

Quality Standards
Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
(DMEPOS)
(8-14-2006)

I. Business Services

Administration

The supplier shall govern its business so that it obtains and provides appropriate quality equipment, items, and services to beneficiaries.

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, and other individuals responsible for managing services provided by the organization.

2. The supplier shall have a physical location and display all licenses, certificates, and permits to operate. The licenses and certificates 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.
3. The supplier shall provide only durable medical equipment, prosthetics, orthotics, and supplies (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.
4. The supplier shall:
 - Comply with Medicare coverage, claim processing, and payment policies; and
 - Comply with the Medicare disclosure of ownership and control information requirements at 42 CFR 420.201 through 420.206.
5. 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.

Financial Management

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. The supplier shall maintain accounts that link equipment and items 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's size and scope of services; and
- Having a mechanism to track actual revenues and expenses.

Human Resource Management

The supplier shall implement policies to specify personnel qualifications, training, experience, and continuing education requirements consistent with the specialized equipment, items, and services it provides to beneficiaries. The supplier shall provide copies, upon request, to accreditation organizations and government officials or their authorized agents.

Technical personnel shall be competent to deliver and set-up equipment and items and train beneficiaries. Professional personnel shall be licensed, certified, or registered and function within their scope of practice as required by the State standard under which the professional is licensed. The supplier shall maintain copies or other verification of licenses, registrations, certifications, and competency assessments for personnel who provide beneficiary services.

Consumer Services

1. When providing equipment, items, and services to beneficiaries, the supplier shall ensure that it:
 - Provides clear instructions related to the use, maintenance, and potential hazards of equipment and items;
 - Provides beneficiaries with information regarding expected time frames for receipt of delivered items;
 - Verifies that the beneficiary has received equipment, items, and services;

- Provides beneficiaries essential contact information for rental equipment and options for beneficiaries to rent or purchase equipment and items, when applicable; and
 - Provides the beneficiary with information and telephone numbers for customer service assistance regarding regular business hours, after-hours access, item repair, and emergency coverage.
2. The supplier shall notify the prescribing physician (for purposes of these standards, we are using this term to include other practitioners who can prescribe DMEPOS under Medicare laws and regulations) or other healthcare team member promptly, but in no case less than five (5) calendar days, if it cannot provide the equipment, items or services that are prescribed for a beneficiary.
 3. Within five (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 that it is investigating. Within 14 calendar days, the supplier shall provide written notification to the beneficiary of the results of its investigation and response. The supplier shall maintain documentation of all complaints that it receives, copies of the investigations, and responses to beneficiaries.

Performance Management

The supplier shall implement a performance management plan that measures the 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 adjustments, repairs, or replacement; or require significant instruction to assure safe use and benefit of items.

At a minimum, each supplier shall measure:

- Beneficiary satisfaction with and complaints about product(s) and service(s);
- Timeliness of response to beneficiary questions, problems, and concerns;
- Impact of the supplier's business practices on the adequacy of beneficiary access to equipment, items, services, 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 or malfunctioning equipment, items, or services (e.g., injuries, accidents, hospitalizations). This may be identified through follow-up with the prescribing physician, other healthcare team members, or the beneficiary or caregiver.

Product Safety

The supplier shall implement an equipment and item management program that promotes the safe use of equipment and items and minimizes safety risks and hazards both for its staff and for beneficiaries.

1. The supplier shall implement and maintain a plan for identifying, monitoring, and reporting (where indicated) equipment and item failure, repair, and preventive maintenance, for equipment and items provided to beneficiaries.
2. The supplier shall investigate any incident or injury in which DMEPOS may have contributed to the injury or incident, when the supplier becomes aware. The investigation should be initiated within 24 hours after a supplier becomes aware of an injury or incident 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 or injury. The investigation includes all necessary information, pertinent conclusions about what happened, and whether changes in systems or processes are needed. The supplier should consider possible links between the items and services furnished and the adverse event.
3. The supplier shall 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.

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.

II. General Product-Specific Service Standards

All DMEPOS must serve a medical purpose to be covered under the Medicare program and may require the physician to collaborate and coordinate clinical services with other healthcare professionals (e.g., orthotists; prosthetists; occupational, physical, and respiratory therapists; pedorthists; etc.). In addition to the general product specific services, a supplier shall implement the supplemental product specific standards in Appendices A through C, as applicable to its business.

Preparation

Intake

The supplier shall:

- Comply with CMS regulations, policies, and Medicare contractor policies and articles;

- Consult with the prescribing physician as needed to confirm the order and to recommend any necessary changes or refinements or additional evaluations to the prescribed items and services; and
- Assure that the item delivered to the beneficiary is consistent with the prescribing physician's order and other identified beneficiary needs, risks, and limitations of which the supplier is aware.

Beneficiary Record

The supplier shall:

- As appropriate, review the beneficiary's record and incorporate any necessary revisions, related to the beneficiary's conditions, which affect the provision of the DMEPOS and related services or to the actual items and services provided, in collaboration with the prescribing physician.

Delivery and Setup

The supplier shall:

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

Training/Instruction to Beneficiary and Caregiver

The supplier shall, as applicable:

- Provide, or coordinate the provision of, appropriate information related to the setup (including preparation of formulas), features, routine use, troubleshooting, cleaning, and maintenance of the items provided;
- Advise the beneficiary and caregiver about appropriate safety considerations;
- Provide relevant information and/or instructions about infection control issues related to the use of the equipment and items;
- Verify that the beneficiary has received training and instructions on the use of items at the time of **initial** mail order delivery of items; and
- Record in the beneficiary's record that such instruction was provided.

Beneficiary training and instructions shall be commensurate with the risks, complexity, and manufacturer's instructions and/or specifications for items. The supplier shall tailor training and instruction materials and approaches to the needs, abilities, learning preferences, language, and readiness to learn of individual beneficiaries or caregivers.

Follow-up

- The supplier shall provide follow-up services to the beneficiary, consistent with the types of equipment, items and service(s) provided, and recommendations from the prescribing physician or healthcare team members.

Appendix A: Respiratory Equipment, Supplies, and Services

Respiratory Services encompass the provision of home medical equipment and supplies (described below) that require technical and professional services.

The supplier shall provide respiratory services 24 hours a day, 7 days a week as needed by the beneficiary.

Home medical equipment and supplies covered in this standard include:

- Oxygen concentrators, reservoirs, high-pressure cylinders, oxygen accessories and supplies, and oxygen conserving devices
- Home Invasive Mechanical Ventilators
- Continuous Positive Airway Pressure (CPAP) Devices
- Respiratory Assist Devices (RAD)
- Intermittent Positive Pressure Breathing Devices
- Nebulizers

Preparation

See General Product-Specific Service Standards

Delivery and Set-up

In addition to the requirements described in the General Product Specific Service Standards, the supplier shall comply with the following current *American Association for Respiratory Care Practice Guidelines*:

- Oxygen Therapy in the Home or Extended Care Facility;
- Long Term Invasive Mechanical Ventilation in the Home; and
- Intermittent Positive Pressure Breathing.

Training/Instruction to Beneficiary and Caregiver

In addition to the requirements described in the General Product-Specific Service Standards, the supplier shall provide training to beneficiaries or caregivers consistent with the following current *American Association for Respiratory Care Practice Guidelines*:

- Long Term Invasive Mechanical Ventilation in the Home;

- Oxygen Therapy in the Home or Extended Care Facility;
- Intermittent Positive Pressure Breathing;
- Providing Patient and Caregiver Training; and
- Suctioning of the Patient in the Home.

Follow-up

See General Product-Specific Service Standards

Appendix B: Manual Wheelchairs and Power Mobility Devices, including Complex Rehab and Assistive Technology

This standard applies to manual wheelchairs, power mobility devices (PMDs), including Complex Rehab and Assistive Technology. PMDs include power wheelchairs and power operated vehicles (POVs) and accessories. Manual wheelchairs include standard recliners, heavy-duty wheelchairs, standard lightweight wheelchairs, and hemi wheelchairs, armrests, leg rests/footplates, anti-tipping devices, and other Medicare-approved accessories.

A. Manual Wheelchairs and PMDs

Preparation

Intake

The supplier shall:

- Comply with CMS regulations and Medicare contractor policies and articles; and
- Ensure that the equipment provided is consistent with the prescribing physician's order.

Delivery/Setup

See General Product-Specific Service Standards

Training/Instruction to Beneficiary and Caregiver(s)

See General Product-Specific Service Standards

B. Complex Rehab and Assistive Technology

1. The supplier shall employ at least one qualified Rehab Technology Supplier (RTS) or be certified as a RTS per location. A qualified RTS is an individual that is or has one of the following credentials:
 - Certified Rehab Technology Supplier (CRTS);
 - Assistive Technology Supplier (ATS); or
 - Assistive Technology Practitioner (ATP).
2. The Rehab Technology Supplier 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:
 - Factory trained by manufacturers of the products supplied by the company;
 - Experienced in the field of Rehab Technology, e.g. on the job training, familiarity with Rehab clients, products and services;

- Completed at least ten hours of continuing education specific to Rehab Technology; and
- Able to program and repair sophisticated electronics associated with power wheelchairs, alternative drive controls, and power seating systems.

3. The Rehab Technology Supplier shall:

- Coordinate services with the prescribing physician to conduct face-to-face evaluations of the beneficiary in an appropriate setting and includes input from other members of the health care team (i.e. PT, OT, prescribing physician etc.);
- Provide the beneficiary with appropriate equipment for trial and simulation, when necessary;
- Maintain in the beneficiary's record all of the information obtained during the assessment; and
- 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.

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

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

Appendix C: Custom Fabricated, Custom Fitted, Custom-Made Orthotics, Prosthetic Devices, Somatic, Ocular and Facial Prosthetics, and Therapeutic Shoes and Inserts

The supplier shall be trained in a broad range of treatment options to ensure that the items prescribed are optimal for the beneficiary's condition. The provision of customized items and devices services (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 and fabrication/modification of the specific device.

Definitions of Terms

The following terms are used to describe the types of devices referred to in this standard:

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.

1. A custom fabricated item is defined as a device which is fabricated based on a clinically derived rectified casting, tracings, measurements, and/or other images (such as x-rays) of the body part. It may involve using calculations, templates, and components. The process starts with 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. It involves substantial work such as vacuum forming, cutting, bending, molding, sewing, drilling, and finishing prior to fitting on the patient.
2. A molded-to-patient-model item is 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 manufacture (CAD-CAM) systems software. This technology includes specialized probe/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.

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. 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.

Prefabricated: A prefabricated (also referred to as custom fitted) device is one which is manufactured in quantity without a specific patient in mind. The device may be supplied as a kit of prefabricated parts that require some assembly and/or fitting and adjustment, or a device that must be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific patient (i.e., custom fitted).

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.

Ocular Prosthetics: Custom-made ocular prostheses 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.

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

Somatic Prosthetics: Custom-made 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.

Preparation

Intake

In addition to the requirements described in the General Product-Specific Service Requirements, the supplier shall:

- Comply with CMS regulations and Medicare contractor policies and articles;
- Perform a diagnosis-specific clinical examination for the use of the item;
- Collect pre-treatment photographic documentation as appropriate for the item;
- Assess the item for structural safety and ensure that manufacturer guidelines are followed prior to fitting/delivery; and

- Assure the implementation plan is consistent with the prescribing physician's dispensing order and/or the written plan of care.

Beneficiary Record

In addition to the requirements described in the General Product-Specific Service Requirements, the supplier shall:

- Establish goals and expected outcomes for the beneficiary;
- Solicit feedback from the beneficiary, and physician as necessary, to determine the effectiveness of the items;
- Communicate to the beneficiary and/or prescribing physician the recommended treatment plan and any optional plans, including disclosure of potential risks/benefits involved;
- Consult with the prescribing physician before finalizing the service plan if it differs from physician's order; and
- Refer the beneficiary back to the prescribing physician for intervention or treatment beyond the supplier's scope of practice.

Delivery and Set-up: Not applicable to this standard.

Training/Instruction to Beneficiary and Caregiver(s)

In addition to the requirements described in the General Product-Specific Service Requirements, the supplier shall provide instructions to the beneficiary and/or caregiver for the specific items and devices as follows:

- Review care and maintenance instructions;
- 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;
- Inspecting and monitoring for complications;
- Reporting any problem to the supplier and/or referring physician of changes in condition or general health.

Follow-up

In addition to the requirements described in the General Product-Specific Service Requirements, the supplier shall:

- Provide appropriate beneficiary follow-up care consistent with the items or service(s) provided, the beneficiary's diagnosis, specific care rendered, and recommendations;
- Inform the beneficiary or caregiver of the procedures for repairing, replacing, and/or adjusting the device or items, the possible risks, and estimated time involved in the process;
- Have access to the equipment (or another provider who has it) needed to modify or adjust the item; and
- Advise the patient to make an appointment with the prescribing physician, as appropriate for the use of the specific items or service.