

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Medicare & Medicaid Services



Official CMS Information for  
Medicare Fee-For-Service Providers

# Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Quality Standards



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# Introduction

## Overview

The Centers for Medicare & Medicaid Services (CMS) established and implemented Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Quality Standards for suppliers of DMEPOS under the Medicare Modernization Act of 2003 (MMA). In order to obtain or maintain Medicare billing privileges, DMEPOS suppliers must comply with the DMEPOS Quality Standards and become accredited unless they are exempt from the accreditation requirement. This booklet contains the DMEPOS Quality Standards and tips for understanding them, lists the 10 Accreditation Organizations (AOs), and provides resources for more information.



Accreditation is a complex and comprehensive process that requires preparation. To meet the DMEPOS Quality Standards and prepare for accreditation, you will need to read and understand the DMEPOS Quality Standards and involve all staff in the process. For more information on the accreditation process, refer to the Resources section of this booklet.

## DMEPOS Quality Standards

The DMEPOS Quality Standards that follow consist of two sections and three appendices:

- **Section I:** Supplier Business Services Requirements;
- **Section II:** Supplier Product-Specific Service Requirements;
- **Appendix A:** Respiratory Equipment, Supplies, and Services;
- **Appendix B:** Manual Wheelchairs, Power Mobility Devices (PMDs), and Complex Rehabilitative Wheelchairs and Assistive Technology; and
- **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.

### TIP

Throughout the presentation of the DMEPOS Quality Standards beginning on page 4, you will find tips to further your understanding of the standards.





Section I addresses administration, financial management, human resources management, consumer services, performance management, product safety, and information management. Section II addresses intake and assessment, delivery and set-up, training/instruction, and follow-up. The Appendices describe the requirements for specific types of DMEPOS items and services.

### **Accreditation Organizations (AOs)**

There are 10 AOs deemed to accredit DMEPOS suppliers using, at a minimum, CMS' DMEPOS Quality Standards. To begin the accreditation process, contact one or more of the AOs listed in this booklet to obtain information about its accreditation process.

### **Resources**

For more information about DMEPOS, the DMEPOS Quality Standards, and accreditation, refer to the Resources section of this booklet.





# Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Quality Standards

## Section I: Supplier Business Services Requirements

### A. Administration

1. The supplier shall have one or more individuals who perform leadership functions, with the authority, responsibility, and accountability to direct the organization and its key activities and operations.

The term “leadership” does not necessarily imply that there must be a formal group or committee. The supplier can meet this requirement through various means as long as essential leadership functions occur. An owner can lead an owner-operated business, such as a physician’s office. The supplier may use any form of organization, such as a partnership, sole proprietorship, or corporation.

Depending on the organization’s structure, examples of leadership positions may include the owners, governing body, CEO, and other individuals responsible for managing services provided by the organization.

2. The supplier shall govern its business so that it obtains and provides appropriate quality equipment, item(s), and service(s) to beneficiaries.
3. The supplier shall have a physical location and display all licenses, certificates, and permits to operate. The licenses, certificates, and permits must be displayed in an area accessible to customers and patients. The supplier shall provide copies, upon request, to government officials or their authorized agents.
4. The supplier shall provide only DMEPOS and other items that meet applicable Food and Drug Administration (FDA) regulations and medical device effectiveness and safety standards. The supplier shall obtain from the manufacturer copies of the features, warranties, and instructions for each type of non-custom fabricated item.

#### TIP

#### Leadership

Leadership requirements can be met by one person or several (e.g., owner, governing body, or Chief Executive Officer [CEO]). The leadership ensures compliance with standards, laws, and regulations and is responsible for all business operations. The leadership relays all rules, policies, and procedures to the staff and contractors. The organizational chart should show that the leadership relaying this information has the legal authority to make all decisions and is accountable for those decisions.

#### TIP

#### FDA Reporting Requirements

For more information on FDA reporting requirements, visit <http://www.fda.gov/MedicalDevices> on the Internet.

**TIP****Partial Listing of Applicable Regulations/Guidance**

The following include some of the regulations/guidance with which suppliers should comply, as applicable:

- Enrollment standards under 42 CFR Section 424.57;
- Department of Transportation regulations on vehicles;
- Occupational Safety & Health Administration (OSHA) regulations on infection control, fire and safety, and local fire codes;
- Business licenses in **all** States;
- Local Coverage Determinations (LCDs) and National Coverage Determinations (NCDs);
- Internet-Only Manuals (IOMs); and
- State law.

The supplier shall comply with all Medicare statutes, regulations (including the disclosure of ownership and control information requirements at 42 Code of Federal Regulations [CFR] Sections 420.201 through 420.206), manuals, program instructions, and contractor policies and articles.

6. The supplier shall implement business practices to prevent and control fraud, waste, and abuse by:

- Using procedures that articulate standards of conduct to ensure the organization’s compliance with applicable laws and regulations, and
- Designating one or more individuals in leadership positions to address compliance issues.

**B. Financial Management**

1. The supplier shall implement financial management practices that ensure accurate accounting and billing to beneficiaries and the Medicare Program. Financial records shall be accurate, complete, current, and reflect cash or accrual base accounting practices.
2. The supplier shall maintain accounts that link equipment and item(s) to the beneficiary and manage revenues and expenses on an ongoing basis, as they relate to beneficiary services, including the following:

**TIP****Compliance**

Establish business practices to ensure compliance with laws and regulations. Designate one person to address compliance issues who has the knowledge, skills, and education to be accountable in this position (typically a risk management or compliance officer).

A compliance plan should, at a minimum, include all training, issues addressed, and the method to determine conflicts of interest.

**TIP****Financial Management**

The following are tips on financial management:

- Develop an operating budget;
- Produce periodic financial statements;
- Develop a method for tracking actual revenues and expenses;
- Take into account any Advance Beneficiary Notices of Noncoverage (ABNs) issued for upgrades;
- Practice proper billing practices, including:
  - Do not bill before you receive the prescription, and
  - Use correct modifiers and codes.

- Reconciling charges to beneficiaries for equipment, supplies, and services with invoices, receipts, and deposits;
- Planning to meet the needs of beneficiaries and maintain business operations by having an operating budget, as appropriate to the business’s size and scope of services; and
- Having a mechanism to track actual revenues and expenses.

### C. Human Resources Management

1. The supplier shall:

- Implement policies and issue job descriptions that specify personnel qualifications, training, certifications/ licensures where applicable, experience, and continuing education requirements consistent with the specialized equipment, items, and services it provides to beneficiaries;
- Provide copies of such policies, job descriptions, and certifications/ licensures (where applicable) upon request to accreditation organizations and government officials or their authorized agents; and
- Verify and maintain copies of licenses, registrations, certifications, and competencies for personnel who provide beneficiary services.

2. Technical personnel shall be competent to deliver and set up equipment, item(s), and service(s) and train beneficiaries and/or caregiver(s).

3. Professional personnel shall be licensed, certified, or registered and function within their scope of practice as required by the State standards under which the professional is licensed, certified, or registered.

### D. Consumer Services

1. When providing equipment, item(s), and service(s) to beneficiaries and/or caregiver(s), the supplier shall:

## TIP

### Human Resources Management

The following are tips on human resources management:

- Job descriptions should include educational requirements;
- Background checks should be performed in accordance with State law;
- Employees should receive orientation on duties and OSHA requirements;
- For contractual relationships, document the contractor’s compliance and accreditation;
- Conduct performance evaluations for both employees and contractors;
- Verify all professional licenses and certificates through the website, including Commercial Driver’s License (CDL) for van drivers, if necessary; and
- Document compliance with all applicable health requirements (e.g., tuberculosis [TB], hepatitis B virus [HBV], or drug screening required by State law).



- Provide clear, written or pictorial, and oral instructions related to the use, maintenance, infection control practices for, and potential hazards of equipment and/or item(s) as appropriate;
  - Provide information regarding expected time frames for receipt of delivered items;
  - Verify that the equipment, item(s), and service(s) were received;
  - Document in the beneficiary’s record the make and model number or any other identifier of any non-custom equipment and/or item(s) provided;
  - Provide essential contact information for rental equipment and options for beneficiaries and/or caregiver(s) to rent or purchase equipment and/or item(s), when applicable; and
  - Provide information and telephone number(s) for customer service, regular business hours, after-hours access, equipment and/or item(s) repair, and emergency coverage.
2. If the supplier cannot or will not provide the equipment, item(s), or service(s) that are prescribed for a beneficiary, the supplier shall notify the prescribing physician (for the purpose of these standards, “prescribing physician” includes other practitioners who can prescribe DMEPOS under Medicare laws and regulations) or other health care team member(s) promptly within 5 calendar days.
  3. Within 5 calendar days of receiving a beneficiary’s complaint, the supplier shall notify the beneficiary, using either oral, telephone, e-mail, fax, or letter format, that it has received the complaint and is investigating. Within 14 calendar days, the supplier shall provide written notification to the beneficiary of the results of its investigation. The supplier shall maintain documentation of all complaints received, copies of the investigations, and responses to beneficiaries.

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| <b>TIP</b> | <p><b>Consumer Services</b></p> <p>Beneficiaries must be able to contact their supplier 24 hours a day, 7 days a week.</p> |
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**E. Performance Management**

1. The supplier shall implement a performance management plan that measures outcomes of consumer services, billing practices, and adverse events. The data collection may target certain aspects of services that have a potential to cause harm or injury; occur frequently (creating a greater than expected number of adjustment(s), repair(s), or replacement(s)); or require significant instruction to assure safe use and benefit of the equipment and/or item(s).

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| <b>TIP</b> | <p><b>Measuring Outcomes</b></p> <p>When designing outcomes measures, target the following:</p> <ul style="list-style-type: none"> <li>• Items or services that are high volume (e.g., diabetic supplies), problem-prone (e.g., PMDs), or high risk (e.g., complex rehabilitation or ventilators);</li> <li>• Consumer services;</li> <li>• Beneficiary service satisfaction;</li> <li>• Timeliness of response;</li> <li>• Billing practices; and</li> <li>• Adverse events.</li> </ul> |
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2. At a minimum, each supplier shall measure:

- Beneficiary satisfaction with and complaints about product(s) and service(s);
- Timeliness of response to beneficiary question(s), problem(s), and concern(s);
- Impact of the supplier's business practices on the adequacy of beneficiary access to equipment, item(s), service(s), and information;
- Frequency of billing and coding errors (e.g., number of Medicare claims denied, errors the supplier finds in its own records after it has been notified of a claims denial); and
- Adverse events to beneficiaries due to inadequate service(s) or malfunctioning equipment and/or item(s) (e.g., injuries, accidents, signs and symptoms of infection, hospitalizations). This may be identified through follow-up with the prescribing physician, other health care team member(s), the beneficiary, and/or caregiver(s).

3. The supplier shall seek input from employees, customers, and referral sources when assessing the quality of its operations and services.

### **TIP**

#### **Seeking Input**

Seek input from **all** customers, including referral sources.

## **F. Product Safety**

1. The supplier shall:

- Implement a program that promotes the safe use of equipment and item(s) and minimizes safety risks, infections, and hazards both for its staff and for beneficiaries;
- Implement and maintain a plan for identifying, monitoring, and reporting (where indicated) equipment and item(s) failure, repair, and preventive maintenance provided to beneficiaries;
- Investigate any incident, injury, or infection in which DMEPOS may have contributed to the incident, injury, or infection, when the supplier becomes aware. The investigation should be initiated within 24 hours after the supplier becomes aware of an incident, injury, or infection resulting in a beneficiary's hospitalization or death. For other

### **TIP**

#### **Maintenance Plan for All Equipment**

The maintenance plan should provide for all inventory, including supplies that are discontinued, obsolete, or not patient-ready. Separate the clean and dirty supplies and log completed repairs.

Keep a tracking system or log of all your equipment by model, serial, or other identifying number to ensure recalled equipment can be located and to identify instances of theft. Show evidence that all equipment has been maintained. Log equipment calibration and temperature checks for refrigerated items.

### **TIP**

#### **Investigations**

When investigating an incident, injury, or infection, check the OSHA requirements for injury reporting under the Medical Devices Reporting Act.

occurrences, the supplier shall investigate within 72 hours after being made aware of the incident, injury, or infection. The investigation includes all necessary information, pertinent conclusions about what happened, and whether changes in system(s) or processes are needed. The supplier should consider possible links between the equipment, item(s), and service(s) furnished and the adverse event;

- Have a contingency plan that enables it to respond to emergencies and disasters or to have arrangements with alternative suppliers in the event that the supplier cannot service its own customers as the result of an emergency or disaster; and
- Verify, authenticate, and document the following prior to distributing, dispensing, or delivering products to an end-user:
  - The products are not adulterated, counterfeit, suspected of being counterfeit, and have not been obtained by fraud or deceit; and
  - The products are not misbranded and are appropriately labeled for their intended distribution channels.

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| <b>TIP</b> | <b>Contingency Plan</b><br>Ensure the contingency plan is specific for the geographical area and considers: <ul style="list-style-type: none"><li>• Patient care/services,</li><li>• Risk assessment,</li><li>• Data storage, and</li><li>• Communications.</li></ul> |
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### G. Information Management

The supplier shall maintain accurate, pertinent, accessible, confidential, and secure beneficiary records in accordance with privacy and security standards of the Health Insurance Portability and Accountability Act (HIPAA) and other applicable State standards.

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| <b>TIP</b> | <b>Information Management</b><br>Information management systems should be designed with consideration of natural disasters, multiple media formats (e.g., electronic, fax, and paper), marketing materials (e.g., not misleading and translated into languages appropriate for the target population), and back-up methods.<br>Evaluate the effectiveness of information management systems after they are in place.<br>Always back up the information on a daily basis. |
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## Section II: Supplier Product-Specific Service Requirements

1. All DMEPOS must serve a medical purpose to be covered under the Medicare Program and may require the prescribing physician to collaborate and coordinate clinical services with other health care professionals (e.g., orthotists; prosthetists; occupational, physical, respiratory therapists; and pedorthists).
2. In addition to the supplier product-specific service requirements in this section, the DMEPOS supplier shall implement the requirements stated in Appendices A through C, as applicable to its business.

### A. Intake & Assessment

1. The supplier shall:

- Consult with the prescribing physician as needed to confirm the order and to recommend any necessary changes, refinements, or additional evaluations to the prescribed equipment, item(s), and/or service(s);
- Review the beneficiary's record as appropriate and incorporate any pertinent information, related to the beneficiary's condition(s) that affect the provision of the DMEPOS and related services, or to the actual equipment, item(s), and service(s) provided, in collaboration with the prescribing physician; and
- Keep the DMEPOS prescription, any CMNs, and pertinent documentation from the beneficiary's prescribing physician unaltered in the beneficiary's record.

#### TIP

#### Intake & Assessment

The beneficiary's record must contain any information necessary to determine medical necessity, including:

- Certificates of Medical Necessity (CMNs),
- Prescriptions,
- Face-to-face evaluations,
- Physical assessments, and
- Telephone communications between the physician and the beneficiary.

### B. Delivery & Set-Up

1. The supplier shall:

- Deliver and set up, or coordinate set-up with another supplier, all equipment and item(s) in a timely manner as agreed upon by the beneficiary and/or caregiver, supplier, and prescribing physician;
- Provide all equipment and item(s) that are necessary to operate the equipment or item(s) and perform any further adjustments as applicable;
- Provide, or arrange for, loaner equipment equivalent to the original equipment during any repair period except for orthotics and prosthetics; and

#### TIP

#### Delivery & Set-Up

Provide the equipment in the time scheduled. The delivery person must be knowledgeable about the equipment.

- Assure that all equipment and item(s) delivered to the beneficiary is consistent with the prescribing physician’s order and identified beneficiary needs, risks, and limitations of which the supplier is aware.

### C. Training/Instruction to Beneficiary and/or Caregiver(s)

1. The supplier shall, as applicable:

- Provide, or coordinate the provision of, appropriate information related to the set-up (including preparation of enteral/parenteral nutrients), features, routine use, troubleshooting, cleaning, infection control practices, and maintenance of all equipment and item(s) provided;
- Provide relevant information and/or instructions about infection control issues related to the use of all equipment and item(s) provided;
- For initial equipment and/or item(s) provided by mail order delivery: verify and document in the beneficiary’s record that the beneficiary and/or caregiver(s) has received training and written instructions on the use of the equipment and item(s); and
- Ensure that the beneficiary and/or caregiver(s) can use all equipment and item(s) provided safely and effectively in the settings of anticipated use.

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| <b>TIP</b> | <p><b>Training/Instruction</b></p> <p>Provide written instructions to the beneficiary and/or caregiver(s) for initial equipment. Tailor the instruction to the ability, needs, learning preferences, and primary language of the beneficiary and/or caregiver(s). Document that the instructions were received and understood. Ensure that the beneficiary and/or caregiver know how to use the equipment safely.</p> |
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2. Beneficiary and/or caregiver(s) training and instructions shall be commensurate with the risks, complexity, and manufacturer’s instructions and/or specifications for the equipment and item(s). The supplier shall tailor training and instruction materials and approaches to the needs, abilities, learning preferences, and language of the beneficiary and/or caregiver(s).

### D. Follow-Up

The supplier shall provide follow-up services to the beneficiary and/or caregiver(s), consistent with the type(s) of equipment, item(s), and service(s) provided, and recommendations from the prescribing physician or health care team member(s).

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| <b>TIP</b> | <p><b>Beneficiary Record</b></p> <p>Document all training and communication in the beneficiary’s record, including the date, time, and signature of the person providing the service.</p> |
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## Appendix A: Respiratory Equipment, Supplies, and Services

1. Respiratory services encompass the provision of home medical equipment and supplies (described below) that require technical and professional services.
2. The supplier shall provide respiratory services 24 hours a day, 7 days a week as needed by the beneficiary and/or caregiver(s).
3. Home medical equipment and supplies covered in this appendix include:
  - Continuous Positive Airway Pressure (CPAP) devices;
  - Home invasive mechanical ventilators;
  - Intermittent Positive Pressure Breathing (IPPB) devices;
  - Nebulizers;
  - Oxygen concentrators, reservoirs, high-pressure cylinders, oxygen accessories and supplies, and oxygen conserving devices; and
  - Respiratory Assist Devices (RADs).



### A. Intake & Assessment

Refer to Section II: Supplier Product-Specific Service Requirements.

### B. Delivery & Set-Up

1. In addition to the requirements described in Section II: Supplier Product-Specific Service Requirements, the supplier shall comply with the current version of the “American Association for Respiratory Care Clinical Practice Guidelines” listed below:
  - “Intermittent Positive Pressure Breathing,”
  - “Long-Term Invasive Mechanical Ventilation in the Home,” and
  - “Oxygen Therapy in the Home or Alternate Site Health Care Facility.”

### C. Training/Instruction to Beneficiary and/or Caregiver(s)

1. In addition to the requirements described in Section II: Supplier Product-Specific Service Requirements, the supplier shall comply and provide training to the beneficiary and/or caregiver(s) consistent with the current version of the “American Association for Respiratory Care Clinical Practice Guidelines” listed below:
  - “Intermittent Positive Pressure Breathing,”
  - “Long-Term Invasive Mechanical Ventilation in the Home,”
  - “Oxygen Therapy in the Home or Alternate Site Health Care Facility,”



- “Providing Patient and Caregiver Training,” and
- “Suctioning of the Patient in the Home.”

#### **D. Follow-Up**

Refer to Section II: Supplier Product-Specific Service Requirements.

### **Appendix B: Manual Wheelchairs, Power Mobility Devices (PMDs), and Complex Rehabilitative Wheelchairs and Assistive Technology**

This appendix applies to manual wheelchairs, PMDs, and complex rehabilitative wheelchairs and assistive technology. Manual wheelchairs include standard recliners, heavy-duty wheelchairs, standard lightweight wheelchairs, and hemi wheelchairs, and armrests, legrests/footplates, anti-tipping devices, and other Medicare-approved accessories. PMDs include power wheelchairs and Power Operated Vehicles (POVs) and accessories. Complex rehabilitative wheelchairs are Group 2 power wheelchairs with power options, Group 3 power wheelchairs, and manual wheelchairs that can accommodate rehabilitative accessories and features (e.g., tilt in place).

#### **I. Manual Wheelchairs**

##### **A. Intake & Assessment**

In addition to Section II: Supplier Product-Specific Service Requirements, the supplier shall verify that seating, positioning, and specialty assistive technology have been evaluated and documented in the beneficiary’s record.

##### **B. Delivery & Set-Up**

Refer to Section II: Supplier Product-Specific Service Requirements.

##### **C. Training/Instruction to Beneficiary and/or Caregiver(s)**

Refer to Section II: Supplier Product-Specific Service Requirements.

##### **D. Follow-up**

Refer to Section II: Supplier Product-Specific Service Requirements.



## II. PMDs

### A. Intake & Assessment

In addition to Section II: Supplier Product-Specific Service Requirements, the supplier shall verify that seating, positioning, and specialty assistive technology have been evaluated and documented in the beneficiary's record.

### B. Delivery & Set-Up

Refer to Section II: Supplier Product-Specific Service Requirements.

### C. Training/Instruction to Beneficiary and/or Caregiver(s)

Refer to Section II: Supplier Product-Specific Service Requirements.

### D. Follow-Up

Refer to Section II: Supplier Product-Specific Service Requirements.



## III. Complex Rehabilitative Wheelchairs and Assistive Technology

In addition to Section II: Supplier Product-Specific Service Requirements, the supplier shall:

1. Employ (W-2 employee) at least one qualified individual as a Rehabilitative Technology Supplier (RTS) per location. A qualified RTS is an individual who has one of the following credentials:
  - Assistive Technology Professional (ATP); and
  - Certified Rehabilitative Technology Supplier (CRTS).
2. The RTS shall have at least one or more **trained technicians** available to service each location appropriately depending on the size and scope of its business. A trained technician is identified by the following:
  - Able to program and repair sophisticated electronics associated with power wheelchairs, alternative drive controls, and power seating systems;
  - Completed at least 10 hours annually of continuing education specific to rehabilitative technology;
  - Experienced in the field of rehabilitative technology (e.g., on-the-job training, familiarity with rehabilitative clients, products and services); and
  - Factory-trained by manufacturers of the products supplied by the company.

3. The RTS shall:

- Coordinate services with the prescribing physician to conduct face-to-face evaluations of the beneficiary in an appropriate setting and include input from other members of the health care team (i.e., physical therapist, occupational therapist);
- Implement procedures for assembly and set-up of equipment, as well as a process to verify that the final product meets the specifications of the original product recommendation approved by the prescribing physician;
- Maintain in the beneficiary's record all of the information obtained during the assessment; and
- Provide the beneficiary with appropriate equipment for trial and simulation, when necessary.

4. If beneficiaries are evaluated in the supplier's facility, the supplier shall:

- Maintain a repair shop and an area appropriate for assembly and modification of products located in the facility, in close proximity, or in a location easily accessible from another location of the supplier; and
- Provide the beneficiary private, clean, and safe rooms appropriate for fittings and evaluations.

**A. Intake & Assessment**

In addition to Section II: Supplier Product-Specific Service Requirements, the supplier shall verify that seating, positioning, and specialty assistive technology have been evaluated and documented in the beneficiary's record.



**B. Delivery & Set-Up**

Refer to Section II: Supplier Product-Specific Service Requirements.

**C. Training/Instruction to Beneficiary and/or Caregiver(s)**

Refer to Section II: Supplier Product-Specific Service Requirements.

**D. Follow-Up**

Refer to Section II: Supplier Product-Specific Service Requirements.



## **Appendix C: Custom Fabricated and Custom Fitted Orthoses, Prosthetic Devices, External Breast Protheses, Therapeutic Shoes and Inserts, and Their Accessories and Supplies; Custom-Made Somatic, Ocular, and Facial Protheses**

The supplier shall be trained in a broad range of treatment options to ensure that the item(s) prescribed is 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 certification and/or licensing and specialized education, training, and experience in fitting.

### **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;
  - 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) that 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 that the condition is of long and indefinite duration, the test of permanence is considered met. (Refer to the Internet-Only Manual [IOM], Publication 100-02, "Medicare Benefit Policy Manual," Chapter 15, Section 120 at <http://www.cms.gov/manuals/Downloads/bp102c15.pdf> on the CMS website.)
  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, hemifacial, 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 the IOM, Publication 100-02, "Medicare Benefit Policy Manual," Chapter 15, Section 120 at <http://www.cms.gov/manuals/Downloads/bp102c15.pdf> on the CMS website.)

11. **Off-The-Shelf Orthoses:** Orthoses that require 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 the IOM, Publication 100-02, "Medicare Benefit Policy Manual," Chapter 15, Section 140 at <http://www.cms.gov/manuals/Downloads/bp102c15.pdf> on the CMS website.)

a) **Custom-Molded Shoes:**

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

b) **Depth Shoes:**

- 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;
- Are made from leather or other suitable material of equal quality;
- 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.)

c) **Inserts:**

- 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 are made of a suitable material with regard to the patient's condition.

## A. Intake & Assessment

In addition to Section II: Supplier Product-Specific Service Requirements, the supplier shall:

- Assess the beneficiary's need for and use of the orthoses/prostheses (e.g., comprehensive history, pertinent medical history [including allergies to materials], skin condition, diagnosis, previous use of an orthoses/prostheses, results of diagnostic evaluations, beneficiary expectations, pre-treatment photographic documentation [when appropriate]);

- Determine the appropriate orthoses/prostheses and specifications based on beneficiary need for use of the orthoses/prostheses to ensure optimum therapeutic benefits and appropriate strength, durability, and function as required for the beneficiary;
- Formulate a treatment plan that is consistent with the prescribing physician's dispensing order and/or the written plan of care, in accordance with Medicare rules, and consult the physician when appropriate;
- Perform an in-person diagnosis-specific functional clinical examination as related to the beneficiary's use and need of the orthoses/prostheses (e.g., sensory function, range of motion, joint stability, skin condition [integrity, color, and temperature], presence of edema and/or wounds, vascularity, pain, manual muscle testing, compliance, cognitive ability, and medical history);
- Establish goals and expected outcomes of the beneficiary's use of the orthoses/prostheses (e.g., reduce pain, increase comfort, enhance function and independence, provide joint stability, prevent deformity, increase range of motion, address cosmetic issues, and/or promote healing) with feedback from the beneficiary and/or prescribing physician as necessary to determine the appropriateness of the orthoses/prostheses;
- Communicate to the beneficiary and/or caregiver(s) and prescribing physician the recommended treatment plan, including disclosure of potential risk, benefits, precautions, the procedures for repairing, replacing, and/or adjusting the device or item(s), and the estimated time involved in the process;
- Assess the orthoses/prostheses for structural safety and ensure that manufacturer guidelines are followed prior to face-to-face fitting/delivery (e.g., beneficiary weight limits, ensuring that closures work properly and do not demonstrate defects); and
- Ensure the treatment plan is consistent with the prescribing physician's dispensing order.

## **B. Delivery & Set-Up**

Not applicable to this appendix.

## **C. Training/Instruction to Beneficiary and/or Caregiver(s)**

In addition to Section II: Supplier Product-Specific Service Requirements, the supplier shall:

- Provide instructions to the beneficiary and/or caregiver(s) for the specific orthoses, prostheses, or therapeutic shoes/inserts as follows:
  - How to use, maintain, and clean the orthoses/prostheses (e.g., wearing schedules, therapy, residual limb hygiene, other pertinent instructions);





- How to don and doff the orthoses/prostheses, including how to adjust closures for proper fit;
- How to inspect the skin for pressure areas, redness, irritation, skin breakdown, pain, or edema;
- How to utilize an appropriate interface (e.g., stockinettes, socks, gloves, shoes) to accommodate the orthoses/prostheses where appropriate;
- How to report any problems related to the orthoses/prostheses to the supplier or the prescribing physician if changes are noted (e.g., changes in skin condition, heightened pain, increase in edema, wound concerns, changes in general health, height, weight, or intolerance to wearing the orthoses/prostheses as applicable);
- How to schedule follow-up appointments as necessary; and
- How to establish an appropriate “wear schedule” and schedule for tolerance of the orthoses/prostheses;
- Provide necessary supplies (e.g., adhesives, solvents, lubricants) to attach, maintain, and clean the items, as applicable, and information about how to subsequently obtain necessary supplies; and
- Refer the beneficiary back to the prescribing physician as necessary for intervention beyond the supplier’s scope of practice.

#### **D. Follow-Up**

In addition to Section II: Supplier Product-Specific Service Requirements, the supplier shall:

- Have access to a facility with the equipment necessary to provide follow-up treatment and fabrication/modification of the specific orthoses/prostheses;
- Review recommended maintenance with the beneficiary and/or caregiver(s);
- Solicit feedback from the beneficiary and/or caregiver and prescribing physician as necessary to determine the effectiveness of the orthoses/prostheses (e.g., wear schedule/tolerance, comfort, perceived benefits/detriments, ability to don and doff, proper usage and function, overall beneficiary satisfaction);
- Review and make changes to the treatment plan based on the beneficiary’s current medical condition;
- Continue to assist the beneficiary until the orthoses/prostheses reaches the optimal level of fit and function consistent with the treatment plan; and
- Provide appropriate beneficiary follow-up treatment consistent with the types of orthoses/prostheses or therapeutic shoe/inserts provided, the beneficiary’s diagnosis, specific care rendered, and recommendations.

# Medicare Deemed Accreditation Organizations (AOs) for Suppliers of DMEPOS

CMS deemed 10 AOs that will accredit suppliers of DMEPOS as meeting DMEPOS Quality Standards under Medicare Part B.

The accreditation requirement applies to suppliers of durable medical equipment, medical supplies, home dialysis supplies and equipment, therapeutic shoes, parenteral/enteral nutrition, transfusion medicine and prosthetic devices, and prosthetics and orthotics.

The AO listing below is in alphabetical order and is based on the DMEPOS Quality Standards. All DMEPOS suppliers need to comply with Section I and Section II of the DMEPOS Quality Standards. Suppliers need to comply with the Appendices as applicable. Suppliers can contact the AOs directly for accreditation information.

Each AO is deemed to provide accreditation for all of the DMEPOS Quality Standards in Section I, Section II, and the Appendices, except as noted below.

## **Accreditation Commission for Health Care, Inc. (ACHC)**

4700 Falls of Neuse Road, Suite 280  
Raleigh, NC 27609  
(919) 785-1214  
<http://www.achc.org>

## **American Board for Certification in Orthotics, Prosthetics & Pedorthics, Inc. (ABC)**

330 John Carlyle Street, Suite 210  
Alexandria, VA 22314  
(703) 836-7114  
<http://www.abcop.org>

## **Board of Certification/Accreditation, International (BOC)**

10451 Mill Run Circle, Suite 200  
Owings Mills, MD 21117  
(877) 776-2200  
<http://www.bocinternational.org>

## **Commission on Accreditation of Rehabilitation Facilities (CARF)**

6951 E. Southpoint Road  
Tucson, AZ 85756  
(888) 281-6531  
<http://www.carf.org/dmepos>

CARF does not provide accreditation for the DMEPOS Quality Standards in Appendix A; external breast prostheses; and custom-made somatic, ocular, and facial prostheses.

### **Community Health Accreditation Program (CHAP)**

1275 K Street, NW, Suite 800  
Washington, DC 20005  
(202) 862-3413  
<http://www.chapinc.org>

### **Healthcare Quality Association on Accreditation (HQAA)**

114 East 4<sup>th</sup> Street  
Waterloo, IA 50703 or  
P.O. Box 1948  
Waterloo, IA 50704  
(866) 909-4722 Fax: (877) 226-5564  
<http://www.hqaa.org>

### **National Association of Boards of Pharmacy (NABP)**

1600 Feehanville Drive  
Mount Prospect, IL 60056  
(847) 391-4406  
<http://www.nabp.net>

NABP does not provide accreditation for the DMEPOS Quality Standards in Appendix B; custom fabricated and custom fitted orthoses and prosthetic devices; and custom-made somatic, ocular, and facial prostheses.

### **The Compliance Team, Inc. (TCT)**

P.O. Box 160  
905 Sheble Lane, Suite 102  
Spring House, PA 19477  
(215) 654-9110  
<http://www.exemplaryprovider.com>

### **The Joint Commission (TJC)**

One Renaissance Boulevard  
Oakbrook Terrace, IL 60181  
(630) 792-5000  
<http://www.jointcommission.org>

### **The National Board of Accreditation for Orthotic Suppliers (NBAOS)**

1500 Commerce Parkway, Suite C  
Mount Laurel, NJ 08054  
(856) 380-6856  
<http://www.nbaos.org>

NBAOS does not provide accreditation for the DMEPOS Quality Standards in Appendix A or Appendix B.

## Resources

For more information about DMEPOS, the DMEPOS Quality Standards, and accreditation, refer to the resources listed below.

### Centers for Medicare & Medicaid Services (CMS)

<http://www.cms.gov>

### CMS Durable Medical Equipment (DME) Center

<http://www.cms.gov/center/dme.asp>

### CMS Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding

<http://www.cms.gov/DMEPOSCompetitiveBid>

### CMS DMEPOS Accreditation

[http://www.cms.gov/MedicareProviderSupEnroll/07\\_DMEPOSAccreditation.asp](http://www.cms.gov/MedicareProviderSupEnroll/07_DMEPOSAccreditation.asp)

- For more information on the CMS DMEPOS Accreditation process, refer to “The Basics of DMEPOS Accreditation Fact Sheet” (ICN 905710) at [http://www.cms.gov/MLNProducts/downloads/DMEPOS\\_Basics\\_FactSheet\\_ICN905710.pdf](http://www.cms.gov/MLNProducts/downloads/DMEPOS_Basics_FactSheet_ICN905710.pdf) on the CMS website.
- For more information on accreditation of pharmacies, refer to the “DMEPOS Information for Pharmacies Fact Sheet” (ICN 905711) at [http://www.cms.gov/MLNProducts/downloads/DMEPOS\\_Pharm\\_FactSheet\\_ICN905711.pdf](http://www.cms.gov/MLNProducts/downloads/DMEPOS_Pharm_FactSheet_ICN905711.pdf) on the CMS website.

### CMS DMEPOS Supplier Standards

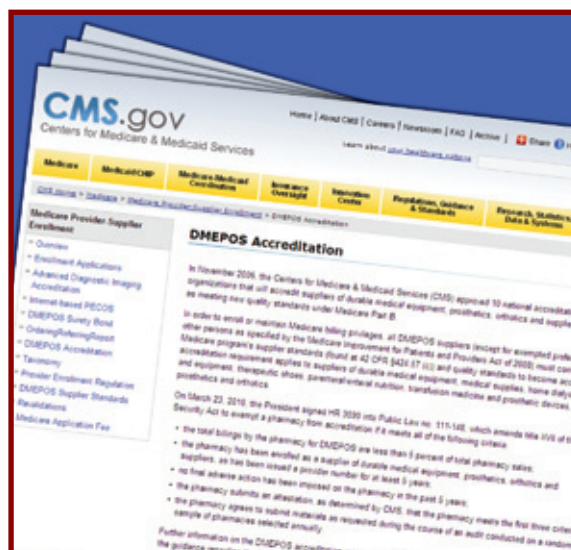
In addition to meeting the DMEPOS Quality Standards, all Medicare DMEPOS suppliers must be in compliance with these supplier standards in order to obtain and retain their billing privileges.

[http://www.cms.gov/MedicareProviderSupEnroll/10\\_DMEPOSSupplierStandards.asp](http://www.cms.gov/MedicareProviderSupEnroll/10_DMEPOSSupplierStandards.asp)

## TIP

### Enrollment for DMEPOS Suppliers

For information on enrollment for DMEPOS suppliers, including the surety bond and application fee, visit <http://www.cms.gov/MedicareProviderSupEnroll> on the CMS website.





## **CMS Internet-Only Manuals (IOMs)**

<http://www.cms.gov/Manuals/IOM/list.asp>

The following IOM chapters contain information of particular importance for DMEPOS suppliers (note that these are not the only IOM chapters relevant to DMEPOS suppliers):

- Publication 100-02, “Medicare Benefit Policy Manual”
  - Chapter 15 discusses coverage of some DMEPOS items and services.
- Publication 100-04, “Medicare Claims Processing Manual”
  - Chapter 20 discusses DMEPOS.
  - Chapter 30 discusses financial liability protections, including proper use of the Advance Beneficiary Notice of Noncoverage (ABN).
- Publication 100-08, “Medicare Program Integrity Manual”
  - Chapter 5 discusses special considerations for medical review of DME claims, including information on prescriptions, orders, and documentation.

## **Department of Health & Human Services (HHS) Office of Inspector General (OIG)**

<http://www.oig.hhs.gov>

## **National Supplier Clearinghouse (NSC)**

<http://www.palmettogba.com/nsc>

## **DME Medicare Administrative Contractors (DME MACs)**

- **Jurisdiction A:** National Heritage Insurance Company (NHIC)  
<http://www.medicarenhic.com/dme>
- **Jurisdiction B:** National Government Services (NGS)  
<http://www.ngsmedicare.com>
- **Jurisdiction C:** Cigna Government Services  
<http://www.cgsmedicare.com/jc>
- **Jurisdiction D:** Noridian Administrative Services (NAS)  
<http://www.noridianmedicare.com/dme>



## **Common Electronic Data Interchange (CEDI)**

<http://www.ngscedi.com>

## **International Classification of Diseases, 9<sup>th</sup> Revision, Clinical Modification (ICD-9-CM) Codes**

<http://www.cdc.gov/nchs/icd/icd9cm.htm>

**International Classification of Diseases, 10<sup>th</sup> Revision, Clinical Modification/  
Procedure Coding System (ICD-10-CM/PCS)**

<http://www.cms.gov/ICD10>

**Claim Adjustment Reason Codes (CARCs) and Remittance Advice Remark  
Codes (RARCs)**

<http://www.wpc-edi.com/reference>

**DME Pricing Data Analysis and Coding (PDAC)**

<https://www.dmepdac.com>

**American Orthotic & Prosthetic Association (AOPA)**

<http://www.aopanet.org>

**American Association for Respiratory Care (AARC) Clinical Practice Guidelines**

<http://www.rcjournal.com/cpgs/index.cfm>





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