**DMEPOS Personnel Requirements**

The information below outlines the personnel requirements necessary to obtain accreditation for specific products/product categories. If your state laws are more stringent than accreditation requirements, then you must abide by your state laws (always follow whatever law/requirement is most strict).

Adding products during an accreditation term (after you are accredited) may require ABC to resurvey your facility (resurvey fees will apply). When selecting products prior to accreditation, ensure you are selecting all that you do provide and want to obtain accreditation for (see additional notes below).

Ensure that you are following all DMEPOS accreditation policy and procedure requirements for the provision of all DME products/services (from your Accreditation Manual). Key points regarding accreditation policy and procedure requirements related to provision of DME products/services include:

- The DME products you selected on your accreditation organization application are the products that you must be able to demonstrate your ability to supply using the policies and procedures from your manual (including having the item available, training the beneficiary/caregiver on the product, conducting home assessments to ensure the beneficiary can use the product effectively if applicable); once you are submitted for survey, your product category selections cannot be changed.
- Remember – the product categories you select are the DME items you will be accredited to supply; you must be accredited to supply all DME available in your pharmacy/facility (you cannot choose to simply not provide a DME item to a Medicare Beneficiary in the hopes of not needing to be accredited to supply said item); the accreditation organization is accrediting you as a supplier of DME – regardless of the payor.
- For all DME products that require any physical evaluation, fitting or exam ensure that you have a separate, private area for fitting and a facility with appropriate equipment for follow-up care.
- Ensure that all credentialing/licensure is displayed appropriately (in an area accessible to patients).
- The patient files maintained at your pharmacy must reflect the DME you provide (if you provide diabetic shoes to patients, the patient files must reflect that shoes were provided); document follow-up care and monitoring as necessary for each product category, including “Goals and Outcomes” and a “Plan of Care”.

*For DME dispensed to Medicare beneficiaries, also ensure that you follow specifications including in the LCD’s (coverage policies) for each product/product category (refer to your DME MAC for this information; links to these websites are included on the “Education” tab).*

**Medicare-required certification – CMS Quality Standards**

Per CMS Quality Standards, all suppliers supplying the item(s) set out in Appendix C (*included at the bottom) must possess specialized education, training, and experience in fitting, and certification and/or licensing.

The Certifications required are:

- orthotics,
- mastectomy,
- therapeutic shoes (custom and non-custom)

**DME Product Category Break-down and associated Personnel Requirements**

**Mastectomy/Prostheses**

Breast Prostheses and Accessories
Certified Post Mastectomy Fitter via ABC or BOC

Facial Prostheses
Certified Prosthist

Ocular Prostheses
Certified Prosthist
Somatic Prostheses
Certified Prosthetist

Therapeutic Shoes

<table>
<thead>
<tr>
<th>Application Sent to ABC</th>
<th>Documentation/Certification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior to 4/1/2010</td>
<td>Manufacturer Training Certificate for the Pharmacist (unless otherwise required by your state)</td>
</tr>
<tr>
<td>After 4/1/2010</td>
<td>NCOPE Training Certificate for the Pharmacist (unless otherwise required by your state)</td>
</tr>
</tbody>
</table>

Diabetic Shoes/Inserts (Custom)
Dependent on date of ABC application submission (contact accreditation specialist for clarification): Certified Pedorthist, NCOPE Trained Pharmacist, Certified Orthotist; Certified Therapeutic Shoe Fitter from ABC or BOC, Manufacturer Trained Pharmacist

Diabetic Shoes/Inserts (Non-Custom)
Dependent on date of ABC application submission (contact accreditation specialist for clarification): Certified Pedorthist, NCOPE Trained Pharmacist, Certified Orthotist; Certified Therapeutic Shoe Fitter from ABC or BOC, Manufacturer Trained Pharmacist

Respiratory Support
See product-specific accreditation manual policies and procedures: Table of Contents Section 4, Consumer Services
If you provide oxygen equipment and supplies – ensure that you do employ a Respiratory Therapist and offer 24 hour respiratory support. If you provide any of the non-oxygen products listed below and the patient is also on oxygen (regardless if it is you who provides the oxygen to that patient), you must also employ a Respiratory Therapist (this includes offering 24 hour respiratory support). NOTE: the Pharmacist working under their State’s Scope of Practice will be permitted to provide these services in place of the Respiratory Therapist, if the state expressly allows it.

- If the pharmacy has a Respiratory Therapist as a contracted employee (not a W2), ABC will need to review the contract to determine if it meets their criteria (contact your Accreditation Specialist for more information in this case). When a contractor is used, you should ensure the contract does not violate any state or federal anti-kickback rules.

Continuous Positive Airway Pressure (CPAP) Devices
Pharmacist as permitted by State or RT; if patient is on oxygen RT is required (or Pharmacist working under their State’s Scope of Practice)

High Frequency Chest Wall Oscillation (HFCWO) Devices
Pharmacist as permitted by State or RT; if patient is on oxygen RT is required (or Pharmacist working under their State’s Scope of Practice)

Intermittent Positive Pressure Breathing (IPPB) Devices
Pharmacist as permitted by State or RT; if patient is on oxygen RT is required (or Pharmacist working under their State’s Scope of Practice)

Intrapulmonary Percussive Ventilation Devices
Pharmacist as permitted by State or RT; if patient is on oxygen RT is required (or Pharmacist working under their State’s Scope of Practice)

Invasive Mechanical Ventilation Devices
Pharmacist as permitted by State or RT; if patient is on oxygen RT is required (or Pharmacist working under their State’s Scope of Practice)
Mechanical In-Exsufflation Devices
Pharmacist as permitted by State or RT; if patient is on oxygen RT is required (or Pharmacist working under their State’s Scope of Practice)

Nebulizer Equipment and Supplies
Pharmacist as permitted by State or RT; if patient is on oxygen RT is required (or Pharmacist working under their State’s Scope of Practice)

Oxygen Equipment and Supplies
RT (or Pharmacist working under their State’s Scope of Practice)

Respiratory Assist Devices
Pharmacist as permitted by State or RT; if patient is on oxygen RT is required (or Pharmacist working under their State’s Scope of Practice)

Respiratory Suction Pumps
Pharmacist as permitted by State or RT; if patient is on oxygen RT is required (or Pharmacist working under their State’s Scope of Practice)

Ventilators Accessories/Supplies
Pharmacist as permitted by State or RT; if patient is on oxygen RT is required (or Pharmacist working under their State’s Scope of Practice)

Orthotics
Orthoses: Custom Fabricated
Certified orthotist

Orthoses: Prefabricated (non-custom fabricated)
Certified orthotist

Mobility
See product-specific accreditation manual policies and procedures: Table of Contents Section 4, Consumer Services

Wheelchair Seating/Cushions
Credentialed Rehabilitative Technology Supplier (RTS), including: CRTS, ATS, ATP

Wheelchairs-Complex Rehabilitative Manual Wheelchairs
Credentialed Rehabilitative Technology Supplier (RTS), including: CRTS, ATS, ATP

Wheelchairs-Complex Rehabilitative Manual Wheelchairs Related Accessories
Credentialed Rehabilitative Technology Supplier (RTS), including: CRTS, ATS, ATP

Wheelchairs-Complex Rehabilitative Power Wheelchairs
Credentialed Rehabilitative Technology Supplier (RTS), including: CRTS, ATS, ATP

Wheelchairs-Complex Rehabilitative Power Wheelchairs Related Accessories
Credentialed Rehabilitative Technology Supplier (RTS), including: CRTS, ATS, ATP

Appendix C items:

Appendix C: Custom Fabricated and Custom Fitted Orthoses, Prosthetic Devices, External Breast Prostheses, Therapeutic Shoes and Inserts, and their Accessories and Supplies; Custom-Made Somatic, Ocular and Facial Prostheses
The supplier shall be trained in a broad range of treatment options to ensure that the item(s) prescribed is/are optimal for the beneficiary’s condition. The provision of custom fabricated or custom fitted devices (i.e., other than off-the-shelf items) requires
access to a facility with the equipment necessary to fulfill the supplier’s responsibility to provide follow-up treatment, including modification, adjustment, maintenance and repair of the item(s). Individuals supplying the item(s) set out in this appendix must possess specialized education, training, and experience in fitting, and certification and/or licensing.

**Definition of Terms**

The terms below are used to describe the types of devices referred to in this appendix.

1. **Custom Fabricated**: A custom fabricated item is one that 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.

2. **Molded-to-Patient-Model**: 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 manufacturing (CAD-CAM) systems software. This technology includes specialized probes/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.

3. **Positive Model of the Patient**: a) Molded to patient model is a negative impression taken of the patient's body member and a positive model rectification is constructed; or b) CAD-CAM system, by use of digitizers, transmits surface contour data to software that the practitioner uses to rectify or modify the model on the computer screen. The data depicting the modified shape is electronically transmitted to a commercial milling machine that carves the rectified model; or c) Direct formed model is one in which the patient serves as the positive model. The device is constructed over the model of the patient and is then fabricated to the patient. The completed custom fabrication is checked and all necessary adjustments are made.

4. **Custom Fitted**: 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.

5. **Prosthetic Devices**: Devices (other than dental) which replace all or part of an internal body organ (including contiguous tissue), or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ. This does not require a determination that there is no possibility that the patient’s condition may improve sometime in the future. If the medical record, including the judgment of the attending physician, indicates the condition is of long and indefinite duration, the test of permanence is considered met. (Refer to Section 120 of Chapter 15 of the Medicare Benefit Policy Manual)

6. **Orthotic Devices**: Rigid and semi-rigid devices used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body.

7. **Ocular Prostheses**: Custom-fabricated ocular prostheses that replace the globe of the eye or cover the existing unsightly eye as a result of traumatic injury, disease and/or ablative surgery, or congenital malformation. Custom-made eye prostheses include conformers, scleral shells, and ocular prostheses that fit within the natural socket tissue and eyelids, as well as the custom-made ocular prosthesis component that is integrated into an orbital, upper facial, or hemifacial prosthesis.

8. **Facial Prostheses**: Custom-fabricated prosthetic restoration of the face including auricular, nasal, mid-facial, orbital (including ocular), upper facial, hemi-facial, partial facial, nasal septal, and other areas of the face disfigured by traumatic injury, disease and/or ablative surgery, or congenital malformation.

9. **Somatic Prostheses**: Custom-fabricated somatic prostheses replace areas of the human body not included under definitions of facial and ocular prosthetics, but require visual and functional integration in order to be acceptable. Somatic prosthetics typically include finger, thumb, partial hand, hand, and toe disfigured by traumatic injury, disease and/or ablative surgery, or congenital malformation.

10. **External Breast Prostheses**: Prefabricated or custom fabricated forms, bras, and sleeves. (Refer to Section 120 of Chapter 15 of the Medicare Benefit Policy Manual)

11. **Off-The-Shelf Orthoses**: Orthoses which requires minimal self adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit the beneficiary. Appendix C does not apply to off-the-shelf orthotics. (Refer to 42 CFR, section §414.402)

12. **Therapeutic Shoes and Inserts**: Includes depth or custom-molded shoes along with inserts for individuals with diabetes (Refer to Section 140 of Chapter 15 of the Medicare Benefit Policy Manual)

**Custom-Molded Shoes**:

1. Are constructed over a positive model of the patient’s foot;
2. Are made from leather or other suitable material of equal quality;
3. Have removable inserts that can be altered or replaced as the patient’s condition warrants; and
4. Have some form of shoe closure.

**Depth Shoes**: **口头解释**
1. Have a full length, heel-to-toe filler that, when removed, provides a minimum of 3/16 inch of additional depth used to accommodate custom-molded or customized inserts;  
2. Are made from leather or other suitable material of equal quality;  
3. Have some form of shoe closure; and  

Are available in full and half sizes with a minimum of three widths so that the sole is graded to the size and width of the upper portions of the shoes according to the American standard last sizing schedule or its equivalent. (The American standard last sizing schedule is the numerical shoe sizing system used for shoes sold in the United States.)

** Inserts: **
1. Are total contact, multiple density, removable inlays that are directly molded to the patient’s foot or a model of the patient’s foot and that are made of a suitable material with regard to the patient’s condition.