related supplies." Definitions concerning the stages of tissue breakdown are removed from the rule. Clinical indications, contraindications, and application guidelines for certain types of wound dressing are extracted from the rule body and summarized instead in a new appendix to the rule. Overly detailed requirements concerning wound evaluation are removed. Type of wound has been added to the list of clinical information that must be reported on a prescription. A provision that appears to require suppliers to maintain copies of treatment records in their own files has been removed. Payment for an amount

in excess of the established limit is subjected to need verification rather than prior authorization.

Existing rule 5160-10-35, "Cranial Orthotic Remolding Devices," sets forth coverage and payment policies for orthotic devices (helmets) designed for the progressive reshaping of the developing skull structure of a young child. The new rule is titled "DMEPOS: cranial remolding devices."

Any person may examine these rules and obtain a copy, without charge, at the following locations:

Ohio Department of Medicaid, 50 West Town Street, Suite 400, Columbus, OH 43215 or
On the internet at <http://www.registerofohio.state.oh.us> through a search for any of the Ohio Administrative Code rule numbers listed in this notice.

Requests for a copy of the rules, as well as testimony on the rules, may be submitted in any of the following ways:

By mail to the Rule Administrator, Office of Chief Legal Counsel, Ohio Department of Medicaid, 50 West Town Street, Suite 400, Columbus, OH 43215;

By fax to (614) 995-1301; or

By e-mail to rules@medicaid.ohio.gov.

Testimony on the proposed rules may also be reviewed at the Ohio Department of Medicaid, 50 West Town Street, Suite 400, Columbus, Ohio 43215.