DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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# DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, and SUPPLIES (DMEPOS) QUALITY STANDARDS

***FINAL***

***Effective: August 12, 2024***

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## 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, 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 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.

5. The supplier shall comply with all Medicare statutes, regulations (including the disclosure of ownership and control information requirements at 42 CFR §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:

    - 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:

    - 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 purpose of theses standards, we are using this term to include 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.

## 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;
- 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 healthcare team member(s), or 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.

## 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 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.

## 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.

Patient medical records must be reviewed as part of the accreditation survey. Patient medical records shouldn't include:

- Mock files
- Fictional patients
- Simulated documentation
- Templates

Non-Medicare patient records can be used during the initial accreditation survey; however, patient records reviewed for reaccreditation must be from Medicare patients.

## 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 healthcare professionals (e.g., orthotists; prosthetists; occupational, physical, respiratory therapists; pedorthists; etc.).

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).

*Beneficiary's Record*

2. The supplier shall:

- Review the beneficiary's record as appropriate and incorporate any pertinent information, related to the beneficiary's condition(s) which 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
- The DMEPOS prescription, any certificates of medical necessity (CMNs), and pertinent documentation from the beneficiary's prescribing physician shall be kept unaltered in the beneficiary's record.

### 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
- 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.

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 healthcare team member(s).

# Appendices

## 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:

    - 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 (IPPB) Devices; and
    - Nebulizers.

### 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 Practice Guidelines*** listed below:

    - Oxygen Therapy in the Home or Extended Care Facility;
    - Long Term Invasive Mechanical Ventilation in the Home; and
    - IPPB.

### 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 Practice Guidelines*** listed below:

    - Long Term Invasive Mechanical Ventilation in the Home;
    - Oxygen Therapy in the Home or Extended Care Facility;

- IPPB;
- 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, and Complex Rehabilitative Wheelchairs and Assistive Technology

This appendix applies to Manual Wheelchairs, Power Mobility Devices (PMDs), and Complex Rehabilitative Wheelchairs and Assistive Technology. Manual wheelchairs include standard recliners, heavy-duty wheelchairs, standard lightweight wheelchairs, and hemi wheelchairs, 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. Power Mobility Devices

#### 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 that has one of the following credentials:

    - Certified Rehabilitative Technology Supplier (CRTS);
    - Assistive Technology Supplier (ATS) (discontinued 12/31/2008);
    - Assistive Technology Practitioner (ATP) (discontinued 12/31/2008);
    - Assistive Technology Professional (ATP) (effective 1/1/2009).

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:

- Factory trained by manufacturers of the products supplied by the company;
- Experienced in the field of Rehabilitative Technology, (e.g., on the job training, familiarity with rehabilitative clients, products and services);
- Completed at least 10 hours annually of continuing education specific to Rehabilitative Technology; and
- Able to program and repair sophisticated electronics associated with power wheelchairs, alternative drive controls, and power seating systems.

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., PT, OT, 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.

**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/are optimal for the beneficiary's condition. The provision of custom fabricated or custom fitted devices (i.e., other than off-the-shelf items) requires access to a facility with the equipment necessary to fulfill the supplier's responsibility to provide follow-up treatment, including modification, adjustment, maintenance and repair of the item(s). Individuals supplying the item(s) set out in this appendix must possess specialized education, training, and experience in fitting, and certification and/or licensing.

### Definition of Terms

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

1. **Custom Fabricated:** A custom fabricated item is one that is individually made for a specific patient. No other patient would be able to use this item. A custom fabricated item is a device which is fabricated based on clinically derived and rectified castings, tracings, measurements, and/or other images (such as x-rays) of the body part. The fabrication may involve using calculations, templates and components. This process requires the use of basic materials including, but not limited to plastic, metal, leather or cloth in the form of uncut or unshaped sheets, bars, or other basic forms and involves substantial work such as vacuum forming, cutting, bending, molding, sewing, drilling and finishing prior to fitting on the patient.
    *a.* Molded-to-Patient-Model: A particular type of custom fabricated device in which one of the following techniques is used:
        i. An impression (*e.g.,* by means of a *foam box impression, 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.
        *iii. For inserts used with therapeutic shoes for diabetes, a digital image of the patient's body part is made using 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 beneficiary-specific insert.*

    *b.* Positive Model of the Patient is created by one of the following:
        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; or

*iv. For inserts used with therapeutic shoes for diabetes, a 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 rectified model is electronically transmitted to a commercial milling machine that carves the patient-specific insert.*

2. **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.

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

4. **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.

5. **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.

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

7. **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.

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

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

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

    **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;*
    - *Are directly molded to the patient's foot or a model of the patient's foot or directly carved from a patient-specific, rectified electronic model; and*
    - *Are made of a suitable material with regard to the patient's condition.*

## A. <u>Intake & Assessment</u>

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 shoe/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. <u>Follow-up</u>**

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.