



AMERICAN BOARD FOR CERTIFICATION IN ORTHOTICS, PROSTHETICS & PEDORTHICS, INC.

Serving the orthotic, prosthetic and pedorthic profession for over 60 years.

ABC FACILITY

Accreditation Standards

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Introduction

The mission of the American Board for Certification in Orthotics, Prosthetics & Pedorthics, Inc. (ABC) is to establish and promote the highest standards of organizational and clinical performance in the delivery of orthotic, prosthetic, and pedorthic services. Patient care facilities that meet the ABC standards are recognized among the finest in the profession, and equally important, they are dedicated to providing excellent patient care.

The Facility Accreditation Committee and ABC staff has worked hard to revise the standards, making them easier to read and understand.

Joining our facility accreditation program confirms your focus on continued improvement and assures others that you are offering exceptional quality services that your patients expect and deserve. As a Centers for Medicare and Medicaid Services (CMS) Deemed Accrediting Organization, ABC has over 140 standards that directly correlate to the care you are providing. Through an onsite evaluation by an experienced surveyor, ABC will ensure that your facility meets the profession's standards and maintains the highest level of excellence in patient care service. Compliance with ABC's accreditation standards will ensure your facility's compliance with CMS' Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Quality Standards as well as their DMEPOS Supplier Standards.

Complete information on the process of

becoming ABC accredited is located in the ABC *Accreditation Guide* and on our website at www.abcop.org/accreditation.

About the Revised Standards: The majority of these revised standards reflect the previous ABC accreditation standards. ABC recognizes that there is a wide variety of facilities that provide patient care. Each facility accreditation standard is written to apply to all facilities pursuing ABC accreditation unless specifically indicated otherwise. Some standards are product-specific and may not apply to your facility.

The standards are now grouped into eight categories: Administrative (AD), Human Resources (HR), Patient Care and Management (PC), Product Safety (PS), Patient Records (PR), Performance Management and Improvement (PM), Facility Safety and Management (FS), and Claims and Billing Compliance (CB).

Additional Resources: ABC's website www.abcop.org is constantly updated to provide you with the latest accreditation information. ABC has many helpful brochures, guides, and checklists that are available under the Forms/Document section. We provide clear guidance to questions and have direct links to Medicare's website for further clarification. Existing ABC accredited facilities may log on to the ABC website for access to special resources such as the standards with a suggested compliance checklist. Please refer to the *Additional Resources* section at the back of this guide.

Thank you for choosing ABC as your accrediting organization, where we continue to set the benchmark for orthotic, prosthetic, and pedorthic care.



Facility Accreditation Eligibility Criteria

The following criteria will help you determine if you are eligible to apply for ABC Facility Accreditation. This is not a comprehensive list but is intended to cover the basic requirements that your facility must have in place before you apply. The majority of the comprehensive eligibility requirements are identified throughout the standards and are relevant to the specific products and services your organization provides.

Your organization must be:

- Located within the United States, one of its territories or possessions, or is a Department of Defense medical treatment facility or program.
- A formally organized and legally established business that provides the type(s) of DMEPOS patient care services for which you are applying.
- Licensed according to applicable state and federal laws and regulations, and maintains all current legal authorization to operate.

- Operational and have a minimum of 10 complete patient charts available at the time of the onsite survey.
- Applying for ABC accreditation for all of the services it provides, regardless of whether Medicare is billed for these services. This requirement extends only to those services for which ABC offers accreditation.
- Applying for ABC accreditation for all patient care locations and each location must be in an appropriate clinical setting. The decision of what is an appropriate clinical setting is solely within ABC's discretion.

In addition, your organization will:

- Clearly define the items and services you provide to patients, insurance companies, referral sources, and regulatory bodies, including Medicare.
- Comply with the ABC **Code of Professional Responsibility**.
- Agree to the terms and conditions in the application materials.
- Not falsify or misrepresent your accreditation status.

Note: *If allowed by state law, Pharmacists are exempt from standard HR.4.1.*



ABC Facility Accreditation Standards

Administrative (AD)

The Administrative Standards address the legal status and legitimacy of the business, compliance with Medicare and HIPAA requirements, and establishment of the internal policies and procedures of the business.

ABC awards accreditation to a legal entity. The standards require that a business be legally constituted, not only in the jurisdiction in which it is based, but also in those localities in which it provides services. Full disclosure of ownership is required at the time of application and all financial records must be complete. The business must have a physical location accessible to the public and make reasonable physical accommodations for its employees and patients. All licenses, certificates, and permits must be displayed in an area accessible to the public. The business must be in compliance with HIPAA and Medicare requirements.

In addition, written policies and procedures which address the clinical and business aspects of the business are required. The policies and procedures must include but are not limited to:

- professional qualifications and continuing competency
- a mechanism to facilitate professional staff communication with the governing body
- patient care and management, including patient and family education and patient rights
- maintenance and confidentiality of patient records
- the protection of private healthcare information

- patient billings, collections, and complaint resolution
- performance management
- facility and safety management.

Administrative Standards (AD):

AD.1

The business provides documentation that it is a legally constituted entity in the state(s) in which it is located and that it is authorized to provide the services for which it is seeking accreditation.

(Previous Standard: OR.1)

AD.1.1

The business complies with all applicable federal, state, and local laws.

(Previous Standard: OR.1)

AD.1.2

The business shall have a physical location accessible to the public.

(Previous Standard: OR.1.2)

AD.1.2.1

All licenses, certificates, and permits to operate the business must be displayed in an area accessible to the public.

(Previous Standard: OR.1.2)

AD.1.2.2

All licenses and certificates held by patient care providers who provide patient care services through the location being accredited must be displayed in an area accessible to the public.

(Previous Standard: OR.1.2)



AD.2

The business 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.

(Previous Standard: OR.3)

AD.3

The business shall disclose its ownership and control information in accordance with the requirements at 42 CFR §420.201 through §420.206.

(Previous Standard: OR.2)

AD.4

The governing body has adopted a mission statement which includes a description of the services provided and its goals and objectives.

(Previous Standard: OR.3.1)

AD.4.1

The business has established documented policies and procedures to efficiently conduct its clinical and business affairs. These policies are communicated and made available to all staff as appropriate.

(Previous Standard: OR.3.2)

AD.4.2

The business shall provide those items as disclosed on its most current CMS 855s (Supplier Enrollment) application.

(Previous Standard: OR.3.4 and OR.3.4.1)

AD.5

The business complies with the appropriate provisions and requirements of the current CMS Supplier Standards, Regulations, and Medicare Contractor policies and articles.

(Previous Standard: OR.6)

AD.6

The business complies with the appropriate provisions and requirements of the Healthcare Insurance Portability and Accountability Act (HIPAA).

(Previous Standard: OR.5)

AD.7

The business makes reasonable physical accommodations for its employees and patient populations.

(Previous Standard: OR.7)

AD.8

Financial records shall be accurate, complete, current, and reflect cash or accrual based accounting practices. The business shall maintain accounts that link equipment and supplies to the patient and manage revenues and expenses on an ongoing basis, as they relate to patient services, including the following: (1) maintaining accounts that link equipment and item(s) to the beneficiary; (2) reconciling charges to patients for equipment, supplies, and services with invoices, receipts, and deposits; (3) planning to meet the needs of patients and maintain business operations by having an operating budget, as appropriate to the business's size and scope of services; and (4) having a mechanism to track actual revenues and expenses.

(Previous Standard: OR.8)



Human Resources (HR)

The Human Resource Standards apply to employed, contract, and volunteer personnel providing patient care and/or services.

The terms *staff* and *staff member* (and their derivatives) as used in these Standards are intended to refer to the facility's various types of care providers and support staff. The facility ownership/leadership has the responsibility for appointing and privileging its staff. The appointments and privileges must be based upon the staff member's competency to perform the necessary skills for the functions and procedures associated with that appointment.

The business must manage the competencies and qualifications of contracted services and personnel in the same manner they manage the competencies and qualifications of direct employees and volunteers. They can define in the contract, or in written policy, criteria for performance of the contracted service; or, the business can review and adopt the contract business's policies and practices. The contract should specify that the contracted business will provide only staff that is qualified in relation to their education, training, licensure, and competence as defined by the business. The facility will be held ultimately accountable for the actions of its contractor's staff.

The Human Resource Standards are applicable to any contracted service that provides any element of care or service, which is eligible for survey. They do not apply to delivery of home medical equipment and pharmaceutical products via a contracted common carrier (i.e. UPS, FEDEX, US Postal Service, local courier companies), where there is no education or set-up involved. The standards, however, do apply when delivery is provided by a direct

employee of the business, or a contractor of the business not excluded in this paragraph.

Human Resources Standards (HR):

HR.1

The business shall establish policies and procedures, including detailed job descriptions, that specify: 1) personnel qualifications and training; 2) required certifications and/or licenses as applicable; 3) required experience; and 4) continuing education requirements consistent with the specialized equipment, items, and services it provides to patients.

(Previous Standard: OR.3.2, OR.4.1, HR.1, and HR.3)

HR.2

The business shall document the verification of all licenses, registrations, and certifications held by staff members who provide patient services.

(Previous Standard: OR.3.3.1)

HR.3

The business provides appropriate orientation and training programs to familiarize all personnel with its facilities and procedures. Appropriate reference materials and educational information are made available to all personnel.

(Previous Standard: OR.4.2, HR.2, and HR.9)

HR.4

The organization verifies, at least annually, the completion of continuing education consistent with the specialized equipment, items, and services provided to patients.

(Previous Standard: OR.3.3)



HR.4.1

If required by state law, personnel providing patient care shall be licensed and function within the scope of practice as determined by the state licensure requirements. Otherwise, personnel providing patient care services must be certified or registered and function within their scope of practice as defined by their credentialing organization, except as permitted in HR.6.

(Previous Standard: PC.3)

HR.4.2

Professional personnel providing custom fit or fabricated orthotic, prosthetic and/or pedorthic services shall be licensed or certified and function within their scope of practice as required by the state regulation under which the professional is licensed or by the ABC Scope of Practice except as permitted in HR.6.

(Previous Standard: PC.3)

HR.5

The business must meet all Medicare requirements for the DMEPOS provided and the employment of specialty personnel. The business must also meet all requirements described on CMS 855S Form.

(New Standard)

HR.6

In compliance with applicable laws and regulations and in accordance with Written Objective Criteria*, the business may privilege non-credentialed or non-licensed staff to provide equipment, items, and services under the supervision of a credentialed or licensed individual practicing within their scope of

practice. Credentialed staff may also be privileged to provide items and services beyond their ABC defined scope of practice based on Written Objective Criteria and under Indirect Supervision of a credentialed or licensed individual practicing within their scope of practice.

**See definition of Written Objective Criteria in the ABC Orthotic, Prosthetic, and Pedorthic Scope of Practice*

(Previous Standard: OR.3.3.1, PC.3.2, and HR.5)

HR.6.1

In compliance with applicable laws and regulations, and in accordance with Written Objective Criteria*, the business may privilege non-credentialed or non-licensed staff to provide orthotic, prosthetic, and pedorthic items and services under the supervision of a credentialed or licensed individual practicing within their scope of practice. However, for the provision of custom fit-high and custom fabricated orthoses and prostheses, the initial patient evaluation and the final fitting and delivery must be done under Direct Supervision of the licensed/credentialed caregiver.

**See definition of Written Objective Criteria in the ABC Orthotic, Prosthetic, and Pedorthic Scope of Practice*

(Previous Standard: OR.3.3.1 and PC.3.2)

HR.7

At least annually, the business performs periodic performance appraisals of its staff to provide feedback on current competency and opportunities to improve performance.

(Previous Standard: OR.3.2 and OR.4)



HR.7.1

At least annually, performance management data are used to assess and document the continuing competency of staff as it relates to the specialized equipment, items, and services they provide.

(Previous Standard: OR.3.3.2)

HR.8

The business shall only use technical personnel who are competent to deliver and set up specialized equipment and train patients on the use of that specialized equipment.

(Previous Standard: HR.6)

HR.8.1

As appropriate, the business's policies and procedures establish the qualifications and competencies of the delivery personnel to provide equipment training and home assessment.

(Previous Standard: PC.5.3.1)

HR.8.1.2

As appropriate, the business's policies and procedures address the qualifications and competencies of delivery personnel to educate the patient on the proper care, use, and maintenance of the equipment provided.

(Previous Standard: PC.5.3.2)

HR.8.2

In the event that the business provides complex rehabilitative technology, it 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:

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

(Previous Standard: HR.10 and HR.11)

HR.8.3

In the event that the business provides respiratory equipment, supplies, and/or services, it shall provide services in compliance with the current version of the *American Association for Respiratory Care Practice Guidelines* listed below:

- 1) Oxygen Therapy in the Home or Extended Care Facility
- 2) Long Term Invasive Mechanical Ventilation in the Home; and/or
- 3) Intermittent Positive Pressure Breathing Apparatus (IPPB).

(Previous Standard: HR.8.1)



Patient Care and Management (PC)

Patient Care and Management Standards address essential components designed to support the delivery of appropriate, safe, and effective patient care and to ensure that patient needs are met.

These Standards are designed to address Physician Interaction, Patient Rights, Patient and Family Education, and Patient Follow-up Care. They will also guide you in your steps to establish mechanisms to help you provide the best quality care for your patients.

1) Physician Interaction and Communication: To support continuity of care between the business and referral sources, mechanisms for communication between the professional staff and a patient's referring physician or appropriately licensed healthcare prescriber must be maintained.

2) Patient Rights: To establish an environment that facilitates the delivery of effective care, the business must create an atmosphere of trust between patients and professional staff.

3) Patient and Family Education: The success of patient care depends not only upon the competency of the practitioner and the quality of the device, but also upon its effective use by the patient.

4) Patient Follow-up Care: The Standards in this section support ongoing patient care and reflect the criteria established by the profession. They require a business to provide follow-up care, appropriate to the patient's condition and complexity of the care, in accordance with the current valid order.

Patient Care and Management Standards (PC):

PC.1

The business establishes documented policies, procedures, and protocols that address the responsibilities of the staff to provide appropriate and effective care to patients in accordance with generally accepted professional practices.

(Previous Standard: PC.1)

PC.1.1

The patient management policies, procedures, and protocols are available to the staff and are consistently followed at each of the business's physical locations. Copies of such policies, procedures, and protocols shall be provided upon request to accreditation organizations and government officials or their authorized agents.

(Previous Standard: PC.2 and PC.1.1)

PC.1.2

The business establishes policies and procedures that facilitate and enhance communication and coordination of patient care. The business shall also implement 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.

(Previous Standard: PC.1.1 and PC.1.2)

PC.1.3

The business informs the patient of the expected time frame for delivery of prescribed items and/or services.

(Previous Standard: PC.2.1 and PC.1.3)



PC.2

Should the business determine that it cannot or will not provide the equipment, item(s), or service(s) that are prescribed for a patient, the business shall notify the appropriately licensed healthcare prescriber within five calendar days.

(Previous Standard: PC.3.1 and PC.2)

PC.2.1

The business maintains the appropriate fitting stock to effectively provide therapeutic footwear patients with the proper fit and function of footwear. ABC requires the following minimum levels of fitting stock: greater than 250 patients requiring therapeutic shoes per year, at least 40 pairs; greater than 500 patients requiring therapeutic shoes per year, at least 60 pairs; greater than 750 patients requiring therapeutic shoes per year, at least 80 pairs; greater than 1,000 patients requiring therapeutic shoes per year, at least 100 pairs.

(Previous Standard: PC.1.3)

This Standard applies to all facilities providing Therapeutic Footwear

PC.2.2

The business maintains the appropriate fitting stock to effectively provide post-mastectomy patients with the proper fit and function of post-mastectomy products. ABC requires that each business maintain a minimum level of fitting stock consisting of 10 forms and 24 bras.

(Previous Standard: PC.1.3)

Standard only applies to Post Mastectomy

PC.2.3

If providing custom fabricated or custom fitted orthoses or prostheses, the business has 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).

(Previous Standard: FS.2.3)

PC.3

The business shall keep unaltered and documented in the patient's record, all referrals, consultations, and other communications from the appropriately licensed healthcare prescriber.

(Previous Standard: PC.5 and PC.3)

PC.3.1

All patient care is delivered in strict accordance with the most recent prescription for the item(s) or service(s) provided and in accordance with the payer requirements.

(Previous Standard: PC.3.1)

PC.3.2

The business reviews the treatment plan during each patient visit and verifies that the chart documentation accurately reflects the most current written order for every patient. Patient visit documentation must accurately reflect care, as documented in the current written order. Patient non-compliance is documented, evaluated, and corrected through the performance management, patient education, and physician communication processes.

(Previous Standard: PC.3.2)

PC.3.3

The business provides appropriate patient follow-up care, consistent with the diagnosis and service(s) provided. All follow-up care is documented in the patient's clinical record. Patient's lack of compliance with follow-up care, if applicable, is also documented in the patient's clinical record.

(Previous Standard: PC.10)



PC.3.4

The staff member responsible for patient care shall perform an in-person diagnosis-specific, functional clinical examination as related to the beneficiary's use and need of the prescribed device [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, functional limitations, compliance, cognitive ability, and medical history].

(Previous Standard: PC.1.2)

PC.3.4.1

The staff member responsible for patient care shall 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.

(New Standard)

PC.3.4.2

The staff member responsible for patient care shall formulate a treatment plan that is consistent with the prescriber's dispensing order and consult the appropriately licensed healthcare prescriber when appropriate.

(Previous Standard: PC.5.1)

PC.3.5

The staff member responsible for complex rehabilitative wheelchairs and assistive technology shall coordinate services with the appropriately licensed healthcare prescriber to conduct face-to-face evaluations of the beneficiary in an appropriate setting and include input from other members of the healthcare team.

(Previous Standard: HR.11)

PC.4

The staff member responsible for patient care documents patient specific goals and expected outcomes for the use of the item.

(Previous Standard: PC.5.2 and PC.4)

PC.4.1

The staff member responsible for patient care documents the patient's progress in meeting the specific goals and expected outcomes for the use of the item.

(New Standard)

PC.5

The business's policies and procedures support the right of the patient to participate in decisions about the scope of treatment, including the establishment of goals and expected outcomes.

(Previous Standard: PC.7 and PC.7.1)

PC.5.1

The business informs patients about their rights which shall include but not be limited to: (1) confidentiality and privacy; (2) after hours contact and care; and (3) timely complaint resolution.

(Previous Standard: PC.7.2 and OR.5)

PC.6

The business provides the patient and appropriate caregivers with documented instructions for the proper care and use of the device. Documentation of patient education is recorded in the patient's clinical record and includes at least: 1) the purpose and function of the device; 2) the proper cleaning, care, and use of the device; 3) disclosure of the potential risks/benefits and precautions; 4) how to report any failures or malfunctions; and 5) when and to whom to report changes in physical condition when it relates to the device.

(Previous Standard: PC.9)



PC.6.1

The business's policies and procedures describe how it provides 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.

(Previous Standard: PC.9.1)

PC.6.2

The business provides relevant information and/or instructions to the patient/caregiver about infection control issues related to the use of all equipment and item(s) provided.

(Previous Standard: PC.9.2)

PC.6.3

The business provides instructions to the beneficiary or caregiver on how to inspect the skin for pressure areas, redness, irritation, skin breakdown, pain, or edema.

(New Standard)

PC.6.4

The business provides necessary supplies (e.g., adhesives, solvents, lubricants) to attach, maintain, and clean the items, as applicable, and information about how to obtain the necessary supplies.

(Previous Standard: PC.9.1)

PC.6.5

For initial equipment and/or item(s) provided by mail order delivery, the business's policies and procedures shall require verification and documentation in the patient's medical record that the patient and/or caregiver(s) has received training and written instructions on the use and care of the equipment and item(s).

(Previous Standard: PC.9.3)

PC.6.6

The business shall ensure that the patient and/or caregiver(s) can use all equipment and item(s) provided safely and effectively in the settings of anticipated use.

(Previous Standard: PC.9.4)

PC.6.7

The business shall tailor training and instruction materials and approaches to the needs, abilities, learning preferences, and language of the patient and/or caregiver(s).

(New Standard)

PC.6.8

Beneficiary and/or caregiver(s) training and instructions shall be commensurate with the risks, complexity, and manufacturer's instructions and/or specifications for the item(s) and service(s) provided.

(New Standard)

PC.6.9

In the event that the business provides respiratory equipment, supplies, and/or services, it shall provide patient and caregiver training in accordance with the current version of the *American Association for Respiratory Care Practice Guidelines* listed below:

- 1) Oxygen Therapy in the Home or Extended Care Facility;
- 2) Long Term Invasive Mechanical Ventilation in the Home;
- 3) Intermittent Positive Pressure Breathing Apparatus (IPPB);
- 4) Suctioning of the Patient in the Home;
- 5) Continuous Positive Airway Pressure (CPAP) devices;
- 6) Respiratory Assist Devices.

(Previous Standard: HR.8.1)



PC.6.9.1

The business shall provide respiratory services 24 hours a day, 7 days a week as needed by the beneficiary and/or caregiver(s).

(Previous Standard: PS.7.1)

PC.7

The business has documented policies that describe how staff will respond to evidence that patients may be at risk from real or perceived abuse, neglect, or exploitation. The policy will address the process by which notification of the proper authorities is made and how the business determines when to contact the appropriate community resources.

(Previous Standard: OR.8)

PC.8

The business establishes a written contingency plan, appropriate to the size and scope of the business's activities, that describes its response to emergencies and disasters affecting patient care in the home setting.

(Previous Standard: PS.6)

PC.8.1

The business assesses its exposure annually and ensures that its contingency plan addresses those identified exposures. Common disasters include but are not limited to: power outages and severe weather such as hurricanes, tornados, floods, fires, ice, earthquakes, wildfires, and mudslides.

(New Standard)

PC.9

The business provides information and telephone number(s) for customer service, regular business hours, after-hours access, equipment and/or item(s) repair, and emergency coverage. This plan should be based in part on the criticality of services provided to assure the continuation of critical care throughout an emergency.

(Previous Standard: PC.7.2)

PC.9.1

The business establishes a written contingency plan that describes its response to after-hours and emergency maintenance, backup or replacement of DMEPOS items. This plan should be based in part in the criticality of services provided to assure the continuation of critical care throughout an emergency.

(Previous Standard: PS.7)

PC.9.2

The business conducts and documents drills to determine the effectiveness and efficiency of its plans to provide these services through a disaster or emergency.

(New Standard)



Product Safety (PS)

The Product Safety Standards require your organization to affirm the safety and appropriateness of the DMEPOS items and services that it provides to patients.

The organization is required to establish a product safety program to promote the safe use of equipment and to minimize the safety risks, infections, and hazards for both its staff and for patients.

The standards require a business to have documented policies and procedures in place that address patient safety, equipment and device failures, repairs, product recalls, and infection control. Effective product safety programs must adhere to four principles:

1) Product Safety: The business must be able to document that all patient items being dispensed are properly labeled, if applicable, and are genuine and not counterfeit or adulterated.

2) Patient Safety: The business should have a plan to ensure that the patient and/or caregiver can use all of the equipment and the items provided safely and effectively in the setting of anticipated use. The business must have a policy for the investigation and documentation of all beneficiary reported incidents. If applicable, a policy must address the requirements for set up, delivery, and pick up of equipment. The business must have a policy documenting the education provided to patients.

3) Equipment and Device Failures, Repairs, Recalls, and Preventative Maintenance:

An equipment management program must be implemented which allows the business to identify, monitor, and communicate throughout the organization in the case of equipment failure, repair, recalls, and preventative maintenance. ABC requires that the business maintain an equipment log, which quickly identifies which patients are affected in the event of a recall.

4) Infection Control: The business must implement a program in accordance with appropriate infection control procedures that does not allow for cross-contamination. As appropriate, the business must establish a policy for cleaning, sanitizing, function testing, maintaining, and preparing items or equipment for reuse or disposal.

Product Safety Standards (PS):

PS.1

The business establishes documented policies, procedures, and protocols that address patient safety, equipment and device failures, repairs or product recalls, and infection control.

(New Standard)

PS.2

The business 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.

(Previous Standard: OR.3.5 and PS.1)

PS.2.1

Prior to distributing, dispensing, or delivering items to a patient, the business shall verify, authenticate, and document that the items are not adulterated, counterfeit, suspected of being counterfeit, and have not been obtained by fraud or deceit.

(Previous Standard: PS.1.1)



PS.2.2

Prior to distributing, dispensing, or delivering items to a patient, the business shall verify, authenticate, and document that the items are not misbranded and are appropriately labeled for their intended distribution channels.

(Previous Standard: PS.1.2)

PS.2.3

As part of its efforts to document the authenticity of items purchased for use in providing patient care, the business shall obtain from the manufacturer copies of the features, warranties, and instructions for each type of non-custom-fabricated item, equipment, and/or service (e.g., a product master file, conformance to FDA requirements).

(Previous Standard: PS.1.3 and OR.3.6)

PS.3

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

(Previous Standard: PS.2)

PS.3.1

The equipment management program requires a complete inventory and the appropriate maintenance of analytical, measuring, and other equipment used in the provision of patient care.

(Previous Standard: FS.6 and PS.2.1)

PS.4

The business shall implement and maintain a plan for identifying, monitoring, and communicating throughout the organization, as appropriate, equipment and item failure, repair, recalls, and preventive maintenance.

(Previous Standard: PS.3 and PM.3)

PS.5

The business shall investigate a beneficiary's complaint in which the provided DMEPOS item may have contributed to an incident, injury, or infection. The investigation should be initiated within 24 hours after the business becomes aware of the incident, injury, or infection resulting in a patient's hospitalization or death. For other occurrences, the business shall investigate within 72 hours after being made aware of the incident or injury. The business shall provide written notification within 14 calendar days to the beneficiary of the results of its investigation and response. The investigation includes all necessary information, pertinent conclusions, and whether changes in protocols or processes are needed. The business should consider possible links between the item(s) and service(s) furnished and the adverse event.

(Previous Standard: PS.5, PC.6.3, and PM.3)

PS.6

The business shall implement and maintain a plan to ensure that the patient and/or caregiver(s) can use all equipment and item(s) provided safely and effectively in the settings of anticipated use.

(Previous Standard: PS.4)

PS.6.1

The business shall determine the specific physical requirements of each type of item or equipment it provides and develop a mechanism to efficiently and consistently record the applicable physical features of the environment in which that equipment is to be used.

(Previous Standard: PS.4)



PS.6.1.1

The business shall have policies and procedures to deal with inconsistencies between the observed physical environment and the physical requirements of the prescribed item(s).

(Previous Standard: PS.4)

PS.7

When providing equipment to beneficiaries, the business shall ensure that it provides essential contact information and options for rental or purchase of the equipment, as applicable.

(Previous Standard: PC.11)

PS.8

As appropriate, the storage of equipment and supplies available for patient use is in accordance with appropriate infection control procedures and does not allow for cross-contamination.

(Previous Standard: PC.5.1)

PS.8.1

As appropriate, the business shall establish a mechanism to segregate clean and dirty equipment. The business shall establish and consistently use a mechanism to assure the proper handling of equipment, both new and used, regardless of how or where those items come into the business's possession. Further, the business shall document each item or piece of equipment's progress through the system.

(Previous Standard: PC.5.3.4)

PS.8.2

Equipment and supplies are maintained in a state of patient-readiness in accordance with manufacturer's guidelines.

(Previous Standard: PC.5.4.3)

PS.9

The business shall deliver and set up, or coordinate set-up with another accredited business, all equipment and supplies in a timely manner as agreed upon by the beneficiary/caregiver, business, and appropriately licensed healthcare prescriber.

(Previous Standard: PC.5)

PS.9.1

As appropriate, the business establishes policies and procedures that address and provide for the documentation of requirements for set up, delivery, and pick up of equipment.

(Previous Standard: PC.5.3)

PS.9.2

Prior to final delivery, the business documents that the product(s) meet(s) the specifications of the current prescription, assesses the equipment and supplies for structural safety, and ensures that manufacturer guidelines are followed.

(Previous Standard: PC.6.2 and PC.5.3.3)

PS.9.3

The Rehab Technology Supplier implements 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 appropriately licensed healthcare prescriber.

(New Standard)

PS.9.4

If beneficiaries are evaluated in the supplier's facility, the supplier shall maintain an appropriate area and the equipment necessary for assembly, modification, adjustment, and repair of the items in the facility or in close proximity and easily accessible.

(New Standard)



PS.9.5

The Rehab Technology Supplier provides the beneficiary with appropriate equipment for trial and simulation, when necessary.

(New Standard)

PS.10

The business tracks and documents the status/condition of all equipment and supplies provided to patients. The business must know at all times the condition and location of all equipment. Thus, the status report must accurately reflect critical information including, but not limited to, contact and emergency contact information for all persons to whom equipment or items have been sold or rented in the event that a recall or other similar event were to occur. The tracking process and status report should track the manufacturer's model and serial number.

(Previous Standard: PC.5.2)

PS.11

As appropriate, the business's policies and procedures establish a mechanism to minimize cross-contamination during the delivery and pickup process.

(Previous Standard: PC.5.3 and PC.5.3.5)

PS.11.1

As appropriate, the business's policies and procedures establish a process for cleaning, sanitizing, function testing, maintaining, and preparing items or equipment for reuse. The area in which the equipment is stored in a patient-ready status is clearly identified as clean.

(Previous Standard: PC.5.1, PC.5.3.4, and PC.5.4)

PS.11.2

The business establishes policies and procedures that provide for the cleaning, disinfection, and/or proper disposal of returned items or equipment.

(Previous Standard: PC.5.4.1)

PS.12

The business implements and maintains a plan for identifying, monitoring, and reporting (where indicated) repair and preventive maintenance for equipment and supplies provided to patients in accordance with manufacturer's specifications.

(Previous Standard: PC.5.4.2)

PS.12.1

The business implements and maintains a process for the documentation of the repair and preventive maintenance of equipment and supplies prior to placement into patient-ready status.

(Previous Standard: PC.5.4.3)

PS.13

The business shall provide or arrange for loaner equipment similar to the original equipment during any repair period.

(Previous Standard: PC.6)

PS.13.1

The business shall provide all items that are necessary to operate the equipment or item(s) and perform any further adjustments as applicable.

(Previous Standard: PC.6.1)



Patient Records (PR)

The Patient Records Standards contain specific requirements on the centralization, accessibility, and protection of patient records, as well as keeping Protective Health Information (PHI) secure and confidential.

Federal HIPAA regulations apply to all facilities providing DMEPOS services.

The business should establish documented policies and procedures that address the creation and maintenance of patient records. An effective patient records program must adhere to three principles:

- 1) Secure and Confidential Patient Records:** The business must maintain a secure patient record system that allows prompt retrieval. Except as required by law, patient records should be treated in a strictly confidential manner.
- 2) Back-up Patient Records:** The business is required to take appropriate measures to back-up patient data.
- 3) Uniform Documentation:** Each patient record should consistently include a patient evaluation/assessment with diagnosis, pre-treatment photographic documentation (if applicable), patient education, the referring physician or appropriately licensed healthcare prescriber's prescription, and the treatment plan.

Patient Records Standards (PR):

PR.1

The business establishes documented policies, procedures, and protocols that address the creation and maintenance of patient records.

(Previous Standard: PC.6.1)

PR.2

The business maintains a secure patient record system that permits prompt retrieval of information.

(Previous Standard: PC.6 and PR.1)

PR.2.1

Federal, state, local, and applicable third party payer required documentation regarding the patient is recorded in the patient's clinical record.

(Previous Standard: PC.6.1.1 and PR.4)

PR.3

Patient records are reasonably protected from all risks and appropriate measures are taken to maintain backups of patient data.

(Previous Standard: PC.6.5 and PR.2)

PR.4

Except as required by law, any record that contains clinical, technical, social, financial, or other data on a particular patient is treated in a strictly confidential manner.

(Previous Standard: PC.6.4 and PR.3)



PR.5

Financial, third party payer, and other non-clinical information regarding a patient is maintained according to generally accepted business and accounting principles.

(Previous Standard: PC.6.1.1 and PR.4)

PR.6

Documentation verifies that policies and procedures establish the content of patient records including but not limited to: (1) written or pictorial, and oral instructions related to the use, maintenance, cleaning, infection control practices for, and potential hazards of equipment and/or item(s); (2) verification that the equipment, item(s), and service(s) were received; (3) the make and model number of any non-custom equipment and/or item(s) provided.

(Previous Standard: PR.5)

PR.6.1

Uniform documentation includes but is not limited to: (1) patient evaluation/assessment, which contains diagnosis, prescription or valid order, relevant patient history, and medical necessity; (2) pre-treatment photographic documentation as appropriate for the item; (3) patient education; and (4) the name of the attending clinician, their findings, recommendations, and treatment plan for a specific course of care and management as well as the appropriate follow-up schedule.

(Previous Standard: PC.5.1)

PR.6.1.1

Documentation includes the beneficiary's need for and use of the orthoses/prostheses (e.g., comprehensive history, pertinent medical history, allergies to materials, skin condition, diagnosis, previous use of orthoses/prostheses, results of diagnostic evaluations, and beneficiary expectations).

(New Standard)

PR.6.2

The Rehab Technology Supplier shall maintain, in the beneficiary's record, all of the information obtained during the assessment.

(New Standard)

PR.7

Technical records relevant to equipment and other items are maintained and include a detailed description of the equipment or item(s) provided.

(Previous Standard: PC.6.2.1 and PR.6)

PR.7.1

The business shall verify that seating, positioning, and specialty assistive technology have been evaluated and documented in the beneficiary's record.

(New Standard)



Performance Management and Improvement (PM)

The Performance Management Standards allow an organization to track the strengths and weaknesses of the business and patient care operations.

Any business providing patient care should have a program in place to monitor, evaluate, and improve the quality of patient care.

Effective performance management programs require the following:

1) Organizational Support: Organizational management must dedicate adequate resources to create and administer a Performance Management and Improvement program. Clinical, administrative, and managerial staff should be motivated and competent to fulfill their responsibilities.

2) Data Collection: Facilities must also identify and measure the factors that affect the quality of patient care. While standards PM.2 – PM.7 specify key indicators to measure, you may determine additional areas to track. Determining performance guidelines and goals help you decide what data elements are most important and relevant to your patients and your business. Questions to consider: How will you know when you are performing well? How will you know if you need to make changes? The answers can help you decide what information to track. A Patient Satisfaction Survey is a powerful tool for performance feedback.

3) Data Analysis: After collecting information, the next step involves making sense of the raw data. Since you used guidelines and goals to decide what to track in your data collection, you can use those same guidelines and goals to compare where you are now to where you

want to be in the future. When you look at data collected over a period of time—monthly, quarterly, or annually, depending on your facility’s size—you are better able to see trends and identify organizational changes that need to be made. A performance management system can help you focus on long-term vision instead of a short-term crisis.

Performance Management and Improvement Standards (PM):

PM.1

There is a written program to monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve services, and resolve identified problems. This performance management program is administered by the governing body and is evidenced by documenting, requiring, supporting, and participating in the operation of the program.

(Previous Standard: PM.1 and PM.1.2)

PM.1.1

The business shall seek input from employees, patients, and referral sources when assessing the quality of its operations and services.

(New Standard)

PM.2

The performance management program includes the establishment and implementation of a patient satisfaction survey.

(Previous Standard: PC.8)



PM.2.1

Results of the patient satisfaction surveys are documented and evaluated as part of the business's performance management program.

(Previous Standard: PC.8.2)

PM.3

The business collects, monitors, and measures beneficiary satisfaction with and complaints about product(s) and service(s).

(Previous Standard: PC.8.1 and PM.2.1)

PM.4

The business collects, monitors, and measures the timeliness of response to beneficiary questions, problems, and concerns.

(Previous Standard: PM.2.2)

PM.5

The business collects, monitors, and measures the impact of the supplier's business practices on the adequacy of beneficiary access to equipment, items, services, and information.

(Previous Standard: PM.2.3)

PM.6

The business collects and measures data to evaluate the frequency of billing and coding errors.

(Previous Standard: PM.2.4)

PM.7

The business collects and measures data to monitor any adverse events to beneficiaries due to inadequate or malfunctioning equipment, items, or services once the business becomes aware of such adverse events (e.g., injuries, accidents, signs and symptoms of infection, hospitalizations).

(Previous Standard: PM.2.5 and PM.3)

PM.8

The business collects and evaluates data that allows it to identify and monitor trends associated with the quality of care for its patients. These trends can be either adverse or beneficial to overall patient care.

(Previous Standard: PM.4)

PM.9

When an opportunity to improve the quality of care is identified, action is taken to improve the care. The effectiveness of the action taken is assessed through continued monitoring of care. The recommendations, actions, and conclusions are documented.

(Previous Standard: PM.5)

PM.10

At least annually, the business reviews and documents the review of its performance management program. Any adjustments to the performance management processes will be documented.

(Previous Standard: PM.1.1.1 and PM.6)



Facility Safety and Management (FS)

ABC's Facility Safety and Management Standards address three critical categories: facility safety, safety management, and environmental safety.

1) Facility Safety: The standards require a facility that appropriately accommodates patients and provides for office space to adequately fulfill its patient care and business activities. Further, the standards require that the facility comply with all appropriate health, fire, and occupancy codes, including appropriate requirements of the Americans with Disabilities Act (ADA).

2) Safety Management: Safety management requires that accredited facilities implement processes designed to maintain and improve the quality of the patient care environment. Facilities are expected to establish a safety management program commensurate with the scope and complexity of the items and services provided in order to assure a continued safe facility and environment.

The standards also require that a Safety Officer be appointed to oversee the program, carry out inspections, and perform an evaluation of those inspections. In addition, the facility must develop specific plans to respond to emergencies and fires. Personnel must be trained to carry out duties and responsibilities specified in the contingency plans. Finally, the facility must have a plan to facilitate the continuation of patient care services in the event of a disaster (including power outages and technical malfunctions) affecting the facility, the region, or a larger area.

3) Environmental Safety: Facilities should implement policies and procedures that minimize patient and staff exposure to environmental risks. The standards require adoption of appropriate infection control procedures, including the use of universal precautions and other requirements of the OSHA blood borne pathogens regulations. In addition, facilities are required to administer an equipment management program that is designed to assure proper performance supported by appropriate preventive maintenance programs.

Facility Safety and Management Standards (FS):

FS.1

The business administrator administers a written safety management program that is designed to provide a physical environment free of hazards and to manage staff activities to reduce the risk of injury. At least annually, safety inspections of the facility and the organization's operations are conducted and the results evaluated. The program includes information concerning specific procedures to be followed by personnel and provisions for the management of patients.

(Previous Standard: FS.1, FS.3, FS.3.4.2)



FS.2

The buildings (interiors and exteriors) and grounds are appropriate to the nature of the services provided and to the patient population served. In compliance with applicable laws, the facility is designed to accommodate the needs of the physically challenged, including but not limited to: (1) providing for appropriate exterior handicap access including the path from the parking lot to the facility; (2) providing ramps and/or elevators complying with federal, state, and local requirements for handicap access; (3) ensuring all interior areas for patient use (including restrooms) are wheelchair accessible, as well as designed and equipped to meet the needs of disabled persons; (4) providing a patient waiting/reception area, as applicable; (5) complying with state and local health and fire codes and occupancy classifications for this location; and (6) ensuring there is adequate space to manage the business.

(Previous Standard: FS.2 and FS.2.1)

FS.2.1

In each patient care location, the business shall provide specific, dedicated private treatment area(s) that are properly equipped for patient care and evaluation.

(Previous Standard: FS.2.2)

FS.2.2

When the business provides items that require modification, maintenance, and/or repair, the business shall provide a specific, dedicated laboratory area for servicing, maintaining, adjusting, repairing, modifying, and/or fabricating those items.

(Previous Standard: FS.2.3)

FS.3

The business conducts and documents safety management orientations for all staff which address general safety management issues, safety plans, emergency preparedness, emergency plans, special hazards related to assigned duties, safety practices, and changes in the safety management program.

(Previous Standard: PC.4, FS.3.4)

FS.3.1

When the business elects to maintain specialized emergency equipment (e.g., Automatic External Defibrillator [AED]), personnel are trained in the proper use of that equipment.

(Previous Standard: PC.4.1 and FS.3.4.1)

FS.3.2

The business has created an emergency evacuation plan that addresses appropriate staff response to fires or other emergencies and provides appropriate education and training to all personnel.

(Previous Standard: FS.3.2)

FS.3.2.1

The business conducts an emergency evacuation drill in accordance with the evacuation plan at least annually for all personnel and all shifts. Based upon occupancy classification, the program includes provisions for appropriate fire alarm and fire suppression systems.

(Previous Standard: FS.3.2)



FS.3.2.2

Written evaluations of the effectiveness of the emergency evacuation plan/drill are prepared and results of the evaluation are included as part of the business's performance management program.

(Previous Standard: FS.3.3)

FS.3.3

There is a disaster preparedness program designed to manage the consequences of natural disasters or other events that threaten the business's structural integrity, infrastructure, and/or ability to service its patients.

(Previous Standard: FS.3.1)

FS.4

The business establishes policies and procedures that prohibit the use of smoking materials within its facility.

(Previous Standard: FS.4)

FS.5

The business establishes policies and procedures to minimize the risk of transmission of infection through the use of universal precautions when caring for patients. As appropriate, these include procedures to comply with the Occupational Safety and Health Administration (OSHA) blood borne pathogen regulations, the Centers for Disease Control (CDC), and World Health Organization (WHO) hand hygiene protocols and other relevant, published standards.

(Previous Standard: FS.5)

FS.5.1

The supplier requires the suitable cleaning of facility areas and equipment used in patient care. Appropriate hazardous waste disposal procedures are established in accordance with the services offered.

(Previous Standard: FS.5.1)



Claims and Billing Compliance (CB)

The Claims and Billing Compliance Standards are designed to support your organization's compliance with billing guidelines set by the Centers for Medicare and Medicaid Services and the Office of the Inspector General (OIG)¹.

Depending upon the size of the business and scope of services provided, the business is expected to develop a compliance program that encompasses the spirit of the OIG's Report. The standards parallel five basic elements present in the OIG's Report:

1) The business adopts a claims and billing compliance program based upon formal policies and procedures.

The compliance program should be based upon formal processes that clearly guide the business in preventing inappropriate billing.

2) A qualified and trained individual is responsible for maintaining the compliance program.

The business must assure that a designated person oversees a consistently administered program.

3) Appropriate staff is properly trained and educated on claims development and billing procedures.

Training assures that employees are provided with the information necessary to competently manage the claims billing process and minimizes opportunities for improper claims to be submitted.

4) Auditing and monitoring mechanisms are implemented to ensure consistent compliance.

A monitoring mechanism not only

¹ For a copy of these guidelines, please see "Publication of OIG Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry." *Federal Register*, v. 64.128 (July 6, 1999). Also available on ABC's website, www.abcop.org.

ensures that the compliance program is followed, it will also help identify those elements of the program that may need improvement.

5) Written employment criteria and disciplinary guidelines are implemented.

The business must demonstrate that it carefully screens potential employees who would be responsible for billing practices and that it administers reasonable disciplinary measures for inappropriate billing activities.

These standards are designed to reflect the primary elements of the OIG Report and encourage facilities to establish procedures to minimize the occurrence of fraud and abuse and to protect the business from its effects.

Many facilities contract with billing and claims services, which is allowed under Medicare and ABC Standards. Please be aware that your organization holds final responsibility for all claims submitted on your behalf.

In addition to claims and billing compliance, the business must prevent identity theft by having systems to verify patient identity, report suspicious activity, and reduce possible losses in case of a breach.

Claims and Billing Compliance Standards (CB):

CB.1

The business administers a claims and billing compliance program with written policies, procedures, and standards that describe the business's compliance with federal and state policies for its staff.

(Previous Standard: SC.1 and SC.1.1)



CB.2

A qualified and trained individual is designated by the governing body to be responsible for maintaining the business's claims and billing compliance program.

(Previous Standard: SC.2)

CB.3

The business conducts claims development and billing education for appropriate staff.

(Previous Standard: SC.3)

CB.4

The business establishes file auditing and monitoring procedures for both clinical and financial records to ensure consistent compliance with all applicable federal, state, and private payer healthcare plans.

(Previous Standard: SC.4)

CB.4.1

The auditing and monitoring procedures of the claims and billing compliance program are ongoing and the written results are evaluated and acted upon.

(Previous Standard: SC.4.1)

CB.4.2

The business should establish written policies and procedures to ensure that investigations of suspected noncompliance are handled appropriately and that the necessary corrective action is taken.

(New Standard)



Additional Resources

Thank you for your interest in ABC's facility accreditation program. We have several easy-to-use and helpful resources available to guide you through the accreditation process. Please log onto ABC's website, www.abcop.org.

1) Getting Started: The Getting Started section of our website offers an overview of the accreditation fees, eligibility requirements, application, and survey process.

2) Accreditation Guide: You can download a copy of the Guide under the Forms/Documents section on the Accreditation page. The Guide provides a detailed look at the accreditation process. It also contains an application for your convenience.

3) Accreditation Standards: The Accreditation page of the ABC website contains a downloadable copy of ABC's accreditation standards.

4) Facility Accreditation FAQs: This page is continuously updated and provides answers to common questions regarding the facility accreditation program. There are detailed explanations on applying for accreditation, the survey process and results, accreditation decisions, Corrective Action Plans (CAPs), accreditation fees, continued compliance, appeals and complaints, how to announce and promote your ABC accreditation, and common Medicare questions. To assist you further, ABC has provided direct links to Medicare's website.

5) Accreditation FAQs brochure: This helpful brochure can be downloaded under the Forms/Documents section on the Accreditation page or you can request a printed version. It provides you with the following tips: what you should

know before you apply for ABC accreditation, how to start the accreditation process, what you should know before your survey, and what to expect after your survey.

6) Pre-Application Survey Checklist: This checklist can be downloaded under the Forms/Documents section on the Accreditation page. The checklist highlights some of the areas that facilities tend to overlook in their preparation for the onsite survey.

7) Top 10 Mistakes & What to Expect During Your ABC Accreditation Onsite Survey brochure: This informative brochure reviews the top 10 mistakes seen by ABC surveyors that could mean the difference between passing and failing. It also explains the onsite survey process.

You must have a login and password to access the following resource on ABC's website.

8) Compliance Guide: With the release of the new Accreditation Standards, ABC has created a suggested compliance guide. *Please note: following this guide **does not** ensure compliance. These are merely suggestions to get you headed in the right direction. Your facility will want to customize these suggestions and expand on them when necessary. Compliance will ultimately be determined by ABC.*



Accreditation Programs

Thank you for your interest in ABC's facility accreditation programs. ABC's accreditation programs are specific to the type of patient care services that you provide at each of your patient care locations. The following is a detailed explanation of each accreditation program and the minimum requirements needed to be eligible for that program.

By choosing the accreditation program that best fits your facility's needs prior to completing the application, you can avoid potential delays in processing your application.

Since the scope of orthotic services overlap, you only need to apply for the accreditation specialty that most fully encompasses your facilities' patient care services.

Applications are available online at www.abcop.org.

Applicants must apply for ABC accreditation in all of the services provided regardless of whether you are billing CMS for those services.

Comprehensive Orthotic & Prosthetic Accreditation

These services must be provided by a board certified or licensed orthotist and prosthetist. Licensure is the minimum credential required in states that require licensure. Comprehensive Orthotic & Prosthetic Accreditation includes all services outlined in Comprehensive Orthotic and Comprehensive Prosthetic Accreditations.

Comprehensive Orthotic Accreditation

These services must be provided by a board certified or licensed orthotist. Licensure is the minimum credential required in states that require licensure. Comprehensive Orthotic Accreditation includes custom fabricated orthoses, prefabricated (custom-fit) orthoses, off-the-shelf orthotic devices, comprehensive pedorthic, and non-custom therapeutic footwear.

Comprehensive Prosthetic Accreditation

These services must be provided by a board certified or licensed prosthetist. Licensure is the minimum credential required in states that require licensure. Comprehensive Prosthetic Accreditation is a stand-alone accreditation and does not encompass any other services, including post-mastectomy and ocular prostheses.

Prefabricated Orthotic Accreditation

Designed for facilities that *only* provide prefabricated custom fit and off-the-shelf orthotic services and devices. These services must be provided by a board certified or licensed orthotic fitter. Licensure is the minimum credential required in states that require licensure.

NOTE: Pedorthic, therapeutic, and diabetic footwear services are not covered under the scope of services for this accreditation program.



Off-the-Shelf Orthotics Accreditation

Designed for facilities that *only* provide off-the-shelf orthotic devices. The scope of services for this accreditation is limited to those orthotic devices that require only minor adjustments by the patient and *does not include therapeutic and diabetic footwear*.

Comprehensive Pedorthic Accreditation

Designed for facilities that provide comprehensive pedorthic, therapeutic, and diabetic footwear items and services. These services must be provided by a board certified pedorthist or appropriately licensed professional. Licensure is the minimum credential required in states that require licensure. The scope of service includes the assessment, treatment, and education of patients and the ability to provide non-custom therapeutic footwear and non-custom diabetic multi-density inserts.

Non-Custom Therapeutic Footwear Accreditation

Designed for facilities that *only* provide non-custom therapeutic footwear and non-custom diabetic multi-density inserts. These services must be provided by a board certified pedorthist or board certified therapeutic shoe fitter, or appropriately licensed professional. Licensure is the minimum credential required in states that require licensure.

Additional Services

Post-Mastectomy Patient Care Accreditation

Designed for facilities that provide patient care services related to post mastectomy prostheses and accessories, including garments and lymphedema pumps. This service must be provided by a board certified or licensed mastectomy fitter. Licensure is the minimum credential required in states that require licensure.

NOTE: Post-Mastectomy Patient Services are not included in any other accreditation program and must be indicated separately on your application.

Ocular Prosthetic Accreditation

Designed for facilities that provide fitting, shaping, painting, and maintenance of ocular prostheses. The services provided by these facilities must be overseen by board certified or licensed ocularist or an ocular diplomate or associate of the American Society of Ocularists. Licensure is the minimum credential required in states that require licensure.

NOTE: The Ocular Prosthetic Accreditation program is not included in any other accreditation program and must be indicated separately on your application.



Durable Medical Equipment Accreditation and Ancillary Assistive Device Accreditation

NOTE: *Durable Medical Equipment or Ancillary Assistive Devices accreditation is necessary for all facilities that provide durable medical equipment (DME) **in addition** to orthotic, prosthetic, and pedorthic services. DME is considered **more comprehensive** than AAD; therefore all AAD services are covered in the DME accreditation, and it is not necessary to select both.*

If your practice provides Durable Medical Equipment (DME), such as canes, walkers, crutches, wheelchairs, diabetic supplies, oxygen and related services to Medicare beneficiaries, you need to be accredited for those specific product categories.

Please note: DME and AAD accreditations are not stand-alone accreditations. To be eligible for DME or AAD accreditation, you must also apply for one of ABC's primary accreditation programs. If you provide respiratory oxygen services (including BiPAPs or nebulizers), supply any type of rental items (such as nebulizers), Group 3 or 4 wheelchairs or Group 2 wheelchairs with seating systems or modifications, you must select the DME accreditation program. These items have a more involved survey process that increases the cost of the survey. That increased cost is reflected on the application.

All other DME items not referenced above can be accommodated by selecting the AAD accreditation program, including, but not limited to, blood glucose monitors, Transcutaneous Electrical Nerve Stimulation units, scooters, Continuous Passive Motion devices, canes, walkers, and Neuromuscular Electrical Stimulator devices.





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