



**Accreditation
Standards Guide**

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An Overview of BOC Facility Accreditation and Continuing Accreditation

The Board of Certification / Accreditation, International (BOC) Facility Accreditation Standards, inclusive of the Centers for Medicare and Medicaid Services (CMS) Quality Standards and National Supplier Standards, were developed to assure the public of the availability of comprehensive orthotic / prosthetic and DME / HME services, consistent with federal, state, and local laws and regulations.

Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) facility accreditation is provided under the deemed authority granted to BOC as an accrediting organization awarded by CMS. BOC requires that all accredited facilities submit any documentation necessary to reflect continued compliance with the standards at the time of annual renewal. Accredited facilities are required to reapply every three years.

Business Administration

Corporate Structure and Governance

The supplier complies with all federal, state, and local laws and is a legally constituted entity in the state in which it is located. When applicable, the organization must have a corporate charter and governing body that sets policy for the entity.

The organization must have one or more individuals who perform leadership functions with the authority, responsibility, and accountability to direct the organization and its key activities. The organization must identify those individuals who serve as its leadership and management. The leadership must ensure that the organization complies with these standards, as well as all other applicable laws and regulations, and that its programs and services meet patient needs. The supplier must submit an organizational chart indicating the lines of authority and accountability.

Governance defines responsibilities in writing, provides for organizational management and planning, approves the written scope of services for the organization, selects the chief executive, provides for the resources necessary to maintain safe quality care, and works with other leaders to annually evaluate the organization's performance in relation to its mission, vision, and goals.

The supplier agrees to notify BOC of any changes in ownership, corporate officers / structure, or practitioners within 30 days of hiring or termination.

The supplier must have a designated **Compliance Officer** to assure

Compliance Officer:

An employee or contracted individual whose responsibilities include ensuring that the company follows outside regulatory requirements and internal policies.

compliance with applicable laws and regulations. This person must be identifiable by employees and patients to enable contact if issues or concerns arise. The supplier must post the contact information in public view.

The supplier's policies and procedures must be designed to promote the provision of high-quality patient care in compliance with all applicable federal and state laws, regulations, and professional certification guidelines (e.g. FDA, HIPAA, ADA, and OSHA), and professional scope of practice.

Physical Location

The supplier is prohibited from sharing a practice location with another Medicare supplier, including a physician, physician group, or another DMEPOS supplier.

The supplier must maintain a physical facility on an appropriate site. The location must be at least 200 square feet and must contain space for storing business records, including the supplier's delivery, maintenance, financial, and patient communication records.

All of the supplier's locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be accredited separately. In the case of a multi-site supplier, records may be maintained at a centralized location.

The supplier must permit CMS or its agents to conduct on-site inspections to ensure the supplier's compliance. The supplier location must be accessible to patients during reasonable business hours and maintain a visible sign and posted hours of operation. The facility may not be located in a gated community or in an area with restricted access.

The supplier must maintain a primary business telephone listed under the name of the business in a local directory or a toll-free number available through directory assistance. The exclusive use of a beeper, answering machine, answering service, or cell phone during posted business hours is prohibited.

The supplier must inform BOC when a new location is opened, and the supplier must not convey or reassign a supplier number.

Scope of Service

The supplier receiving payment must be the entity furnishing and billing for the items and services.

Suppliers must have individuals on staff to support the specialties, products, and services provided. Professional personnel (e.g. orthotists, prosthetists, or respiratory therapists) who are required by the **National Supplier Clearinghouse**

A post office box or commercial mailbox is **not** considered a physical facility.

NSC Website:
www.palmettogba.com

(NSC) or regulation to be licensed or certified must be employed by the supplier and not contracted. However, a supplier may contract services for cleaning, delivery, and repair.

The supplier must inform CMS and BOC when they have a change in their product line or service. The supplier may be subject to an additional site survey.

The supplier must fill, fabricate, or fit prescribed items from its own inventory or contract with other companies for the purchase of items necessary to fill the order. A supplier may not contract with any entity that is currently excluded from the Medicare program and **third-party payors**, any state health care programs, or from any other federal procurement or non-procurement programs.

Standard Business Practices

The supplier must have a comprehensive liability insurance policy in the amount set by CMS. If a supplier manufactures its own items, the insurance must also cover product liability and completed operations. Failure to maintain required insurance at all times will result in revocation of the supplier's billing privileges retroactive to the date the insurance lapsed. NSC and BOC must be listed as certificate holders.

Prevention of Fraud, Waste, and Abuse

The organization implements 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 CMS quality and supplier standards, applicable laws, and regulations.

The Compliance Officer must train and educate employees, contractors, and agents on compliance policies, procedures, internal monitoring, and reporting of deficiencies. Management must document and keep records regarding compliance efforts (e.g. training, situations, and actions taken).

Ethics

The supplier and practitioner must subscribe to a body of ethical statements respective to supplier or professional categories, credentials, or licensure. The supplier must recognize its responsibility to patients.

Third-party payor:

An insurance carrier other than Medicare (e.g. Workman's Comp., Blue Cross Blue Shield, or Aetna)

In order for a contract to be considered acceptable, it *must*:

- be current
- identify both parties with signatures
- contain an established, reasonable credit limit (cash on delivery is not acceptable)
- provide the credit terms with the net due amount stated
- show both companies identified within the contract
- contain the effective dates of the contract

Examples of *compliance* to this standard are risk management policies / procedures and satisfaction surveys.

Financial Management

The supplier must implement financial management practices that ensure accurate accounting and billing to CMS, patients, and third-party payors.

Financial records must be accurate, complete, and current. Records must reflect cash- or accrual-based accounting practices and maintain a mechanism to track actual revenues and expenses. The supplier must maintain accounts that link equipment and items to the patient and manage revenues and expenses on an ongoing basis related to patient services.

The supplier agrees to produce records as requested by the BOC site surveyor for the purpose of completing the site survey and proof of compliance with BOC and CMS standards.

Annual Operating Budget

The supplier must have an annual operating budget, as appropriate to the business's size and scope of services, to meet the needs of patients and maintain business operations.

Management must periodically review the business's actual financial performance in relation to the operating budget, making adjustments as necessary utilizing year-end projections on services and appropriate infrastructure to determine budget variance.

Income Statements and Balance Sheets

The supplier must periodically produce financial statements that include a balance sheet denoting the company's assets and liabilities and an income statement reflecting the revenue earned over a specific time period. Guidelines for corporate balance sheets are provided by the [International Accounting Standards Committee \(IASC\)](#).

The supplier's financial statements should all be related so that changes in assets and liabilities on the balance sheet will also be reflected in the revenues and expenses reported on the income statement, showing the company's gains or losses.

Service Contracts

The supplier must maintain [service contracts](#), as needed. The supplier should ensure that contracts specify job requirements, including policies and related qualifications for contracted personnel to include necessary licensures and certifications. The contracts must be signed by both parties with date of execution noted.

IASC Website:

<http://www.iasplus.com/standard/standard.htm>

Service Contracts:

Agreements between the supplier and outside entities to perform certain functions at an agreed price over a fixed period of time (e.g. delivery repair, and maintenance)

Human Resource Management

The supplier must document the individual skills, qualifications, health assurances, and number and types of personnel needed. These are defined by the mission, scope, complexity of services, equipment and products provided, and laws and regulations as applicable. This applies to all employees and contractors. A supplier must maintain a personnel file on each employee.

All technical personnel must be competent to deliver, set up, and train patients or caregivers. The supplier must monitor performance in providing patient services. The supplier must document personnel issues and how they are addressed within individual employee records and implement procedures for similarly established compliance among contractors.

Where applicable, each facility location must employ or have access to the employed services of at least one credentialed practitioner who is certified, licensed, or registered to provide respective patient care. Each location must have at least one credentialed practitioner either on site or off site during regular business hours.

The facility may employ credentialed or non-credentialed **privileged personnel** to provide orthotic or prosthetic patient care with either direct or indirect supervision. Direct supervision occurs on site and in person while indirect supervision means the supervising practitioner is readily available for consultation. A designated credentialed practitioner or supervisor is a certified, licensed, or registered orthotist or prosthetist who directly or indirectly supervises credentialed or non-credentialed privileged personnel to provide patient care.

The designated supervisor is responsible for the specific training/education taken by privileged personnel. The designated supervisor must document the training/education in the form of **written objective criteria** in the privileged personnel's employee file. Documentation may be in the form of the following, each specific to the patient care service:

- Proof of completion of continuing education courses
- Documented in-house/in-service training
- Documented work experience

The facility must comply with all applicable federal and state licensure regulations. When off site, the credentialed practitioner or supervisor will be available for on-site patient care services within a reasonable travel time or will be accessible via **telemedicine** to respond to on-site consultative needs.

Competency Assessments and Continuing Education

The supplier must develop, implement, and maintain a written staff education for all facility employees, specific to the respective responsibilities and the individual tasks and services provided to patients.

Privileged personnel:

Individuals who provide patient care within the scope of practice for orthotics or prosthetics under the direct or indirect supervision of a designated credentialed practitioner. Privileged individuals' competency is determined by the supervising practitioner, who is responsible for clinical actions taken.

Written objective criteria:

The means by which privileged personnel are assessed. This documentation must show the knowledge and skill required to provide a specific patient care service and must be related to the associated diagnosis.

Telemedicine: The use of communications and information technologies for the delivery of clinical care; it may be as simple as professionals discussing a case together over the phone and as complex as using videoconferencing equipment to conduct real-time consultations.

The staff education plan informs employees of requirements for safe and competent patient services based on criteria derived from standards, clinical manuals, manufacturers' guidelines, etc. It should also include prevention and control of infection, patient rights, and HIV / AIDS education.

Licenses, Registrations, and Certifications

The supplier must display all federal, state, or local licenses, registrations, or certifications in public view as required. For more information on licensure, visit our [external relations page](#).

Employee Manual

A supplier must provide a manual to each employee that includes the following:

- Job descriptions for each position
- Policies and procedures
- Facility hours of business and closures
- Emergency contacts
- Employee benefits
- Health assurance

Background Checks

The supplier must conduct background checks and [Office of the Inspector General \(OIG\)](#) exclusion list reviews for all employees and contractors as required by law or regulation.

BOC's external relations page:

www.bocusa.org/external-relations

OIG Website:

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

Consumer Services

The supplier must ensure that any healthcare professional staff member provides patient care services complete with continuing education and consistent with the **specialized equipment** and services provided.

The facility must have policies, procedures, and outcomes in compliance with the appropriate provisions and requirements of the CMS Quality Standards and Supplier Standards in effect. The supplier must provide a copy of CMS Supplier Standards to each patient who receives a Medicare-covered item.

The supplier must implement and maintain a management program for equipment and items that promote safe use and minimize infections and hazards for its staff and patients.

The supplier must advise the patient to follow up with the prescribing physician for additional instructions.

A supplier that provides equipment or services *must* provide the following to patients and caregivers:

- instructions
- information regarding expected delivery time
- verification of receipt
- documentation of make and model
- option to rent or purchase when applicable
- contact information for regular business hours and after hours

Patient Training and Education

The supplier must document that it or another qualified party has provided patients with necessary information and instructions on how to use prescribed devices safely and effectively. The supplier is 100% responsible for the delivery and instruction of items and for maintaining the proper documentation.

Plan of Care

Depending on federal, state, and local laws and regulations, credentialed healthcare professionals should perform the initial setup via an assessment by instructing and monitoring the patient and caregiver. Patients are to be monitored according to physician orders and manufacturer's instructions after the initial evaluation to identify and resolve potential problems and assess the continued quality of patient care.

The supplier must consult with the prescribing physician before finalizing the service plan if it differs from the physician's order. Special attention should be given to the family support system, the patient's abilities and readiness to learn, the barriers and safety hazards in the home environment, and any other relevant information that may affect the goal. When the supplier cannot or will not provide equipment or services that are prescribed for the patient, the supplier must notify the prescribing physician, practitioner, or other healthcare team member promptly, within five business days.

The supplier must formulate a treatment plan that is consistent with the prescribing physician's dispensing order or the written plan of care, in accordance with Medicare rules, and consult the physician when appropriate.

Training materials must be tailored to the needs, abilities, and languages of the patients or caregivers and may include:

- Procedures to follow in case of emergency
- Infection prevention and control
- Habilitation and rehabilitation techniques
- Instructions for use of supplies needed to attach, maintain, and clean devices
- Instructions for reporting changes in the patient's condition
- Established goals and outcomes for the patient

Coordination of Healthcare with the Physician

The communication between the supplier and the prescribing physician is extremely important. All communication is to be documented in the patient's file. At no time can a patient's prescription be altered by the supplier. If a change of prescription is agreed upon between the supplier and the physician due to

the patient's needs or abilities, the physician must submit a replacement prescription to the patient or supplier prior to the patient receiving his or her device or equipment. A **Certificate of Medical Necessity (CMN)** must be kept in the patient's records along with the physician's prescription, maintained and updated by the physician as deemed necessary.

CMN: A document completed and signed by the prescribing physician that verifies the patient's need for durable medical equipment.

Verification of Delivery

It is important to note that the supplier is responsible for the delivery of and instruction for items and for maintaining the proper documentation in patient records.

The supplier must ensure that the item delivered is consistent with the prescribing physician's orders and identify the patient's needs, risks, and limitations. The supplier must provide associated supplies (e.g. adhesives, solvents, lubricants) to attach, maintain, and clean the items as necessary.

Preventative Maintenance

The supplier must provide instructions related to setup, features, routine use, troubleshooting, cleaning, infection control, and maintenance of the equipment provided. The supplier must identify, monitor, and report equipment and item failure, repair, and preventative maintenance for items provided to patients.

Emergency Management Plan

Each facility must have a written plan with procedures enabling it to maintain operations and provide continuing patient care and support in the event of a disaster or emergency. The plan may include arrangements with alternative suppliers in the event the supplier cannot service its patients. The initiation, development, and maintenance of this plan should be in consultation with the state or county emergency management agency.

Performance Management

The supplier must implement a performance management plan that measures consumer services, billing practices, and adverse events. Certain aspects of services that have an increased potential to cause harm or injury or that create a greater-than-expected number of adjustments, repairs, or replacements must be documented and improved.

The supplier must measure patient satisfaction, problems, and concerns. The frequency of billing and coding errors must be documented and corrected.

The supplier must seek input from staff, patients, and outside sources when assessing the quality of its operations and services. Annually, the supplier must

evaluate its performance with respect to its mission, goals, and objectives.

Consumer Surveys

The supplier must generate data from patient satisfaction surveys and complaints about products and services. Data should be gathered regarding response times to patient questions, problems, and concerns. Data should reflect the impact of supplier's business practices on the adequacy of patient access to DMEPOS items, services, and information.

The supplier must agree not to contact a patient by telephone when supplying a Medicare-covered item unless one of the following applies:

- the individual has given written permission to the supplier to contact them concerning the furnishing of a Medicare-covered item
- the supplier is contacting the individual to coordinate the delivery of the item
- the contact concerns the furnishing of a Medicare-covered item other than those already furnished to the individual

Adverse Events

The supplier must implement a policy and procedure for avoiding adverse events to patients due to inadequate or malfunctioning equipment, items, or services. The supplier must keep records of all adverse events that occur in the use of prescribed equipment, including date, nature of the event, and resolution.

A physician may prescribe a particular brand and method of use for an item if the physician determines that this specification would avoid an adverse medical outcome. The specification reasoning must be documented in the patient's record. Any change in the prescription requires a revised written prescription by the physician.

Adverse Events:

Unfavorable occurrences in which a patient is injured or a patient's condition is worsened due to faulty equipment or inappropriate fitting of an O&P device.

Incident Report

The supplier must define and implement a process for identifying, analyzing, reporting, managing, and preventing incidents. This includes a risk-reduction strategy and action plan that measures the effectiveness of process and system improvements.

Data collected will measure potentially high-risk processes (e.g. blood-borne pathogens). Analyzing the collected data will assist the supplier in determining whether there are unacceptable levels of performance.

The supplier must investigate any incident or injury in which the equipment provided may have been involved. The investigation must be initiated within 24 hours of the supplier's awareness of the incident, injury, or infection resulting in the patient's hospitalization or death. Other incidents, injuries, or infections must be investigated within 72 hours of supplier awareness.

Complaint Resolution

The supplier must respond to a complaint within five business days. **Complaint records** must be kept at the supplier's physical location and made available to CMS or BOC upon request.

The supplier must provide written notification to the patient regarding the results of its investigation within 14 calendar days if an investigation has occurred.

Vehicle Maintenance, Use, and Documentation

Delivery vehicles must be supplied with a first aid kit, eye wash, fire extinguisher, cleaning and disinfectant supplies, and exam gloves. The vehicle must be clean and maintained in a safe condition.

Clean and contaminated equipment must be separated during transportation and placed on flooring material that is easily disinfected. No carpeting can be used in the equipment storage areas. Contaminated equipment should be covered in plastic to avoid contact with non-contaminated items.

Complaint records *must* contain the following:

- Patient's name, address, telephone number, and insurance claim number
- Date received, name of the person receiving the complaint, as well as a summary of the complaint and resolution
- Supplier respondent's name
- Summary of investigation

Product Safety

The supplier must implement an equipment management program that promotes the safe use of equipment for staff and patients. The supplier must document and log equipment failure. The supplier must provide education and training that details all the risks and manufacturer recommendations for DMEPOS items.

Maintenance Plan

The supplier must perform preventative and routine maintenance according to the manufacturer's guidelines. All medical equipment should be inspected for safety between patient uses. The inspection should be documented for ongoing maintenance and testing procedures.

When storing equipment, separate items according to the following designations: patient-ready and dirty equipment, cleaning and disinfecting equipment, damaged equipment, and obsolete inventory.

Considerations must be made for temperature requirements, expiration dates, and maintaining battery charges. Equipment must be checked by intervals based on manufacturers' recommendations, risk levels, and amount of use.

All medical equipment provided to patients must be documented and tracked upon delivery and pickup. In the case of recall, equipment is to be tracked by make, model, and serial number. Staff, patients, caregivers, and prescribing physicians are to be notified by the Compliance Officer in the case of equipment hazard notices and recalls.

Monitoring and reporting incidents in which a medical device is connected to serious illness, injury or death should meet the requirements of the [Safe Medical Devices Act of 1990](#).

The supplier must conduct a home assessment to determine adequacy of home care by evaluating the following:

- Electrical compatibility
- Exposure to liquids
- Specific electrical and power requirements for equipment such as ventilators, oxygen concentrators and infusion pumps
- Battery condition and charge

Safety of the Workplace

The supplier must provide a place of employment that is free from hazards and complies with standards, rules, and regulations issued under the Occupational Health & Safety Administration (OSHA) Act.

Retired and Expired Items

The supplier must use the information from the item management plan to identify and implement changes that will improve care, treatment, and service. The supplier must have a plan to remove, quarantine, and destroy expired or retired items from its inventory.

Exposure Control Plan

The supplier must be committed to providing a safe and healthy work environment for their entire staff. In pursuit of this goal, the supplier must create an Exposure Control Plan (ECP) to eliminate or minimize occupational exposure to blood-borne pathogens in accordance with OSHA standard 29 CFR 1910.1030.

The supplier must have a copy of the [ECP](#) accessible to employees in compliance with appropriate OSHA standards

For information on the Safe Medical Devices Act of 1990, visit:

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>

The supplier must conduct a workplace hazard assessment to ensure compliance with OSHA.

ECP Website:

http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=10051

Universal precautions must be observed to prevent contact with blood or other potentially infectious materials. The Exposure Control Plan must be reviewed and updated annually to reflect new or modified tasks and procedures that affect occupational exposure.

The suppliers must provide hand-washing stations and personal protective equipment, such as gloves, gowns, lab coats, face masks, and eye protection, according to the care provided. The facility must be clean and sanitary. Newly received equipment for patient use must be kept in a clean area, separated from dirty or used equipment. Clean equipment must be kept covered until it is used.

Hazard Communication

The supplier must maintain a written hazard communication plan that describes how the OSHA Hazard Communication Standard (HCS) will be implemented. Suppliers are responsible for informing and training employees on potential hazards associated with the chemicals currently in their facility.

A manual of hazardous materials must be clearly posted and available to employees; warning signs should be posted in appropriate areas. The inventory must include **Material Safety Data Sheets (MSDS)**.

Each hazardous material must be labeled, tagged, or marked with the identity of the material and appropriate hazard warning. If the material is transferred by the supplier from the original container to another container, all information must clearly be marked on the new container. Injuries or chemical exposures must be documented on an Incident Report Form.

A **Hazardous Communication Manual (HCM)** describes how the requirements for warnings, material safety data sheets, employee information, and training will be met.

Employee Information and Training

All employees with occupational exposure must participate in training programs provided at no cost to the employee and during working hours by the supplier. Employees who may be exposed to hazardous chemicals when working must be provided information and training prior to the initial assignment to work with a hazardous chemical, as well as when hazards change.

MSDS:

Detailed information bulletins prepared by the manufacturer of a chemical describing the physical and chemical properties, physical and health hazards, routes of exposure, precautions for safe handling and use, emergency and first-aid procedures, and control measures.

The HCM *must* include the following:

- The person responsible for ensuring labeling of containers
- The location of hazardous materials
- A description of the labeling system
- The procedure for reviewing and updating label information
- Safety rules and procedures, including the cleanup and disposal of hazardous materials
- The procedure for reporting non-compliance
- The appropriate steps to limit exposure to employees
- The location of protective equipment
- A plan for emergency evacuation
- A list of emergency phone numbers

Information Management

Patient's Bill of Rights and Responsibilities

The supplier must develop a Patient's Bill of Rights and Responsibilities to be given to each patient served that includes information on individual dignity, financial information and disclosure, access to healthcare, and experimental research. The supplier must have the patient sign for the receipt and understanding of the Patient's Bill of Rights and Responsibilities; verification must be kept in the patient's file.

Business Associate Agreement

The supplier must obtain satisfactory assurances from its business associates that they will safeguard the protected health information received or created on behalf of the covered supplier. Satisfactory assurances must be in writing in the form of a contract or other agreement between the supplier and the business associate.

The Health Insurance Portability and Accountability Act (HIPAA)

For information on HIPAA standards, refer to the [HIPAA website](#).

Confidentiality Responsibilities

The supplier must have appropriate administrative, technical, and physical safeguards in place that protect against uses and disclosures not permitted by HIPAA. Supplier safeguards are not expected to guarantee the privacy of protected health information from any and all potential risks.

Reasonable safeguards vary from supplier to supplier, depending on factors (e.g. size of facility or nature of business). In implementing reasonable safeguards, the supplier must analyze its own needs and circumstances, including the nature of the protected health information it holds, and assess the potential risks to patients' privacy.

Internet and Email Policies

CMS has delegated authority to enforce the HIPAA Security Standards for safeguarding the confidentiality, integrity, and availability of Electronic Protected Health Information (EPHI). The supplier that conducts business activities by portable media and devices, laptops, personal digital assistant (PDA), home computers, or other non-corporate equipment must follow HIPAA standards and train its employees accordingly.

Training must cover policies prohibiting use over open networks (e.g. internet and email) and downloading to public or remote computers. Refer to [HIPAA Security Rule 164.308\(a\)\(4\) and](#)



HIPPA Website:

<http://www.hhs.gov/hipaa/privacy.html>



HIPPA security and privacy rules:

<http://www.hhs.gov/ocr/privacy/hipaa/understanding/srsummary.html>

HIPAA Privacy Rule 164.508 in regard to implementation of policies and procedures for authorizing EPHI access, including information on safeguards to be implemented.

Other devices that may be causes of concern due to vulnerability include: smart phones, flash drives, memory cards, CDs, DVDs, backup media, email accounts, and other remote access devices. Hotel, library, or other public workstations would also be included.

Records Storage and Shredding

The supplier must maintain accurate, confidential, and secure records in accordance with HIPAA and other applicable state standards. The supplier must take reasonable measures to store records in a location and manner that minimizes damage from fire, water, or natural disaster. Personal information that is not stored in a patient's record and is discarded must be shredded.

Service Requirements

Supplier and Physician Collaboration

The supplier, in collaboration with the prescribing physician, must review the patient's record and incorporate any necessary revisions related to the patient's condition that affect the equipment or services provided.

The supplier must review the patient's record and incorporate any necessary information related to the patient's condition that affects the provision of the DMEPOS and related services, or to the actual items or services provided.

Certificate of Medical Necessity (CMN)

The supplier must complete the appropriate sections based on CMN instructions and submit them to the referring physician for review, completion (as needed), and physician's signature. The supplier must have a photocopy, facsimile, or original signed order in the patient's record. The supplier must meet Chapter 5 of Medicare's **Program Integrity Manual**.

Program Integrity Manual

Website:

<http://www.cms.gov/Manuals/IOM/itemdetail.asp?itemID=CMS019033>

Confirmation of Physician's Orders

The supplier must communicate with the prescribing physician before finalizing a treatment plan. Any changes or suggestions should be discussed and approved by the physician in writing.

Documentation must be noted in the patient's file.

The supplier must refer the patient to the prescribing physician for intervention or treatment beyond the supplier's scope of practice.

Coordination

The supplier must incorporate information from other healthcare team members in the delivery of the device or equipment. The supplier must solicit feedback from the physician to determine the effectiveness of the device provided to the patient.

Product Information, Delivery, and Documentation

Order Intake Form

The supplier may develop and use an **order intake form** during the initial evaluation of the patient.

Patient Instructions for Equipment Use

The supplier must provide or coordinate the provision of appropriate information related to the setup, features, routine use, troubleshooting, cleaning and maintenance of items provided. The supplier must advise the patient or caregiver of any safety considerations and provide relevant information and instructions on infection control. A notation of patient or caregiver instructions should be documented in the patient's file.

Release of Information

The Privacy Rule allows a supplier to obtain patient consent for uses and disclosures of protected health information for treatment, payment, or healthcare operations. Suppliers that do so have complete discretion to design a process that best suits their needs.

By contrast, an **authorization** is required by the Privacy Rule for uses and disclosures of protected health information not otherwise allowed by the Privacy Rule. An authorization must include: a description of the protected health information to be used and disclosed, the person authorized to make the use or disclosure, the person to whom the supplier may make the disclosure, an expiration date, and, in some cases, the purpose for which the information may be used or disclosed.

Patient Record

The supplier must develop patient records that are kept in a locked file cabinet or locked room. The patient record should

Order Intake Form may include:

- Type of equipment and service prescribed
- Pertinent diagnoses, including mental status
- Frequency of visits
- Prognoses
- Potential for rehabilitation
- Functional limitations
- Permitted activities
- Safety measures to protect against injury
- Instructions

Authorization:

a detailed document that gives suppliers permission to use protected health information for specified purposes, which are generally those other than treatment, payment, or healthcare operations, or to disclose protected health information to a third party specified by the patient.

have an information form, physicians' prescriptions, a CMN, practitioner notes, delivery tickets, measurements, pretreatment photographs when appropriate, medical history, signed HIPAA form, instructions, and billing information.

Warranty, Repair, and Return Policies

The supplier must honor all warranties expressed and implied under applicable federal, state, or local laws and regulations. A supplier must not charge the patient, the Medicare program, or third-party payors for the repair or replacement of Medicare-covered items or for services covered under warranty. The supplier must provide upon request documentation that it has provided patients with information about items covered under warranty, in the form of copies of letters, logs, or signed notices.

The item must function as required and intended after being repaired or replaced. This standard applies to all purchased and rented items. The supplier must provide or arrange for loaned equipment that is equal to the originally prescribed items, with the exception of orthotics and prosthetics. The supplier may contract with a qualified entity to repair or service equipment. The supplier must accept returns for items of substandard quality from patients.

Mail Orders

For initial equipment or items provided by mail order delivery, the supplier must verify and document it in the patient's chart that the patient and caregiver have received all instructions.

The supplier ensures the patient and caregiver are able to use all prescribed items safely and effectively.

Follow Up

The supplier must provide appropriate patient follow-up care consistent with the services rendered. The supplier must inform the patient or caregiver of the procedures for repairing, replacing, and adjusting the device or equipment, as well as the possible risks.

The supplier must give instructions on reporting any problem to the supplier or referring physician.

Training to Patient or Caregiver

Patient and caregiver training should be performed by a credentialed practitioner as required. The credentialed practitioner is to monitor the patient and recommend changes as

needed.

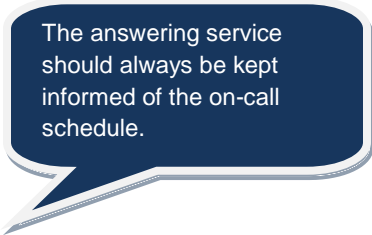
Training should be done as often as requested by the patient, caregiver, or physician until objectives of the training are reached. Detailed clinical notes of all training and outcomes should be kept in the patient's file.

After-Hours Emergency Care

The supplier must provide patients with a telephone number to be used in the case of an emergency after facility business hours. This number should be an **answering service** able to contact the supplier at all times by beeper, home phone, or cell phone.

The emergency number is to be provided to the patient in written form upon delivery of an item and should be clearly noted on the facility's exterior entrance.

All emergency situations are to be addressed immediately and documented by the supplier in an emergency log and in the patient's record. Documentation should indicate the reason for the emergency, the action taken, and the follow up with the patient.



The answering service should always be kept informed of the on-call schedule.

Product – Specific Service Requirement

Appendix A: Respiratory Services

The supplier must follow CMS quality standards as written in Appendix A.

Respiratory Services encompasses the provision of home medical equipment and supplies that require technical and professional services. The supplier must provide respiratory services 24 hours a day, seven days a week as needed by the patient or caregiver.

Oxygen Therapy in the Home

Home medical equipment and supplies covered in this section 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
- Nebulizers

Instruction and Delivery

The supplier must provide training to the patient or caregiver in compliance with the most current *American Association for Respiratory Care Practice Guidelines*. This includes guidelines for 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 as required by state.

The supplier must employ a credentialed professional (e.g. respiratory therapist, respiratory therapy technician, or respiratory care practitioner) or other state-required personnel. The use of contracted professionals in states where certification or license is required is prohibited.

For oxygen delivery, the supplier must meet Department of Transportation Pipeline and Hazardous Materials Safety Administration [Standard 49 CFR](#).

Standard 49 CFR

website:

<http://www.phsma.dot.gov/regulations>

Emergency Maintenance and Back-Up Systems

The supplier must ensure that patients receiving oxygen have ample back-up parts or supplies to meet their needs, in case of equipment failure, emergency, or disaster, relative to the supplier's maximum anticipated response time.

For oxygen patients, the supplier must provide emergency maintenance, replacement, or back up in a timely manner to prevent an interruption in prescription requirements. Calibration of all respiratory equipment must be performed by a credentialed practitioner or respiratory therapist.

The supplier must develop and maintain a plan for maintaining respiratory equipment that includes the daily inspection of equipment, the service of equipment according to manufacturers' instructions, a back-up system, and an emergency plan. Refer to the [American Association of Respiratory Therapist Guidelines](#).

American Association of

Respiratory Therapist

Guidelines website:

<http://www.aarc.org/>

Oxygen Safety and Hazard Information

The supplier must warn patients and caregivers of hazards associated with the use of oxygen and respiratory equipment. "No smoking" signs must be posted in surrounding areas. Equipment must be checked according to the equipment manufacturer's recommendations or annually at a minimum.

Record Keeping

The supplier must show the disbursement of equipment and oxygen in a log and track it in case of recall by the manufacturer.

Maintenance, repair, and calibration by a certified respiratory therapist must be recorded in both the patient's record and on the equipment inventory log. The calibration of oxygen is to be checked according to established manufacturer guidelines.

Appendix B: Complex Rehabilitation-Assistive Technology, Manual Wheelchairs, and Power Mobility Devices

The supplier must follow CMS Quality Standards as written in Appendix B.

Intake and Assessment

The supplier must verify that seating, positioning, and specialty assistive technology have been evaluated and documented in the patient's record.

Personnel and Assessment Requirements

The supplier providing complex rehabilitative wheelchairs and assistive technology must employ (W2 employees) at least one qualified individual as a **Rehabilitative Technology Supplier (RTS)** per location.

The RTS must 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 or familiarity with rehabilitative clients, products, and services)
- completed at least ten hours annually of continuing education specific to Rehabilitative Technology
- able to program and repair sophisticated electronics associated with power wheelchairs, alternative drive controls, and power seating systems.

The RTS must coordinate services with the prescribing physician to conduct face-to-face evaluations of the patient in an appropriate setting and include input from other members of the health care team (e.g. physical therapist or occupational therapist) to provide the patient with appropriate equipment for trial and simulation. The RTS must maintain all of the information

Qualified RTS: An individual that is a Certified Rehabilitative Technology Supplier (CRTS) or an Assistive Technology Professional (ATP).

obtained during the assessment in the patient's record.

The RTS must also implement procedures for assembly and set up of equipment and a process to verify that the final product meets the specifications of the original product recommendation approved by the prescribing physician.

If a patient is evaluated in the supplier's facility, the supplier must provide private, clean, and safe rooms appropriate for fittings and evaluations. The RTS must maintain a repair shop located in the facility or easily accessible from another location of the supplier, as well as an area appropriate for assembly and modification of products.

Delivery and Set Up

For suppliers of complex rehabilitation and assistive technology, the supplier must include information from other healthcare team members (e.g. physical therapists or occupational therapists) and the prescribing physician upon the delivery of the device or equipment.

Appendix C: Custom-Fabricated and Custom-Fitted Orthotic and Prosthetic Devices, External Breast Prostheses, Therapeutic Shoes and Inserts; Custom-Made Somatic, Ocular and Facial Prostheses

The supplier must follow CMS Quality Standards as written in Appendix C.

Personnel Requirements

The supplier must be trained in a broad range of treatment options to ensure that the items prescribed are optimal for the patient's condition. The provision of custom-fabricated or custom-fitted devices (i.e. those 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. This includes modification, adjustment, maintenance, and repair of the items. Credentialed individuals supplying these items must possess specialized education, training, and experience in fitting.

Intake and Assessment

The supplier must assess the patient's need for and use of the orthoses and prostheses, including comprehensive history, pertinent medical history that includes allergies, skin conditions, diagnoses, results of diagnostic evaluations, patient expectations, and pre-treatment photographic documentation when appropriate.

The supplier must determine the appropriate orthoses or prostheses and specifications based on the patient's need for use to ensure optimum therapeutic benefits and appropriate strength, durability, and function as required. The supplier must also formulate a treatment plan that is consistent with the prescribing physician's dispensing order or the written plan of care, in accordance with Medicare rules, and consult the physician when appropriate

The supplier must perform an in-person diagnostic examination as related to the patient's use and need of the orthoses or prostheses, such as sensory function, range of motion, joint stability, skin condition, presence of edema or wounds, vascularity, pain, manual muscle testing, and cognitive ability.

The supplier must establish goals and expected outcomes for the patient's use of the orthoses or prostheses, including pain reduction and comfort, enhancement of function, joint stability, prevention of deformity, and cosmetic issues. The supplier must seek feedback from the patient or prescribing physician as necessary to determine the appropriateness of the orthoses or prostheses.

The supplier must communicate the recommended treatment plan, including disclosure of potential risk, benefits, and precautions, as well as procedures for repairing, replacing, or adjusting items and the estimated time involved in the process to the patient, caregiver, and prescribing physician. The supplier must ensure the treatment plan is consistent with the prescribing physician's dispensing order.

The supplier must assess the orthoses or prostheses for structural safety and ensure that manufacturer guidelines are followed (e.g. proper closure function and patient weight limits) prior to the face-to-face fitting and delivery.

Training and Instruction

The supplier must provide instructions to the patient or caregiver for the specific orthoses, prostheses, or therapeutic shoe inserts as follows:

- using, maintaining, and cleaning the orthoses or prostheses
- putting on, adjusting, and taking off orthoses and prostheses
- inspecting the skin for pressure areas, redness, irritation, pain, or edema
- using an appropriate interface (e.g. socks, gloves, or shoes)
- reporting problems related to the orthoses or prostheses
- scheduling follow-up appointments as necessary
- establishing an appropriate "wear schedule"

The supplier must provide the necessary supplies to attach, maintain, and clean the items, as applicable, and information about how to subsequently obtain the necessary supplies. The supplier must refer the patient to the prescribing physician as necessary for intervention beyond the supplier's scope of practice.

Follow Up

The supplier must have access to a facility with the equipment necessary to provide follow-up treatment and fabrication or modification of the specific orthoses and prostheses.

The supplier must follow these steps:

Step 1: Review recommended maintenance with the patient or caregiver

Step 2: Solicit feedback from the patient, caregiver, or prescribing physician as necessary to determine the effectiveness of the orthoses or prostheses

Step 3: Review and change the treatment plan based on the patient's condition

Step 4: Continue to assist the patient until the orthoses or prostheses reach the optimal level of fit and function

Step 5: Provide appropriate patient follow-up treatment