



DMEPOS QUALITY STANDARDS

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Introduction

Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) must meet DMEPOS Quality Standards established by the Centers for Medicare & Medicaid Services (CMS) under the Medicare Modernization Act of 2003 (MMA).

DMEPOS suppliers must comply with the [DMEPOS Quality Standards](#) and become accredited to obtain or maintain Medicare billing privileges unless exempted from the accreditation requirement. Understanding the DMEPOS Quality Standards and involving all staff in the process will help you meet the DMEPOS Quality Standards and obtain accreditation. This booklet outlines the DMEPOS Quality Standards, gives specific standards for some DMEPOS items, and provides resources for more information.

Please note: The information in this publication applies only to the Medicare Fee-For-Service Program (also known as Original Medicare).

Table 3. Hyperlink Table, at the end of this document, provides the complete URL for each hyperlink.

Face-to-Face Requirement

The Affordable Care Act requires a physician to document when the physician or a physician assistant, nurse practitioner, or clinical nurse specialist had a face-to-face encounter with a Medicare beneficiary in the 6 months prior to the written order for certain items of Durable Medical Equipment (DME). For more information on the face-to-face encounter requirement, refer to MLN Matters® Article MM8304, [Detailed Written Orders and Face-to-Face Encounters](#).

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

- **Section I: Supplier Business Services Requirements**, which addresses administration, financial management, human resources management, consumer services, performance management, product safety, and information management
- **Section II: Supplier Product-Specific Service Requirements**, which addresses intake and assessment, delivery and set-up, training/instruction, and follow-up
- **Appendices**, which describe the requirements for specific types of DMEPOS items and services:
 - **Appendix A:** Respiratory Equipment, Supplies, and Services
 - **Appendix B:** Manual Wheelchairs, Power Mobility Devices (PMDs), and Complex Rehabilitative Wheelchairs and Assistive Technology
 - **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

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, Chief Executive Officer (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

One person or several can meet leadership requirements (for example, the owner, governing body, or 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. An organizational chart should show the leadership has the legal authority to make all decisions and is accountable for those decisions.

FDA Reporting Requirements

For more information, visit the [FDA reporting requirements](#) webpage.

5. The supplier shall comply with all Medicare statutes, regulations (including the disclosure of ownership and control information requirements at [42 Code of Federal Regulations \[CFR\] 420.201–420.206](#)), 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.

Create a Compliance Program

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

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-based 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:
 - 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’ size and scope of services; and
 - Having a mechanism to track actual revenues and expenses.

Tip: Financial Management

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

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.

Human Resources Management

- Conduct performance evaluations for both employees and contractors
- Document compliance with all applicable health requirements (for example, tuberculosis [TB], hepatitis B virus [HBV], or drug screening required by State law)
- Document the contractor's compliance and accreditation for contractual relationships
- Include educational requirements in job descriptions
- Instruct employees on duties and Occupational Safety & Health Administration (OSHA) requirements
- Perform background checks according to State law
- Verify all employees and contractors are eligible to participate in Federal health care programs at [SAM.gov](https://www.sam.gov)
- Verify all professional licenses and certificates through the appropriate website, including Commercial Driver's Licenses (CDLs) for van drivers, if necessary

D. Consumer Services

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

Customer Service

Beneficiaries must be able to contact their supplier 24 hours a day, 7 days a week.

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).
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;

Tip: Measuring Outcomes

When designing outcomes measures, target:

- Adverse events
- Beneficiary service satisfaction
- Billing practices
- Consumer services
- Items or services that are:
 - High risk (for example, complex rehabilitation or ventilators)
 - High volume (for example, diabetic supplies)
 - Problem-prone (for example, PMDs)
- Timeliness of response

- Frequency of billing and coding errors (for example, 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) (for example, 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

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;

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 is maintained. Log equipment calibration and temperature checks for refrigerated items.

- 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

Tip: Investigations

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

the supplier becomes aware of an incident, injury, or infection resulting in a beneficiary's hospitalization or death. For other 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.

Tip: Contingency Plan

Ensure the contingency plan is specific for the geographical area and considers:

- Communications
- Data storage
- Patient care/services
- Risk assessment

Always back up your information daily!

Design information management systems considering:

- Back-up methods
- Multiple media formats (for example, electronic, fax, and paper)
- Natural disasters
- Suitability of marketing materials (that is, translated into languages appropriate for the target population and not misleading)

Evaluate the effectiveness of information management systems after they are in place.

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.

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 (for example, 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

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 Certificates of Medical Necessity (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)
- Face-to-face encounter records
- Physical assessments
- Prescriptions
- Telephone communication logs between the physician and the beneficiary

B. Delivery & Set-Up

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

Tip: Delivery & Set-Up

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

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.

Tip: Training/Instruction

Provide written instructions to the beneficiary and/or caregivers for initial equipment. Tailor the instructions to the ability, needs, learning preferences, and primary language of the beneficiary and/or caregivers. Document that you provided the instructions and the beneficiary and/or caregivers understood them. Ensure the beneficiary and/or caregivers know how to use the equipment safely.

- ### 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).

Beneficiary Record

Document all training and communication in the beneficiary's record, including the date, time, and signature of the person providing the service.

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).

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

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)

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 (for example, tilt in space).

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); or
 - 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 (for example, 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 encounters of the beneficiary in an appropriate setting and include input from other members of the health care team (that is, 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 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 optimal for the beneficiary's condition.

The provision of custom fabricated or custom fitted devices (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

These terms 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.

Key Terms

For more information about the terms used in this appendix, refer to the Internet-Only Manual (IOM), Publication 100-02, [Medicare Benefit Policy Manual, Chapter 15](#) or [42 CFR 414.402](#).

- a) **Molded-to-Patient-Model:** A **particular type** of custom fabricated device in which either:
- i. 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
 - ii. 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.
- b) **Positive Model of the Patient:**
- i. Molded-to-patient-model is a negative impression taken of the patient's body member and a positive model rectification is constructed;
 - ii. 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
 - iii. 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.
2. **Custom Fitted:** Custom fitted orthotics are defined as devices that are prefabricated. They may or may not be supplied as a kit that requires some assembly. They all require fitting and adjustment (for example, the item must be trimmed, bent, molded [with or without heat], or otherwise modified by an individual with expertise in customizing the fit in order for it to be used by a specific patient). Custom fitted requires modification of the item in order to provide an individualized fit. Modifications must result in alterations in the item beyond simple adjustments made by bending, trimming, and/or molding of the item, installation of add-on components or assembly of the item.

3. **Off-The-Shelf:** Off-the-shelf (OTS) orthotics are defined as those prefabricated items which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual. Appendix C does not apply to OTS orthotics.
4. **Minimal Self-Adjustment:** Minimal self-adjustment is defined at 42 CFR 414.402 as an adjustment 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 Orthotics/Prosthetist Certification) or an individual who has specialized training.
5. **Specialized Training:** Individuals with specialized training necessary to provide custom fitting services for patients with a medical need for orthotics include: a physician, a treating practitioner (a physician assistant, nurse practitioner, or clinical nurse specialist), an occupational therapist, or physical therapist in compliance with all applicable Federal and State licensure and regulatory requirements.
6. **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.
7. **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.
8. **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.
9. **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.
10. **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.
11. **External Breast Prostheses:** Prefabricated or custom fabricated forms, bras, and sleeves.

12. Therapeutic Shoes and Inserts: Includes depth or custom-molded shoes along with inserts for individuals with diabetes.

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 (for example, reviewing the beneficiary's comprehensive history, pertinent medical history [including allergies to materials], skin condition, diagnosis, previous use of an orthoses/prostheses, results of diagnostic evaluations, beneficiary expectations, and 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 (for example, 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 (for example, 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 encounter for fitting/delivery (for example, 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 (for example, 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 (for example, 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 (for example, 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 (for example, 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 (for example, 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.

Accreditation Organizations (AOs) for Suppliers of DMEPOS

To enroll or maintain Medicare billing privileges, all DMEPOS suppliers (except for exempted professionals and other specified persons) must comply with the Medicare Program's supplier standards and quality standards to become accredited. CMS deemed AOs to accredit DMEPOS suppliers 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
- Prosthetics and orthotics

Suppliers can contact the AOs directly for accreditation information using this [AO list](#).

Supplier Standards and Quality Standards

Suppliers must be in compliance with the current supplier standards to obtain and/or maintain Medicare billing privileges through the National Supplier Clearinghouse (NSC). The supplier standards are published in [42 CFR 424.57\(c\)](#).

The quality standards are guidelines used by the CMS-approved AOs that suppliers must comply with to become accredited.

The NSC and the AOs are completely autonomous. Compliance with one entity does not guarantee compliance with the other.

Resources

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

Table 1. Applicable Regulations and Guidance

Resource	Description and Website
Coverage Determinations	Local Coverage Determinations (LCDs) and National Coverage Determinations (NCDs) in the Medicare Coverage Database CMS.gov/medicare-coverage-database
Enrollment Standards	42 CFR 424.57 GPO.gov/fdsys/pkg/CFR-2015-title42-vol3/pdf/CFR-2015-title42-vol3-sec424-57.pdf
Internet-Only Manuals (IOMs)	CMS.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html IOM chapters with important information for DMEPOS suppliers: <ul style="list-style-type: none"> • Publication 100-02, Medicare Benefit Policy Manual <ul style="list-style-type: none"> ◦ Chapter 15 discusses coverage of some DMEPOS items and services • Publication 100-04, Medicare Claims Processing Manual <ul style="list-style-type: none"> ◦ 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 <ul style="list-style-type: none"> ◦ Chapter 5 discusses special considerations for medical review of DME claims, including information on prescriptions, orders, and documentation
Occupational Safety & Health Administration (OSHA)	Regulations on infection control, fire and safety, and local fire codes OSHA.gov
State Law	DMEPOS suppliers must comply with local business licenses, fire codes, and transportation regulations. Contact your local agency or administration for information.
U.S. Department of Transportation	Follow regulations applicable to vehicles Transportation.gov

Table 2. DMEPOS Resources

Resource	Website
CMS Resources	<p>DME Center CMS.gov/Center/Provider-Type/Durable-Medical-Equipment-DME-Center.html</p> <p>DMEPOS Accreditation CMS.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/DMEPOSAccreditation.html</p> <p>“DMEPOS Accreditation” publication at CMS.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/MLN-Publications-Items/CMS1246764.html</p> <p>“DMEPOS Information for Pharmacies” publication at CMS.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/MLN-Publications-Items/CMS1246766.html</p> <p>DMEPOS Competitive Bidding CMS.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid</p> <p>DMEPOS Supplier Enrollment CMS.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll</p> <p>DMEPOS Supplier Standards CMS.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/downloads/DMEPOSSupplierStandards.pdf</p>
U.S. Department of Health & Human Services (HHS) Office of Inspector General (OIG)	OIG.hhs.gov
DME Medicare Administrative Contractors (DME MACs)	CMS.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map
Medicare Learning Network® (MLN) Guided Pathways	CMS.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/Guided_Pathways_Provider_Specific_Booklet.pdf
National Supplier Clearinghouse (NSC)	Palmettogba.com/nsc

Table 2. DMEPOS Resources (cont.)

Resource	Website
Other Resources	<p>American Association for Respiratory Care (AARC) Clinical Practice Guidelines RCjournal.com/cpgs</p> <p>American Orthotic & Prosthetic Association (AOPA) AOPAnet.org</p> <p>Claim Adjustment Reason Codes (CARCs) and Remittance Advice Remark Codes (RARCs) WPC-EDI.com/reference</p> <p>Common Electronic Data Interchange (CEDI) NGSCEDI.com</p> <p>DME Pricing Data Analysis and Coding (PDAC) DMEPDAC.com</p> <p>International Classification of Diseases CDC.gov/nchs/icd</p>
Physician Self-Referral Law (Stark Law) Considerations for DMEPOS Suppliers	<p>42 CFR 411.355 GPO.gov/fdsys/pkg/CFR-2015-title42-vol2/pdf/CFR-2015-title42-vol2-sec411-355.pdf</p> <p>Physician Self-Referral CMS.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral</p> <p>“Physician Self-Referral Law” Health Care Fraud Prevention and Enforcement Action Team (HEAT) Provider Compliance Training Video YouTube.com/watch?v=hmWG4o5zrvQ</p>

Table 3. Hyperlink Table

Embedded Hyperlink	Complete URL
42 CFR 414.402	https://www.gpo.gov/fdsys/pkg/CFR-2015-title42-vol3/pdf/CFR-2015-title42-vol3-sec414-402.pdf
42 CFR 424.57(c)	https://www.gpo.gov/fdsys/pkg/CFR-2015-title42-vol3/pdf/CFR-2015-title42-vol3-sec424-57.pdf
42 Code of Federal Regulations [CFR] 420.201–420.206	https://www.gpo.gov/fdsys/pkg/CFR-2015-title42-vol3/pdf/CFR-2015-title42-vol3-part420-subpartC.pdf
American Association for Respiratory Care Clinical Practice Guidelines	http://www.rcjournal.com/cpgs
AO List	https://www.cms.gov/Medicare/provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/DeemedAccreditationOrganizationsCMB.pdf
Detailed Written Orders and Face-to-Face Encounters	https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8304.pdf
DMEPOS Quality Standards	https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/DMEPOSAccreditationStandardsCMB.pdf
FDA Reporting Requirements	http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm
Medicare Benefit Policy Manual, Chapter 15	https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf