



# ABC Accreditation

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**DURABLE MEDICAL EQUIPMENT**

## **Durable Medical Equipment Accreditation Standards**

**The American Board for Certification in Orthotics, Prosthetics and Pedorthics, Inc.**

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# ABC Accreditation

## DURABLE MEDICAL EQUIPMENT

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# ABC Accreditation

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## DURABLE MEDICAL EQUIPMENT

## Introduction

**Durable Medical Equipment Accreditation is designed for organizations providing DME services in addition to orthotic, prosthetic and/or pedorthic patient care. This level of accreditation may not be applied for or held independently; organizations accredited in AAD must maintain a separate, primary ABC Accreditation. Thus, awarding of DME Accreditation is predicated on the awarding and/or maintaining of ABC Accreditation in another discipline, such as Comprehensive Orthotics and Prosthetics Accreditation.**

The scope of services for DME Accreditation includes any item covered by Appendix A or B of the Centers for Medicare & Medicaid Services (CMS) Quality Standards.

Complete information on the process of becoming ABC accredited is in the **ABC Accreditation Guide**.

**About the Standards:** ABC accreditation standards create a baseline for minimal expectations of the physical environment and organizational function of O&P patient care locations. Understanding the accreditation standards is the first step to compliance, as accreditation decisions are based on the degree of conformity with the standards. Standards are grouped into five categories: Organizational (OR), Human Resources (HR), Patient Care and Management (PC), Product Safety (PS), Performance Management (PM), Facility Safety (FS), and Supplier Compliance (SC). Each of the above categories contains multiple standards unique to the specific level of accreditation.

**Understanding the Standards:** ABC accreditation standards are comprised of the standard itself and a statement of intent.

**Standard:** The accreditation standard is a description of the specific criterion related to the provision of services.

**Intent:** The intent statement establishes the framework for a given standard. Not all standards will have a separately stated intent, as some standards may be straightforward and self-explanatory.

OR

## **ORGANIZATIONAL, GOVERNANCE AND ADMINISTRATIVE MANAGEMENT STANDARDS (OR)**

**The organization and administrative standards address the legal status, governance responsibilities and administrative issues with which DMEPOS Suppliers must comply.**

**Organization:** ABC awards accreditation to a legal entity. Thus, the standards require that an organization be legally constituted, not only in the jurisdiction in which it is based, but also in those localities in which it provides services. For ABC to verify the legal owners of an applicant organization, the standards require full disclosure of ownership at the time of application for accreditation.

**Governance:** The standards require a governing body, or an individual who functions as such, to be responsible for the organization's activities. While functional tasks associated with these standards may be delegated to individuals within the organization, ultimate accountability for compliance with the standard rests with the governance. The minimum set of responsibilities assigned to the governing body addresses organizational policies associated with essential components of quality patient care.

**Administration:** Structured administration is present in every organization, no matter how simple it may be. Administrative responsibilities affect the organization's operations and the provision of care, treatment, and patient services. In some cases, these responsibilities will be shared among leaders, and in other cases primary responsibility is assigned to a particular leader. Individual leaders may have several different roles. Regardless of the organization's administrative structure, all responsibilities are to be carried out.

A number of individuals may work for the organization, including licensed independent practitioners, staff, volunteers, students, and independent contractors. These standards describe the overall responsibility of the governance for the safety and quality of care, treatment, and services provided by all of these individuals.

Cooperation among the leadership is key to effective organizational performance and this is reflected in the standards. Leaders with different responsibilities governance, management, and the clinical staff bring different skills, experiences, and perspectives to the organization. Collaboration allows the comingling of ideas and provides a forum to advance those that propel the organization forward. Though the governing body may delegate decision making to certain leaders, final decisions are always the ultimate responsibility of the governing body; this principle is assumed in any standard that describes administration or the governing body.

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Notes

## OR.1

**Standard:** The organization is a legally constituted entity in the state(s) in which it is located and in which it provides services. The organization complies with all federal, state and local laws.

**Intent:** ABC limits its accreditation award to an organization that legally functions as a provider of allied health care. An organization with multiple locations must demonstrate that site(s) seeking accreditation are all legally constituted. Further, ABC requires that an applicant organization comply with all federal, state and local laws as they pertain to the organization's operations. Thus, as part of the Application for Accreditation process, an organization will be required to provide the necessary documents that establish its legal status and identity of its legal owners. An Application for Accreditation will be denied if an applicant organization is not legally constituted, fails to provide ABC with necessary documentation to demonstrate that it is legally constituted, or is found to be in violation of applicable laws.

## OR.1.2

**Standard:** The organization shall have a physical location and display all licenses, certificates, and permits to operate. The licenses and certificates must be displayed in an area accessible to the public.

**Intent:** The provision of DMEPOS services requires that the organization maintain a physical location accessible to the public.

## OR.2

**Standard:** The organization shall comply with all Medicare statutes, regulations (including the disclosure of ownership and control information requirements at 42 CFR 420.201 through 420.206), manuals, program instructions, and contractor policies and articles.

**Intent:** ABC accreditation requires that organizations are eligible to participate in Medicare or other Federal programs and abide by those program's requirements.

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Notes

### OR.3

**Standard:** The organization has a governing body, or designated person(s) so functioning, that sets policy and has overall responsibility for the organization.

**Intent:** Since ABC awards accreditation to an organization rather than to an individual, it expects that the organization will have a governing body or a designated individual, so functioning, that is accountable for the activities of the organization. The governing body may take a variety of forms, such as a board of directors, partnership committee, owner/operator, etc. In addition, the governing body may choose to delegate its authority to a designated individual, such as CEO, regional site manager, etc. to facilitate daily operations. However, the standard requires that the governing body or designated individual, so functioning, retain ultimate accountability for the actions of the organization, its personnel and patient care.

### OR.3.1

**Standard:** The governing body adopts a mission statement and goals and objectives of the organization, which includes a description of the services provided.

**Intent:** To facilitate the orderly operation of an organization, the governing body is expected to establish the framework for the delivery of patient care. Thus, the standards require that the governing body adopt a mission, goals, objectives and a description of its services for the organization. The complexity and comprehensiveness of the organization's mission, goals and objectives will depend upon its unique characteristics, including scope of services offered, types of patients treated, relationship with hospitals, service area, etc.

### OR.3.2

**Standard:** The governing body adopts such written policies and/or procedures deemed necessary for the orderly conduct of the organization. These shall include but are not limited to: addressing professional qualifications and continuing competency; creating a mechanism to facilitate professional staff communication with the governing body; addressing patient care and management, including patient and family education and patient rights; addressing the maintenance and confidentiality of patient records; addressing the protection of private healthcare information; addressing patient billings, collections, complaint resolution; addressing performance management; and addressing facility and safety management.

**Intent:** The organization may establish a number of policies and procedures to efficiently conduct its clinical and business affairs. For the most part, many of these policies and procedures would likely be administratively established and approved. However, these standards identify policies and procedures that are particularly critical to quality patient care. Thus, it is important that the governing body engage in a thoughtful and deliberative process to identify and explicitly approve policies and procedures for these specific areas.

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### OR.3.3.3

**Standard:** The governing body is responsible for documenting the appointment of staff members and permitting the delivery of patient care services only under the direction of a qualified and competent staff member. The appointment process includes a monitoring function designed to verify at least annually, the completion of continuing education consistent with the specialized equipment, items and services provided to patients and, as applicable, the current good standing of staff members with their respective credentialing organization(s) and, where appropriate, licensure board(s).

**Intent:** The governing body has an obligation to assure that equipment, items and services are properly delivered. While the governing body may delegate the delivery function to key personnel, it ultimately is responsible for such delegation.

### OR.3.4

**Standard:** The organization shall provide only those items as disclosed on their current CMS 855s (Supplier Enrollment) application.

**Intent:** The governing body has an obligation to fully disclose the services it provides or intends to provide for its patient population.

### OR.3.4.1

**Standard:** Notwithstanding OR.3.4, the organization shall fully disclose to ABC all DMEPOS items and services provided, and shall notify ABC at least 30 days prior to a change in items or services provided.

**Intent:** The governing body has an obligation to fully disclose the services it provides or intends to provide for its patient population.

### OR.3.5

**Standard:** The organization shall provide only those items that meet applicable Food and Drug Administration (FDA) regulations and medical device effectiveness and safety standards.

**Intent:** The governing body has an obligation to assure that only appropriate equipment, items and services are provided and that they are compliant with all applicable standards.

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Notes

**OR.3.6**

**Standard:** The organization shall obtain from the manufacturer copies of the features, warranties, and instructions for each type of equipment, item and/or service.

**Intent:** The governing body has an obligation to assure that the equipment and supplies it provides as a part of its services are genuine. The supplier shall obtain from the manufacturer, copies of the features, warranties, and instructions for each type of equipment and/or item provided. These standards require the organization has systems to create and maintain records of the quality, authenticity, warranties and features of the equipment and supplies it provides to patients (e.g. a product master file, conformance to FDA requirements, SADMERC recommended coding requirements, etc.).

**OR.4**

**Standard:** Administrative policies, procedures and controls are established, implemented and reviewed at least annually to promote the orderly and efficient management of the organization.

**Intent:** Accreditation is awarded to an organization that is devoted to the delivery of high-quality care. Quality care depends on the effective administration of the organization by processes that enable the fulfillment of the organization's mission, goals and objectives.

To provide for its effective administration, it is expected that the organization will have established a number of policies and procedures. For purposes of accreditation those necessary policies and procedures must be designed to promote effective organizational management. Additionally, these policies and procedures must be reviewed at least annually, to assure that management practices remain relevant to daily operations and the delivery of DMEPOS patient care.

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Notes

#### OR.4.1

**Standard:** Personnel policies and procedures are established and implemented to facilitate attainment of the organization's goals and objectives. These policies and procedures should include, but are not limited to, a periodic appraisal of each individual's job performance (at least annually) and the employment of administrative personnel who have qualifications commensurate with their job responsibilities and authority.

**Intent:** The ability of any organization to effectively pursue its mission, goals and objectives rests upon the recruitment and retention of personnel who are qualified for the job responsibilities to which they are assigned. Thus, these standards require organizations to establish and implement personnel policies and procedures that support effective staff and human resources management. In addition, if the organization uses individuals who by law or organizational policy must maintain current licensure or certification, then policies and procedures should also address these issues. Finally, organizations must also engage in periodic performance appraisals to provide feedback on current competency and opportunities to improve performance.

#### OR.5

**Standard:** The organization complies with the appropriate provisions and requirements of the Healthcare Insurance Portability and Accountability Act (HIPAA).

**Intent:** The Healthcare Insurance Portability and Accountability Act (HIPAA) has profound implications for DMEPOS patient care practices because of the requirements it places on any organization with access to Protected Health Information (PHI). The nature of the business of DMEPOS is such that professional staff must have access to personal information about the patients they see in order to effectively treat them. It is important for all persons with access to this information to understand the provisions of this act and to be sensitive to how that PHI is used.

The HIPAA was first passed in 1996 with two basic sections. The fully-implemented first section deals with protecting the ability of people with current or pre-existing conditions to obtain health insurance. Its applicability to DMEPOS is only tangential. However, the second section, "Administrative Simplification," is intended to improve health care processes by standardizing electronic data transactions and protecting the confidentiality and security of health care data.

ABC is committed to patient's rights and privacy so the concepts presented in this Standard are not new to accredited facilities. However, the level of detail required and the attention focused on these issues is unprecedented in the DMEPOS industry.

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#### Notes

**OR.6**

**Standard:** The organization complies with the appropriate provisions and requirements of the CMS Supplier Standards, Regulations and Medicare Contractor policies and articles.

**Intent:** Policies and procedures must be established to guide the organization in compliance with the appropriate provisions and requirements of the CMS Supplier Standards. These policies and procedures may address, but are not limited to: Personnel assignments and responsibilities, appropriate standards of conduct in claims development and submission, patient billing, training, and an audit and monitoring process. Organizations must ensure that these policies and procedures are available, understood by staff and uniformly followed for all patients regardless of the site of care or service delivered.

**OR.7**

**Standard:** The organization complies with the appropriate provisions and requirements of the Americans with Disabilities Act.

**Intent:** Accredited organizations are expected to comply with all federal, state and local laws related to patient care. However, the Americans with Disabilities Act of 1990 (ADA) has been explicitly identified in the standards as a particularly critical federal statute upon which an accreditation award will be based, largely because of its attention to the role of the organization as an employer and as a commercial entity engaged in the care of disabled patients. The ADA addresses two key considerations for patient care organizations: (a) Title I prohibits discrimination, as an employer, of disabled employees or otherwise eligible employee candidates, and (b) Title III requires private entities engaged in commercial activities to provide access by the disabled. Title I prohibitions apply to an DMEPOS patient care organization that employs 15 or more people on a full-time basis. Such employers (organizations) will be required to provide 'reasonable accommodation' for a disabled employee. Further, the employer may not refuse employment or may not prevent continued employment solely on the basis of an employee's disability or the employer's reluctance to provide for such 'reasonable accommodation'. Title III prohibitions apply to private entities engaged in commerce, including a health care provider office. Except for organizations that qualify under the Fair Housing Act, no private entity is exempt from this section.

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Notes

**OR.8**

**Standard:** The organization has a policy that describes how it will, to the best of its ability, protect patients from real or perceived abuse, neglect or exploitation. The policy will address the process by which notification of the appropriate authorities is made.

**Intent:** The organization should train its staff and representatives to identify potential abuse, neglect or exploitation and how to communicate their concerns to organizational leadership. Policies should identify how the organization determines when it is appropriate to contact the appropriate community resources. A listing of these community resources and contact information is available to the leadership.

**OR.9**

**Standard:** Financial records shall be accurate, complete, current, and reflect cash or accrual base accounting practices. The organization 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) reconciling charges to patients for equipment, supplies, and services with invoices, receipts, and deposits; (2) 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 (3) having a mechanism to track actual revenues and expenses.

**Intent:** Organizations should develop and implement financial management policies, procedures, and practices to ensure accurate accounting, business integrity, and accountability. This exercise will benefit the organization by providing the tools necessary to make sound business decisions.

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Notes

## HUMAN RESOURCES STANDARDS

The following Human Resources standards are designed to support organizational activities toward providing appropriate health care services. The standards in the Human Resource section apply to employed, contract, and volunteer personnel providing patient care and/or services on behalf of an organization. The organization has the responsibility for appointing and privileging the organization's 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.

Organizations must manage the competencies and qualifications of contracted services and personnel in the same manner they manage the competencies and qualifications of direct employees. They can either define in the contract, or in policy, criteria for performance of the contracted service; or, the organization can review and adopt the contract organization's policies and practices. The contract should specify that the contracted organization will provide only staff who are qualified in relation to their education, training, licensure, and competence as defined by the organization.

The human resource standards are applicable to any contracted service which provides any element of care or service which is eligible for survey except that the human resource standards do not apply to delivery of home medical equipment and pharmaceutical products via a contracted common carrier, i.e., UPS, FEDEX, or similar, US Postal Service, local courier companies, etc., where there is no education and setup involved. The standards do apply when delivery is provided by a direct employee.

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Notes

## HR.1

**Standard:** The organization shall establish policies and procedures, including detailed job descriptions, that specify 1) personnel qualifications, training, certifications and/or licensures where applicable; 2) relevant experience; and 3) continuing education requirements consistent with the specialized equipment, items, and services it provides to patients.

**Intent:** The provision of quality health care is dependent on the strength of the personnel charged with providing that care. Therefore, the creation of specific policies and procedures addressing the qualifications and expectations of the staff is essential to a well-run organization.

## HR.2

**Standard:** The organization 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.

**Intent:** Accreditation is awarded to an organization that is devoted to the delivery of high-quality patient care. Quality care depends on the effective administration of the organization by processes that enable the fulfillment of the organization's mission, goals and objectives. To provide for its effective administration, it is expected that the organization will have established a number of policies and procedures. For purposes of accreditation those necessary policies and procedures must be designed to promote effective organizational management. Additionally, these policies and procedures must be reviewed at least annually to assure that management practices remain relevant to daily operations and the delivery of DMEPOS care.

## HR.3

**Standard:** The organization shall provide copies of its policies and job descriptions, upon request, to accreditation organizations and government officials or their authorized agents.

**Intent:** The organization has a duty to facilitate the onsite survey process and cooperate with the survey process.

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Notes

**HR.4**

**Standard:** The organization shall document the verification, and maintain copies, of licenses, registrations and certifications of personnel who provide patient services.

**Intent:** Due diligence requires an organization to remain current with the credential status of its staff.

**HR.5**

**Standard:** Professional personnel shall be licensed, certified, or registered and function within their scope of practice as required by the state standard under which the professional is licensed.

**Intent:** The underlying foundation of quality patient care is the provision of care by qualified and competent staff. Thus, HR.6 requires that professional personnel be licensed, certified, or registered and function within their scope of practice as required by the state standard under which the professional is licensed. While aspects of patient care may be directly provided by another individual, it must only be delivered under the explicit direction of appropriate professional personnel.

**HR.6**

**Standard:** The organization shall use technical personnel who are competent to deliver, set-up and train patients on the use of specialized equipment.

**Intent:** The provision of quality health care is dependent on the knowledge, skills and aptitude of the personnel charged with providing that care. Therefore, the monitoring and assessment of the competencies of the staff is expected.

**HR.7**

**Standard:** In compliance with applicable laws and regulations and in accordance with written objective criteria, the organization 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.

**Intent:** The governing body has an obligation to assure that only qualified and competent staff provide or supervise the provision of patient care. While the governing body may delegate the appointment function to key personnel, it ultimately is responsible for such appointments.

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Notes

## HR.8

**Standard:** At least annually, relevant indicators are used to assess and document the continuing competency of personnel as it relates to the specialized equipment, items and services they provide.

**Intent:** The governing body has an obligation to assure that only qualified and competent staff provide or supervise the provision of patient care. While the governing body may delegate the appointment function to key personnel, it ultimately is responsible for such appointments.

The appointment process is based upon an administrative mechanism that verifies, from primary sources, training, education and licensure/certification. By "primary sources" the standards intend that the organization accept verification only from those bodies that have issued a license/certification rather than accept only attestations or unverified information from the staff. In addition to administering an appropriate appointment process, it is critically important for the organization to periodically evaluate each staff member's continuing competency. In so doing, the organization may apply a number of criteria. However, in order to promote objective evaluations, the standards require that relevant performance management information be included within those criteria.

## HR.8.1

**Standard:** Organizations that provide Respiratory Services as delineated in Appendix A of the CMS DMEPOS Quality Standards shall assess the competency of their technical and professional service staff through objective measures consistent with the current version of the appropriate American Association for Respiratory Care Practice Guidelines.

**Intent:** It is critical that Organizations that provide Respiratory Services as delineated in Appendix A of the DMEPOS Quality Standards assure the competence of its staff in service delivery. That competency must be tied back to the measures of the effectiveness of patient education and training. The organization should assess the degree of patient compliance with and comprehension of the instructions provided.

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Notes

**HR.9**

**Standard:** Personnel policies and procedures are established and implemented to facilitate attainment of the organization's goals and objectives. These policies and procedures should include, but are not limited to, the employment of administrative personnel who have qualifications commensurate with their job responsibilities and authority.

**Intent:** The ability of any organization to effectively pursue its mission, goals and objectives rests upon the recruitment and retention of personnel who are qualified for the job responsibilities to which they are assigned. Thus, these standards require organizations to establish and implement personnel policies and procedures that support effective staff and human resources management. In addition, if the organization uses individuals who by law or organizational policy must maintain current licensure or certification, then policies and procedures should also address these issues. Finally, organizations must also engage in periodic performance appraisals to provide feedback on current competency and opportunities to improve performance.

**HR.10**

**Standard:** In the event that the organization provides complex rehabilitative technology, it shall shall employ at least one qualified Rehabilitative Technology Specialist (RTS) per location. A qualified RTS is an individual that has one of the following credentials:

1. **Certified Rehabilitative Technology Organization (CRTS);**
2. **Assistive Technology Organization (ATS); or**
3. **Assistive Technology Practitioner (ATP).**

**Intent:** For Suppliers that provide Rehabilitative Technology Services, the organization must employ personnel competent to provide the appropriate care for its patient population.

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Notes

**Standard:** In the event that the organization 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 ten hours of continuing education specific to Rehabilitative Technology; and
4. Able to program and repair sophisticated electronics associated with power wheelchairs, alternative drive controls, and power seating systems.

**Intent:** For Suppliers that provide Rehabilitative Technology Services, the organization must employ personnel competent to provide the appropriate care for its patient population.

## PATIENT CARE AND MANAGEMENT STANDARDS (PC)

**Patient care and management standards address essential components designed to support the delivery of high-quality patient care and to ensure patient needs are met.**

**Policies and Procedures:** The standards require the development of organizational policies and procedures for patient care management. These policies and procedures should be available to appropriate personnel at any patient care location operated by the organization.

**Patient Management Protocols:** These standards require that patient care be the responsibility of a qualified and privileged practitioner who has been appointed by the governing body. This includes direct responsibility for patient evaluations and consultation and the supervision of care provided by other organizational care givers.

In addition, the organization must be able to respond to the occasional emergencies that occur in the normal course of any clinical setting. The standards, therefore, require organizations to provide appropriate emergency resources, including personnel trained in basic first aid and CPR, and to make information available to organizational staff concerning procedures to follow for securing additional assistance.

**Physician Interaction and Communication:** To support continuity of care between the organization and referral sources, it is important that mechanisms for communication between the professional staff and a patient's referring physician be maintained. This includes appropriate documentation of a referral. The standards require that all communication with referral sources, whether it be consultations or information relating to the patient's care, be documented in a patient's clinical record.

**Patient Rights:** To establish an environment that facilitates the delivery of effective care, it is important that the organization create an atmosphere of trust between patients and members of the organization. Thus, when an organization provides care, each patient should be treated with respect, dignity and consideration. It is the responsibility of the organization to define other specific rights of the patient. However, at a minimum, the standards stipulate that organizations must recognize the right of patients to participate in decisions about their care and to receive certain information, including fees for services, required methods of payment and provisions for after-hours coverage. Patients represent an important source of information about an organization's performance. Patient satisfaction, as a fundamental feature of any performance management initiative, should be evaluated regularly. Thus, the standards require that organizations periodically conduct patient satisfaction evaluations to determine the degree to which the organization has fulfilled patients' expectations.

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Finally, the standards require the organization to provide a mechanism to resolve patient complaints.

**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. The standards thus require that the organization provide appropriate education to the patient (and/or significant others if appropriate) in the purpose, function, care and use of the prescribed device.

**Patient Follow-up Care:** The standards in this section support ongoing patient care and reflect the criteria established by the profession. They require an organization to provide follow-up care, appropriate to the patient's condition, or care, or recommendations of an appropriate legal referral.

## PC.1

**Standard:** The organization establishes policies and procedures that address the responsibilities of the staff to provide quality care to patients according to generally accepted professional practices.

**Intent:** A quality health care organization will assure that its professional staff members are qualified and competent to carry out their responsibilities. This standard requires the organization to establish a mechanism by which the education, training and competence, as they relate to each professional staff member's responsibilities, are confirmed. Information and attestations provided by the applicant may serve as a basis for evaluating their competence. However, it is the responsibility of the organization to use a process by which it confirms from primary sources the qualifications of the applicant.

## PC.1.1

**Standard:** The organization establishes written patient management policies and procedures which are available at each physical location of the organization.

**Intent:** To assure the organization provides services in a consistent manner for all patients, policies and procedures are established to guide the delivery of patient care. These policies and procedures may address but not be limited to evaluation, design, development, fitting and follow-up for DMEPOS services. Organizations with multiple sites of care must also ensure these policies and procedures are available, understood by professional staff and uniformly followed for all patients regardless of the site of care.

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Notes

## PC.1.2

**Standard:** The organization establishes policies and procedures to facilitate communication and coordination of care among all personnel involved in the provision of durable medical equipment and supplies.

**Intent:** Cooperation and communication among the providers of care is key to effective patient management. Different responsibilities bring different skills, experiences, and perspectives to the patient care process. Collaboration allows the opportunity to recognize needs and provide the most appropriate patient care for each individual patient.

## PC.1.3

**Standard:** The organization establishes a mechanism to inform the patient of the expected time frame for receipt of delivered items.

**Intent:** It is important for the organization to establish consistent time frames in which patients are initially seen and evaluated on a timely basis that gives consideration to the patient's needs. This not only supports quality equipment, items and services but contributes to overall patient satisfaction. These time frames may vary, depending upon a patient's condition and reason for referral; however, it is expected that the organization will ensure that the time frames are consistently followed for similar patient circumstances.

## PC.2

**Standard:** When the organization determines that it cannot or will not provide the equipment, item(s) or service(s) that are prescribed for a patient, the organization shall notify the prescribing physician, practitioner or other healthcare team member within five calendar days.

**Intent:** The underlying foundation of quality patient care is the timely provision of care by qualified providers. If an organization cannot or will not provide a patient with the prescribed equipment, it will notify all affected parties, including the prescribing physician, within five calendar days.

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Notes

### PC.3

**Standard:** Physician referrals, consultations and all other communications with the referring physician are documented in the patient's record (see PR.5) by a letter of referral, prescription, patient evaluations and/or chart notes.

**Intent:** Patient care should not be rendered without the appropriate support of a referring physician. This standard requires the organization to document, within the patient's record, such referrals and prescriptions for services. As with referrals and requests for care, it is important that any formal consultations with referring physicians be documented within the patient's record and should include the elements outlined above. This not only creates an historical record of these communications, but it also enhances continuity of patient care by providing a record from which future patient encounters and care may be guided.

### PC.3.1

**Standard:** All patient care is delivered in strict accordance with the most recent prescription.

**Intent:** Through a process flow from documented verbal orders to receipt of a valid prescription, this standard requires the organization ensure that the care process appropriately reflects the most recent needs of the patient as determined by the attending physician.

### PC.3.2

**Standard:** The organization's policies address its procedures for responding to changes in the treatment plan or identification of patient non-compliance with the current written order.

**Intent:** This standard requires the organization review the treatment plan on each home visit and verify that the chart documentation accurately reflects the most current physician order for every patient. Home visits must accurately reflect care as documented in the current written order. Patient non-compliance is documented, evaluated and corrected through the performance management and patient education and physician communication processes.

### PC.4

**Standard:** As appropriate, the organization documents patient specific goals and expected outcomes for the use of the device.

**Intent:** Properly establishing patient goals and expectations lays the groundwork for establishing realistic outcomes measurement (e.g., reduce pain/increase comfort, enhance function and independence, promote healing, increase range of motion, maintain Oxygen saturation and/or provide continuous use of CPAP, maintain proper nourishment and/or prescribed medication levels (e.g. infusion pump).

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Notes

## PC.5

**Standard:** The supplier shall deliver and set up, or coordinate set up with another supplier, all equipment and supplies in a timely manner as agreed upon by the beneficiary/caregiver, supplier, and prescribing physician.

**Intent:** Suppliers should strive to provide the needed equipment, items and services items as expeditiously as practical.

## PC.5.1

**Standard:** Equipment and supplies available for patient use are properly stored in a designated clean area.

**Intent:** To reduce the risk of cross contamination and to maximize the organization's efficiency, it is imperative that the equipment and supplies ready for patient use are bagged and stored in separate "clean" area.

## PC.5.2

**Standard:** The organization's policies and procedures provide a mechanism to track all equipment and supplies provided to patients.

**Intent:** Organizations must know at all times the condition and location of all equipment and supplies. Thus, the organization's reporting function must accurately reflect the 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 tool should be able to trace back to manufacturer's model and serial number.

## PC.5.3

**Standard:** The organization establishes policies and procedures that address and provide for the documentation of requirements for setup, delivery and pickup of equipment.

**Intent:** Organizations should implement consistent processes for conducting regular activities. These policies should address such issues as proper storage on and off vehicles, lifting procedures, hand washing procedures, home inspection procedures, material handling procedures, recognition of abuse, and other related activities.

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Notes

### PC.5.3.1

**Standard:** The organization's policies and procedures establish the qualifications and competencies of the delivery personnel to provide equipment setup, training and home assessment.

**Intent:** A quality health care organization will assure that its delivery staff members are qualified and competent to provide equipment setup, training and home assessment. This series of standards requires the organization to establish a mechanism by which the education, training and competence of each staff member are confirmed. Patient feedback and other evaluation criteria may serve as a basis for documenting their competence. However, it is the responsibility of the organization to use a consistent process when assessing staff competency.

### PC.5.3.2

**Standard:** The organization's policies and procedures address the qualifications and competencies of the delivery personnel to educate the patient on the proper care use and maintenance of the equipment provided.

**Intent:** A quality health care organization recognizes the importance of appropriate patient education. This standard requires the organization to establish a mechanism of each staff to effectively provide that education.

### PC.5.3.3

**Standard:** Prior to final delivery, the organization verifies that the product meets the specifications of the current prescription, assesses the equipment and supplies for structural safety and ensures that manufacturer guidelines are followed.

**Intent:** The organization has an obligation to provide equipment and supplies that are appropriate and safe for patient use. The organization shall document that the equipment and supplies provided meet the current prescription criteria and have been set up properly according to manufacturer guidelines.

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#### PC.5.3.4

**Standard:** The organization's policies and procedures establish a mechanism to segregate clean and dirty equipment.

**Intent:** The organization must take every precaution to ensure that the equipment and supplies it supplies are clean and sanitary. This standard requires the organization to 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 organization's possession. Further, it is intended that the organization will document each item or piece of equipment's progress through the system.

#### PC.5.3.5

**Standard:** The organization's policies and procedures establish a mechanism to minimize cross-contamination during the delivery and pickup process.

**Intent:** These standards, PC.5.3 through PC.5.3.5, require that the organization provides equipment and supplies that are ready for patient use (e.g. sanitary, clean and undamaged); obtains delivery receipts; secures the equipment during transport to prevent injury or damage; unpacks, assembles and performs safety and operational checks of medical equipment; satisfies the equipment's physical, electrical and other requirements; and correctly stores the equipment in the patient's home. The organization shall use appropriate tools to document these activities.

#### PC.5.4

**Standard:** As appropriate, the organization's policies and procedures establish a process for cleaning, function testing, maintenance, and preparing items or equipment for re-use.

**Intent:** The organization's has a clearly defined process supported by policy and procedure for identifying separate areas for clean and dirty equipment, cleaning and sanitizing equipment, equipment that is in need of maintenance or repair and patient ready status. The area in which the equipment is in a patient-ready status is clearly identified as clean. A quality healthcare organization will have a consistent process established for the cleaning, function testing, maintenance and storing of equipment and supplies. This process is necessary to diminish the possibility of cross contamination.

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#### PC.5.4.1

**Standard:** The organization establishes policies and procedures that provide for the cleaning, disinfection, and or proper disposal of returned items or equipment.

**Intent:** The prevention of cross contamination is vitally important in a healthcare facility. Therefore, the organization is required to establish rigid guidelines for the cleaning and disinfection of returned rental equipment. In addition, all equipment that is considered unsafe for further patient use should be disposed of in accordance with local and state regulations.

#### PC.5.4.2

**Standard:** The organization 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.

**Intent:** A quality healthcare organization is responsible for maintaining its rental equipment in proper working order. Periodic repair, maintenance and manufacture recalls of all rental items should be documented.

#### PC.5.4.3

**Standard:** The organization establishes policies and procedures that require the documentation of the repair and preventive maintenance of equipment and supplies prior to placement into patient-ready status and are maintained in a state of patient-readiness in accordance with manufacturer's guidelines.

**Intent:** This standard is intended to document that any device provided has been thoroughly checked for structural integrity and appropriateness for the patient. (e.g. patient weight limits, no defects in materials and workmanship).

#### PC.6

**Standard:** The supplier shall provide, or arrange for, loaner equipment similar to the original equipment during any repair period.

**Intent:** Organizations must provide, or arrange for, loaner equipment equivalent to the original equipment during any repair period.

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**PC.6.1**

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

**Intent:** Organizations shall provide all equipment properly adjusted and complete with all items necessary to operate the equipment.

**PC.7**

**Standard:** The organization supports the rights of each patient and treats patients with respect, dignity and consideration.

**Intent:** It is important for the organization to establish an environment that facilitates the delivery of effective care. To do so, the organization must create an atmosphere of trust by demonstrating concern and respect for basic human rights.

**PC.7.1**

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

**Intent:** Quality patient care can be enhanced when patients are provided the opportunity to express their preferences for care. Patient desires should not replace the prescriptions of the referring physician nor a substitute for the sound judgment of the professional staff member. However, patient participation can strengthen commitment to accepting and complying with the rehabilitation plan.

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## PC.7.2

**Standard:** The organization makes information available to patients concerning their rights which includes but is not limited to: (1) its fees for services and policies concerning payment of fees; (2) its policies regarding after hours contact and care; and (3) its process for resolving patient complaints in a timely manner.

**Intent:** Patients have a right to adequate information to make decisions about their care and to voice any concerns that arise out of their relationship with the organization. To facilitate a patient's decision making, it is important that the organization make available at least information that tells the patient:

- How to obtain care in the event of an emergency or after the organization has closed for the day;
- What fees and charges the patient will be expected to pay, and how to make payment; and
- How to voice any concerns that may arise in the course of the patient's relationship with the organization. The complexity of this process will depend upon the size of the organization.

However, the process should embody the ultimate goal of attempting to reasonably resolve a patient's grievance in a timely manner.

**FURTHERMORE:** Within five (5) calendar days of receiving a patient complaint, the organization shall notify the patient, using either oral, telephone, e-mail, fax, or letter format, that it has received the complaint and that it is investigating. Within 14 calendar days, the organization shall provide written notification to the patient of the results of its investigation and response. The organization shall maintain documentation of all complaints that it receives, copies of the investigations, and responses to patients.

## PC.8

**Standard:** The organization's performance and the services it provides are assessed through patient satisfaction surveys.

**Intent:** The organization must monitor patient satisfaction as part of its overall performance management activities. While objective determinations of quality may include other factors, patient's subjective viewpoints can frequently be a source for identifying key problematic areas or other opportunities to improve the organization and its services. Thus, these standards require that the organization engage in a patient satisfaction assessment program, the elements of which include an evaluation of satisfaction with the item. In addition, the organization is required to use the results of such assessments in evaluating, at least annually, the overall performance of the organization and its ability to improve the services it provides.

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Notes

## PC.8.1

**Standard:** Patients are requested to participate in a patient feedback assessment within two months following provision of a new or replacement device. The assessments shall include an evaluation of satisfaction with the patient's device, including its clinical function.

**Intent:** The organization must monitor patient satisfaction as part of its overall performance management activities. While objective determinations of quality may include other factors, patient's subjective viewpoints can frequently be a source for identifying key problematic areas or other opportunities to improve the organization and its services. Thus, these standards require that the organization engage in a patient satisfaction assessment program, the elements of which include an evaluation of satisfaction with the equipment, items and services. In addition, the organization is required to use the results of such assessments in evaluating, at least annually, the overall performance of the organization and its ability to improve the services it provides.

## PC.8.2

**Standard:** Results of patient satisfaction assessments are documented and evaluated as part of the organization's performance management program. These evaluations are conducted at least annually.

The organization must monitor patient satisfaction as part of its overall performance management activities. While objective determinations of quality may include other factors, patient's subjective viewpoints can frequently be a source for identifying key problematic areas or other opportunities to improve the organization and its services. Thus, these standards require that the organization engage in a patient satisfaction assessment program, the elements of which include an evaluation of satisfaction with the equipment, items and services. In addition, the organization is required to use the results of such assessments in evaluating, at least annually, the overall performance of the organization and its ability to improve the services it provides.

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Notes

## PC.9

**Standard:** The organization provides the patient and appropriate caregivers with instructions for the proper care and use of the device. Evidence 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 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 or general health.

**Intent:** The long-term effectiveness of rehabilitative care depends on a number of factors, not the least of which is the care and use of the device by the patient. An uninformed or improperly informed patient increases the opportunity for a device to be misused, risking further physical disability or failure of the device. In the worst of circumstances, patients may not use the device, thus, defeating the purpose for which it is intended—improved mobility, physical function and daily living. Therefore, organizations must provide the requisite education of the patient or significant others to enhance the opportunity for proper and effective use.

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

## PC.9.1

**Standard:** The organization's policies and procedures provide, or coordinate the provision of, appropriate information related to the set-up (including preparation of formulas), features, routine use, troubleshooting, cleaning, infection control practices, and maintenance of all equipment and item(s) provided.

**Intent:** The organization verifies and documentation supports patient, caregiver or family member education specific to the item or service provided. The increased likelihood of positive patient outcomes occurs in an environment of pro-active education specific to patient's needs.

## PC.9.2

**Standard:** The organization's policies and procedures provide relevant information and/or instructions out infection control issues related to the use of all equipment and item(s) provided.

**Intent:** The organization verifies and documentation supports patient, caregiver or family member education specific to the item or service provided. The increased likelihood of positive patient outcomes occurs in an environment of pro-active education specific to patient's needs.

Notes

**PC.9.3**

**Standard:** The organization's policies and procedures require, for initial equipment and/or item(s) provided by mail order delivery, the verification and documentation (in the patient's medical record) that the patient and/or caregiver(s) has received instructions on the use of the equipment and item(s).

**Intent:** The organization verifies and documentation supports patient, caregiver or family member education specific to the item or service provided. The increased likelihood of positive patient outcomes occurs in an environment of pro-active education specific to patient's needs.

**PC.9.4**

**Standard:** The organization 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.

**Intent:** Patient and/or caregiver(s) training and instructions shall be commensurate with the risks, complexity, and manufacturer's instructions and/or specifications for items. The supplier shall tailor training and instruction materials and approaches to the needs, abilities, learning preferences, and language of the patient and/or caregiver(s).

**PC.9.10**

**Standard:** The organization provides appropriate patient follow-up care, consistent with the service(s) provided. All follow-up care is recorded in the patient's clinical record. Patient's lack of compliance with follow-up care, if applicable, is also recorded in the patient's clinical record.

**Intent:** Patients have a right to expect that initial services will be supported by appropriate follow-up care. Thus, these standards require an accredited organization to provide such services. However, the organization may be guided by the patient's condition, type of care and referral recommendations concerning the scope and intensity of follow-up care. Regardless of its type, it is expected that all follow-up care will be recorded in the patient's clinical record to facilitate the continuity of future care.

**PC.9.11**

**Standard:** When providing equipment to beneficiaries, the supplier shall ensure that it provides beneficiaries with essential contact information and options for beneficiaries to rent or purchase the equipment, when applicable.

**Intent:** It is important to fully inform the beneficiary of all options to acquire the durable medical equipment being supplied.

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Notes

## PRODUCT SAFETY STANDARDS (PS)

The American Board for Certification in Orthotics, Prosthetics and Pedorthics believes in the importance of improving safety for patients in allied health care organizations and settings. These product safety standards are placed in effect for DMEPOS suppliers at ABC accredited facilities. Most notably, these standards require the organization affirm the fitness and appropriateness of equipment and supplies that it provides to patients. These standards also address the implementation of product safety programs, the responsibility of leadership to create a culture of safety, and the prevention of medical errors through the analysis and redesign of vulnerable patient systems (for example, the intake, inspection and replacement for duty of rental DMEPOS).

### PS.1

**Standard:** The supplier shall provide only durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) and other items that meet applicable Food and Drug Administration (FDA) regulations and medical device effectiveness and safety standards.

**Intent:** It is the responsibility of the organization to verify and document that all of the DMEPOS equipment and supplies that the organization provides to the patient are approved through the Food and Drug Administration.

### PS.1.1

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

**Intent:** The provision of quality healthcare supplies is dependent on the clear tracking of authentic equipment and supplies from the manufacture to the patient. A healthcare organization is responsible for verifying and documenting that DMEPOS equipment and supplies that are provided to patients are authentic and traceable to the original manufacturer.

### PS.1.2

**Standard:** Prior to distributing, dispensing, or delivering products to a patient, the organization shall verify, authenticate, and document that the products are not misbranded and are appropriately labeled for their intended distribution channels.

**Intent:** The healthcare organization will verify that all DMEPOS equipment and supplies provided to the patient are labeled correctly for their intended use.

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Notes

### PS.1.3

**Standard:** Prior to distributing, dispensing, or delivering products to a patient, the organization shall verify, authenticate, and document that the products were obtained from a distributor or wholesaler approved and authorized by the manufacturer of the products.

**Intent:** The healthcare organization will only purchase DMEPOS equipment and supplies from suppliers and vendors approved by the original manufacturer. The healthcare organization maintains shipping and receiving logs that reflect the products ordered from the manufacturers.

### PS.2

**Standard:** The organization shall implement an equipment and item management program that promotes the safe use of equipment and supplies and minimizes safety risks, infections and hazards both for its staff and for patients.

**Intent:** To minimize the risk to patients of acquiring or transmitting infections, this standard requires health care organizations to continuously monitor the presence of and spread of infection, take the necessary steps to prevent the introduction and spread of infection, and institute plans designed to control infection. The standard requires that organizations establish clear and comprehensive plans and processes that promote the safe use of equipment and supplies and minimizes safety risks, infections and hazards.

### PS.2.1

**Standard:** The organization shall implement an equipment management program that provides for a complete inventory of, and the appropriate maintenance of, analytical measuring and other equipment used in the provision of patient care (e.g. CPM, Oxygen analyzers, dosimeters, and CPAP monometers).

**Intent:** The organization has designed an equipment management program designed to oversee and document the periodic maintenance and repair of all diagnostic equipment used in the facility.

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Notes

**PS.3**

**Standard:** The organization shall implement and maintain a plan for identifying, monitoring, and reporting (where indicated) equipment and item failure repair, recalls and preventive maintenance, for equipment and item(s) provided to patients.

**Intent:** The organization's policies, procedures and documentation demonstrate its efforts to reduce the likelihood of incidents recurring by performing and documenting routine and preventative maintenance at the manufacturer's recommended guidelines and between patients. In addition, equipment failures and item recalls are communicated throughout the organization as appropriate.

**PS.4**

**Standard:** The organization shall implement and maintain a plan for identifying, documenting and monitoring the suitability of the patient's home (or the environment in which the item is to be used) for the use of the equipment and supplies provided.

**Intent:** The organization's must determine the specific physical requirements of each type of item or equipment it provides. In addition, it must develop a mechanism to efficiently and consistently record the applicable physical features of the environment in which that equipment is to be used. Finally, the organization's processes must provide a "decision tree" or alternatives to deal with inconsistencies between the physical environment and the physical requirements.

**PS.5**

**Standard:** The organization shall create policies and procedures which detail its mechanism(s) to investigate any incident, injury or infection in which DMEPOS may have contributed to the incident, injury or infection, when the supplier becomes aware. The investigation should be initiated within 24 hours after a supplier becomes aware of an incident, injury or infection resulting in a patient's hospitalization or death. For other occurrences, the supplier shall investigate within 72 hours after being made aware of the incident or injury. The investigation includes all necessary information, pertinent conclusions about what happened, and whether changes in systems or processes are needed. The supplier should consider possible links between the item(s) and service(s) furnished and the adverse event.

**Intent:** Organizations have a special duty to determine if their services or materials were responsible for or partially responsible for an adverse patient incident. The organization should make a concerted effort to reduce the likelihood of similar incidents recurring through its performance management program.

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Notes

**PS.6**

**Standard:** The organization establishes a written contingency plan that describes its response to emergencies and disasters or its arrangements with alternative suppliers in the event that the supplier cannot service its own customers as the result of an emergency or disaster.

**Intent:** Organizations must prospectively establish procedures for responding to emergencies that may occur during the course of daily operations. The complexity of the plan will depend upon the size and scope of the organization's activities. However, it must address how the organization will protect and evacuate patients and staff. Additionally, if the emergency is restricted to the interior environment of the organization, then procedures should address how the emergency is to be managed and eliminated. The organization assesses its vulnerabilities annually and ensures that its contingency plan addresses those identified vulnerabilities. Common disasters include but are not limited to: power outages, and severe weather such as hurricanes, tornados, floods, fires, ice, earthquakes, wildfires, and mudslides.

**PS.7**

**Standard:** The organization establishes a written contingency plan that describes its response to after- hours and emergency maintenance, backup or replacement of DMEPOS items.

**Intent:** Allied health care organizations should establish and practice emergency contingency plans, based in part in the criticality of services provided, to assure the continuation of care throughout an emergency.

**PS.7.1**

**Standard:** When respiratory services, as described in the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Quality Standards Appendix A, are provided, the organization establishes a written policy that assures the availability of these services 24 hours a day, 7 days a week as needed by the patient.

**Intent:** Due to the critical nature of these products and services, the organization has a duty to ensure that it can respond to the needs of its patient population.

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Notes

## PATIENT RECORDS STANDARDS (PR)

Accuracy and consistency in documenting patient care are essential to the delivery of high quality health care. The principles used in developing these standards are derived from the guiding principles adopted by the Secretary of Health and Human Services, which were published in the HIPAA administrative simplification standards.

1. Improve the efficiency and effectiveness of the health system for delivering high quality care.
2. Protect patient privacy, confidentiality and security.
3. Meet the data needs of the health community, particularly providers, patients, health plans, clearinghouses, and public health organizations.
4. Bring consistency and uniformity to the uses of the other HIPAA standards--to their data element definitions and codes and their privacy and security requirements--and, secondarily, with other private and public sector health data standards.
5. Have low additional standards development and implementation costs relative to the benefits of using patient medical record information standards.
6. Are precise and unambiguous, but as simple as possible. When the Standards refer to patient medical record information, it means "information about a single patient which is generated by health care professionals as a direct result of interaction with the patient, or with individuals who have personal knowledge of the patient, or with both." This definition comes from the Institute of Medicine's report entitled *The Computer-based Patient Record: An Essential Technology for Health Care*.

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Notes

## PR.1

**Standard:** The organization maintains a secure patient record system that permits prompt retrieval of information. Except as required by law, patient records are maintained in a uniform and legible manner, are documented accurately in a timely manner, and are readily accessible to staff members only on a "need-to-know" basis in accordance with HIPAA regulations.

**Intent:** The clinical record is the principle support tool for appropriate health care. It represents the diary of the patient's past and present clinical history and serves as the "road map" for continuing the care of the patient. Thus, it is critical that a patient record system permit effective use of the record, including ready access and accurate, intelligible entry. As with systems to manage its administrative documentation, the organization must maintain a management system to control its technical and medical patient care records. The complexity of a patient care record system will depend upon the size of the organization, patient volume and professional staff. However, any system, whether automated or manual, will feature attributes that permit efficient storage and retrieval, maintenance and archiving, and distribution. Further, the system must be managed according to generally accepted business and accounting principles and must be consistent with laws and regulations governing business and health records.

Finally, the organization must provide for adequate and secure space to maintain patient records. This does not imply that a separate storage area or dedicated records room is required. The amount of space and location for record storage will depend upon the organization's record archiving, retention and destruction policies. Regardless of space allocation, the method of storage must ensure the safety and integrity of the records, including minimizing risks of inadvertent destruction and unauthorized access.

## PR.2

**Standard:** All patient records are reasonably protected from unauthorized access, loss, tampering, alteration, destruction, and unauthorized or inadvertent disclosure of information.

**Intent:** To promote and facilitate effective patient care, the integrity of the professional/patient relationship must be carefully protected. A fundamental feature of this relationship is the collaborative sharing of, and knowledge of, sensitive patient information which is necessary for treatment and the provision of services. These standards set forth the framework upon which the organization fulfills its duty to ensure the confidentiality of this information.

The policies and procedures followed by the organization will depend on federal, state and local laws; however, it is expected that in circumstances not mandated by law, the organization will secure patient approval of any

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release of confidential information. It should be noted that these standards are not intended to prohibit the "need to know" exchange of confidential information between the organization's personnel or between professional staff members and referring physicians. However, these standards do infer that the organization has established a mechanism to secure patient approval for the release of information to other outside sources such as insurance companies or health care providers other than the patient's referring physician.

### PR.3

**Standard:** 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.

**Intent:** To promote and facilitate effective patient care, the integrity of the professional/patient relationship must be carefully protected. A fundamental feature of this relationship is the collaborative sharing and knowledge of sensitive patient information which is necessary for treatment and the provision of services. These standards set forth the framework upon which the organization fulfills its duty to ensure the confidentiality of this information. The policies and procedures followed by the organization will depend on federal, state and local laws; however, it is expected that in circumstances not mandated by law, the organization will secure patient approval of any release of confidential information.

It should be noted that these standards are not intended to prohibit the "need to know" exchange of confidential information between the organization's personnel or between professional staff members and referring physicians. However, these standards do infer that the organization has established a mechanism to secure patient approval for the release of information to other outside sources such as insurance companies or health care providers other than the patient's referring physician.

### PR.4

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

**Intent:** The clinical record is the principle support tool for the health care provider. It represents the diary of the patient's past and present clinical history and serves as the "road map" for continuing the care of the patient. Thus, it is critical that a patient record system permit effective use of the record, including ready access and accurate, intelligible entry. As with systems to manage its administrative documentation, the organization must maintain a management system to control its technical and medical patient care records. The complexity of a patient care record system will depend upon the size of the organization, patient volume and professional staff. However, any system, whether automated or manual, will feature attributes that permit efficient storage and

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retrieval, maintenance and archiving, and distribution. Further, the system must be managed according to generally accepted business and accounting principles and must be consistent with laws and regulations governing business and health records.

Finally, the organization must provide for adequate and secure space to maintain patient records. This does not imply that a separate storage area or dedicated records room is required. The amount of space and location for record storage will depend upon the organization's record archiving, retention and destruction policies. Regardless of space allocation, the method of storage must ensure the safety and integrity of the records, including minimizing risks of inadvertent destruction and unauthorized access.

#### PR.5

**Standard:** The organization develops and documentation verifies that written policies and procedures establish the content of patient records including but not be limited to: (1) written and oral instructions related to the use, maintenance, 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.

**Intent:** A quality healthcare organization will develop a patient record system that allows for prompt retrieval of patient information. Notwithstanding the requirements of the standard, organizational best practices may include such information as patient demographics, history, prescriptions, diagnosis, equipment provided, critical values, emergency contact, advanced directives, and other information that impact the organization's ability to provide appropriate care.

#### PR.6

**Standard:** Technical records relevant to equipment, items or supplies or are maintained and include a detailed description of the equipment or item(s) provided.

**Intent:** This standard requires the organization maintain, when applicable, a technical record which may include polysomnogram reports, Complex Rehabilitative Wheelchairs and Assistive Technology order forms, orthometric forms, measurement forms, or other documents which record critical values specific to care, treatment and service.

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Notes

## PERFORMANCE MANAGEMENT AND IMPROVEMENT STANDARDS (PM)

Any organization providing patient care should be engaged in a proactive process to assess and improve the quality of that patient care. As an organization-wide initiative, monitoring and evaluating care embraces several principles:

1. An organization can improve patient care and service quality.
2. The process involves all organization members, including the professional, technical and managerial staff and members of the governing body.
3. The process must be coordinated and integrated and requires the attention and action of the organization's leadership.

Clinical, support and managerial staff should be motivated and competent to fulfill their responsibilities. Therefore, opportunities to improve most often are associated with deficits in processes and the underlying systems that support patient care. Consequently, organizations, without avoiding corrective actions to improve knowledge and personal skill, should focus upon the underlying processes that influence the delivery of quality patient care. Based upon these principles, the standards motivate organizations to engage in a comprehensive monitoring and evaluation process that assesses important aspects of care, establish indicators which, if not met, will trigger further evaluation of the important aspect of care, and require actions to be taken when problems or opportunities to improve are identified.

The standards embrace two important elements of a monitoring and evaluation program: (1) Important Aspects of Care, (Clinical or administrative activities that most influence the quality of care delivered to a patient. These activities may relate to a high volume of patients or services, entail a high risk for patients, or be prone to produce problems for the organization's staff or patients). (2) Indicators (A defined characteristic or variable of an important aspect of care. Indicators may be activities, events or outcomes for which data can be collected and evaluated against comparable experience within the organization or from other organizations. Indicators may also be based upon professional standards of care or practices that are objectively quantifiable. In many instances, this objective information can be drawn from professional literature or consensus panels convened by the profession.)

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### Notes

## PM.1

**Standard:** There is an ongoing performance management program designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve services, and resolve identified problems. The program is administered by the governing body and is evidenced by requiring, supporting and participating in the establishment, maintenance and operation of an organization-wide program.

**Intent:** In an era of accountability for not only the cost of care, but for its quality and effectiveness as well, performance management has become a fundamental organizational initiative. While quality assurance has been a feature of many organizations, it has, for the most part, been a program of limited focus and only intermittent administration. This standard requires an organizational commitment to the implementation and administration of an ongoing and comprehensive process that monitors and evaluates important aspects of care on a continuous basis. The program must embrace objective (not subjective or opinion-based) criteria, must be systematically administered, and must embody the goal of identifying and resolving problems and initiating improvements to patient care.

### PM.1.1

**Standard:** The governing body strives to assure high-quality patient care by requiring and supporting the establishment and maintenance of an effective, organization-wide performance management program.

**Intent:** The standards address the role of the organization's leadership in supporting an effective program. They emphasize the importance of their participation in decision-making to improve patient care. Thus, the governing body must be kept informed and must demonstrate that, when appropriate, actions are taken by the organization to solve problems and to initiate improvements in patient care.

#### PM.1.1.1

**Standard:** The governing body participates in the performance management program by periodically receiving reports of activities and taking actions on recommendations to improve or resolve identified problems in the quality of patient care.

**Intent:** In order for the governing body to improve or resolve identified problems in the quality of patient care, the performance management program must provide periodic activity reports.

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Notes

### PM.1.2

**Standard:** There is a written plan for the performance management program that describes the program's objectives, organization, scope and mechanisms for overseeing the effectiveness of monitoring, evaluating and problem solving activities.

**Intent:** To promote a consistently administered program, organizations must develop a thoughtfully constructed program. By establishing a written plan, uniform understanding of the program is promoted throughout the organization and consistent management of the program is facilitated.

The identification of important aspects of care permits an organization to efficiently and effectively use its management resources on those issues for which there will be the greatest return. As noted in the preamble to this section, important aspects of care are clinical or administrative activities that most influence the quality of the care delivered to patients. Typically, they address those characteristics that may be problem-prone, high risk or high volume activities. Clinical activities are patient care services delivered by the professional staff or under their supervision. Administrative activities are those which support the delivery of clinical care.

### PM.1.3

**Standard:** Those aspects of care that are most important to the health and safety of the patients served are identified and are being monitored and evaluated.

**Intent:** To promote a consistently administered program, organizations must develop a thoughtfully constructed program. By establishing a written plan, uniform understanding of the program is promoted throughout the organization and consistent management of the program is facilitated.

The identification of important aspects of care permits an organization to efficiently and effectively use its management resources on those issues for which there will be the greatest return. As noted in the preamble to this section, important aspects of care are clinical or administrative activities that most influence the quality of the care delivered to patients. Typically, they address those characteristics that may be problem-prone, high risk or high volume activities. Clinical activities are patient care services delivered by the professional staff or under their supervision. Administrative activities are those which support the delivery of clinical care.

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Notes

## PM.2

**Standard:** Key indicators are identified and data are collected and measured to monitor the quality of important aspects of care.

**Intent:** As noted in the preamble to this section, indicators are variables associated with, or descriptive of, important aspects of care such as those required in standards PM.2.1 through PM.2.5. An accredited organization will select additional indicators depending upon the identified important aspects of care.

Whatever indicators are selected by the organization, they must be objective, measurable and based on current professional knowledge and experience. They may include clinical criteria (sometimes called "clinical standards," "practice guidelines" or "practice parameters"). It is also important to note that indicators need not have a one-to-one correspondence to the important aspects care. That is, one indicator may relate to two or more important aspects, or two indicators may be used to monitor one important aspect.

## PM.2.1

**Standard:** Key indicators are identified and data are collected and measured to monitor the patient's acceptance of and satisfaction with the equipment and supplies.

**Intent:** This standard is designed to help assess the level of patient satisfaction with the services, the function of any equipment, and quality of any supplies provided in the performance of those services. Assessing and understanding patient satisfaction will give the organization tools necessary to improve those aspects of care and create a loyal, satisfied customer base.

## PM.2.2

**Standard:** Key indicators are identified and data are collected and measured to monitor the timeliness of response to beneficiary questions, problems, and concerns.

**Intent:** This standard is designed to help assess the level of organizational response to patient inquiries. Assessing and understanding organizational responsiveness provides information necessary to ensure that the organization's patient management policies are being properly followed.

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Notes

### PM.2.3

**Standard:** Key indicators are identified and data are collected and measured to assess the impact of the organization's business practices on the adequacy of beneficiary access to equipment, items, services, and information.

**Intent:** The ability to collect data which describes the experience of the indicator is the underlying foundation for an effective monitoring and evaluation process. The use of data assists the efforts of the organization to identify, address and correct problems and to pursue opportunities to improve care. Organizations will collect and organize data so that the evaluation of the quality of care is facilitated. Additionally, data must be collected to evaluate single events that adversely impact patient care for an individual patient as well as data that permits the evaluation of trends or patterns of unacceptable quality. Finally, the use of data may be associated with comparisons of the organization's own performance with that of other organizations ("benchmarking") when comparison against national profession-wide experience is not possible.

### PM.2.4

**Standard:** Key indicators are identified and data are collected and measured to evaluate the frequency of billing and coding errors.

**Intent:** The accuracy of the billing process is an important aspect of care. By identifying pertinent indicators respecting the billing activity, an organization can identify and correct process errors or other errors or omissions. Examples of indicators that may be used include: the number of Medicare claims denied, the reasons for the denial, or errors the organization finds in its own records.

### PM.2.5

**Standard:** Key indicators are identified and data are collected and measured to monitor the adverse events to beneficiaries due to inadequate or malfunctioning equipment, items, or services.

**Intent:** When the organization becomes aware that one of its patients suffered an adverse event (e.g., injuries, accidents, hospitalizations), in which the device provided by the organization was a factor, this standard requires that the organization's PM program record the relevant data and use it to help determine the magnitude of the event, the likelihood of re-occurrence, and whether systems or processes should be adjusted.

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Notes

### PM.3

**Standard:** Key indicators are identified and data are collected and measured to evaluate single (sentinel) events that reduce the quality of care for an individual patient.

**Intent:** The ability to collect data which describes the experience of the indicator is the underlying foundation for an effective monitoring and evaluation process. The use of data assists the efforts of the organization to identify, address and correct problems and to pursue opportunities to improve care. Organizations will collect and organize data so that the evaluation of the quality of care is facilitated. Additionally, data must be collected to evaluate single events that adversely impact patient care for an individual patient as well as data that permits the evaluation of trends or patterns of unacceptable quality. Finally, the use of data may be associated with comparisons of the organization's own performance with that of other organizations ("benchmarking") when comparison against national profession-wide experience is not possible.

### PM.4

**Standard:** Key indicators are identified and data are collected and measured to evaluate trends associated with the quality of care for a patient population.

**Intent:** The ability to collect data which describes the experience of the indicator is the underlying foundation for an effective monitoring and evaluation process. The use of data assists the efforts of the organization to identify, address and correct problems and to pursue opportunities to improve care. Organizations will collect and organize data so that the evaluation of the quality of care is facilitated. Additionally, data must be collected to evaluate single events that adversely impact patient care for an individual patient as well as data that permits the evaluation of trends or patterns of unacceptable quality. Finally, the use of data may be associated with comparisons of the organization's own performance with that of other organizations ("benchmarking") when comparison against national profession-wide experience is not possible.

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Notes

## PM.5

**Standard:** 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 and the findings, conclusions, recommendations and actions taken are documented.

**Intent:** When an analysis of data identifies opportunities to improve care or when a problem is identified, the organization must initiate actions to improve the care or correct the deficiency. The action taken may be an interim measure. That is, action may take the form of a testing of a proposed solution prior to full implementation. Regardless of the form of a testing of a proposed solution prior to full implementation. Regardless if the form of action, also requires the organization to monitor and evaluated the effectiveness of the actions taken and make appropriate modifications to solutions as warranted.

When multiple opportunities to improve are identified, the organization may prioritize the order in which solutions are implemented.

## PM.6

**Standard:** There is a minimum of an annual written reappraisal of the organization's performance management program and the effectiveness of the monitoring and evaluating process.

**Intent:** An annual reappraisal of the program guides the organization in refining its approach to monitoring and evaluating and assures that the program remains current with the overall mission, goals and objectives of the organization.

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Notes

## FACILITY AND SAFETY MANAGEMENT STANDARDS (FS)

**Health care settings are inherently risky environments for patients and organizational staff. Adequate and well-equipped space facilitates the safe care of patients and minimizes opportunities for injury or exposure to hazardous conditions. Thus, this section of the standards addresses three critical categories: facility safety, safety management and environmental safety.**

**Facility Safety:** The standards require an organization to provide a facility that is appropriately designed to accommodate patients, including the physically challenged, and to provide for minimum office space to undertake 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.

**Safety Management:** Safety management is the process that accredited organizations are required to implement to maintain and improve the quality of patient care environment. Organizations are expected to establish a safety management program, commensurate with their size and complexity, to assure a continued safe facility and environment.

The standards require that a safety officer (duties may be assigned to an existing employee) be appointed to oversee the program and to carry out inspections and evaluations of risk-related aspects of the organization. In addition, the organization must develop specific plans to respond to emergencies and fires, and personnel must be trained to carry out duties and responsibilities specified in the plans. Finally, the organization must have a plan to facilitate the continuation of patient care services in the event of a disaster, either concentrated on the facility, the region, or a larger area.

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

## FS.1

**Standard:** The organization's facility complies with appropriate provisions of state and local health and fire codes and occupancy classifications and is designed and maintained to protect patients, personnel, visitors and property from safety hazards and to provide for its safe use.

**Intent:** Safety management is the process by which an accredited organization staff works. The standards establish the expectation that the facility is constructed and maintained in accordance with fire safety and occupancy classification codes.

## FS.2

**Standard:** All buildings (interiors and exteriors) and grounds are appropriate to the nature of the services provided and the ages and other characteristics of the patient population served and 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) providing all interior areas for patient use (including restrooms) which are wheelchair accessible and designed and equipped to meet the needs of disabled persons; and (4) there is a patient waiting/reception area.

**Intent:** Given that organizations care for patients with unique physical challenges, it is important that its facilities and grounds be configured to meet the needs of the patient. Additionally, since many organizations combine patient care services with fabrication capabilities, it is also important that a facility be structured to adequately accommodate both activities. Any professional organization engaged in patient care must present a similar public image. Further, a clean environment minimizes risks of injury or adverse occurrences. Organizations which perform fabrications may have laboratories or other non-patient areas that are dusty or otherwise unkempt. It is expected, however, that measures are taken to minimize these conditions in those areas. This standard addresses areas accessible to patients.

## FS.2.1

**Standard:** Adequate space is provided within the facility to manage the business affairs of the organization, including patient reception.

**Intent:** An organization must provide the necessary space to permit the performance of its services. It is also important that the various functions of the organization enjoy their own spaces to permit efficient and effective administration. Thus, this standard requires organizations to provide the necessary physical capacity to carry out the requisite activities.

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Notes

## FS.2.2

**Standard:** As appropriate, the organization provides a specific, dedicated private treatment areas, properly equipped for patient care and evaluation.

**Intent:** If patient care is provided on location, the organization must provide the necessary space to permit the performance of its services.

## FS.2.3

**Standard:** As appropriate, the organization provides a specific, dedicated laboratory area for servicing, maintaining, adjusting, repairing and/or modifying complex rehab. equipment and supplies.

**Intent:** An organization must provide the necessary space to permit the performance of its services. It is also important that the various functions of the organization enjoy their own spaces to permit efficient and effective administration. Thus, this standard requires organizations to provide the necessary physical capacity to carry out the requisite activities.

## FS.3

**Standard:** The organization administers a safety management program that is designed to provide a physical environment free of hazards and to manage staff activities to reduce the risk of human injury. A trained individual is responsible for developing, implementing and monitoring the safety management program. At least annually, safety inspections of the facility and organizational operations are conducted and results evaluated. The program includes information concerning specific procedures to be followed by organizational personnel and provisions for the management of patients.

**Intent:** The safety management standard establishes the expectation that an accredited organization will prepare its personnel to manage its physical environment in a manner that will effectively avoid injury due to hazards that can otherwise be eliminated.

An organization needs not designate a full-time position as responsible for the safety management program. Rather, it may include this responsibility within the scope of responsibilities of an existing staff member. However, it is expected that this staff member will be properly trained and accountable for safety management within the organization.

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Notes

### FS.3.1

**Standard:** There is an emergency preparedness program designed to manage the consequences of natural disasters or other emergencies that threaten the organization's structural integrity, infrastructure, visitors, or staff.

**Intent:** Notwithstanding PS.5, organizations must prospectively establish procedures for responding to emergencies that may occur during the course of daily operations. The complexity of the plan will depend upon the size and scope of the organization's activities. However, it must address how the organization will protect and evacuate patients and staff. Additionally, if the emergency is restricted to the interior environment of the organization, then procedures should address how the emergency is to be managed and eliminated.

### FS.3.2

**Standard:** There is an on-going program designed to establish and maintain fire safety. The program includes a fire plan that addresses appropriate staff response to a fire emergency and appropriate education and training for all personnel in all elements of the fire plan. There is an annual implementation of the fire plan for all personnel on all shifts. Based upon occupancy classification, the program includes provisions for appropriate fire alarm and fire suppression systems.

**Intent:** As with emergency preparedness, the organization must implement a program of fire safety. The program includes adequate fire alarm and fire suppression systems as required by local occupancy classification as well as a fire plan for personnel. The plan should address procedures personnel are to follow in evacuating patients and themselves.

Depending upon the requirements of the organization's occupancy classification, the fire alarm may be localized only to the building itself (pull boxes and/or central detection systems). It may also feature alert linkages to local fire departments. Fire suppression systems may simply be properly located and maintained extinguishers or they may also include sprinkler systems.

Fire plans will detail procedures to be followed by the organization in minimizing the risks of fire in the preservation of staff and patients from fire and products of combustion, in the safe evacuation of patients and personnel, and the type and extent of training for all personnel.

An organization's fire plan and /or local fire regulations may require the conducting of fire drills at specified intervals. At a minimum, however, these standards require the organization to perform at least one fire drill per year. Such drills are to be performed on all shifts and may be completed at convenient times to minimize disruptions on patient care. As a cautionary note, however, organizations should evaluate how well it can safely manage and evacuate patients in the event of a fire.

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#### Notes

### FS.3.3

**Standard:** Written evaluations of the conduct and effectiveness of the emergency preparedness and fire plans are prepared and results of the evaluation are included as part of the organization's performance management program.

**Intent:** For similar reasons that were noted for safety inspections, evaluations of the organization's emergency preparedness and fire plans are important components of the organization's overall Performance management program. These evaluations should be designed to identify deficiencies or areas of improvement to increase their effectiveness.

### FS.3.4

**Standard:** Documented periodic safety management orientations which address general safety management issues, safety plans, emergency preparedness, fire plans, special hazards related to assigned duties, safety practices and changes in the safety management program are conducted for all organizational personnel.

**Intent:** To effectively support its overall safety management program, it is important for the organization to assure that its staff members are adequately trained and oriented concerning safety management practices, including emergency preparedness, fire plans and any special hazards to which a staff member may be exposed. Thus, organizations are required to conduct periodic orientation and training programs to inform staff members about specific safety management practices and changes to the safety management program.

### FS.3.4.1

**Standard:** When the organization elects to maintain specialized emergency equipment (e.g. Automatic External Defibrillator (AED)), personnel are trained in the proper use of that equipment.

**Intent:** If an allied health care organization provides specialized emergency equipment for on premise resuscitative or first aid capabilities, it has an obligation to ensure that staff are trained in the proper use of that equipment and that the training is documented in a permanent record.

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Notes

#### FS.3.4.2

**Standard:** Written instructions are posted that outline procedures to be followed by organizational personnel for securing additional assistance.

**Intent:** It is the nature of any health care setting to care for patients who may otherwise have health or medical conditions that are not being treated by the organization. While perhaps not common, it is not, nonetheless, unusual for a patient to experience an emergency episode that is associated with those other conditions. It is not expected that an organization will be able to treat all emergencies. Yet as a health care organization, it is important that provisions be made to assist patients should an emergency occur. Therefore, an organization should provide at least basic CPR and first aid capabilities and secure additional assistance for that patient. Additionally, the organization must post written instructions throughout its site(s) of care that instruct personnel on how to obtain additional assistance.

#### FS.4

**Standard:** The organization establishes policies and procedures that prohibit the use of smoking materials in publicly accessible areas. However, if smoking is permitted elsewhere, there must be designated areas and appropriate policies established to control the use of smoking materials.

**Intent:** Smoking in the work site presents two potential hazards to a patient care organization: exposure of patients and staff members to the consequences of second-hand smoke, and fire associated with fabrication activities due to the use of resins and other highly flammable materials.

#### FS.5

**Standard:** The organization establishes policies and procedures to minimize the transmission of infections with procedures that require the use of universal precautions when caring for patients. As appropriate, these include procedures to comply with OSHA blood borne pathogen regulations, CDC hand hygiene protocols, and other relevant, published standards.

**Intent:** Organizations must institute preventive measures to control the transmission of infections and to minimize opportunities for staff and patients to be exposed to hazardous health risks. Thus, organizations must establish procedures to properly manage the delivery of care to patients and to minimize human exposure to hazardous waste and materials. An adequate infection control program will also address the suitable cleaning (and appropriate disinfecting) of the facility and patient equipment.

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Notes

#### FS.5.1

**Standard:** Written procedures are established for, and documentation verifies, the suitable cleaning of facility areas and equipment used in patient care. Appropriate hazardous waste disposal procedures are established in accordance with the scope of services offered.

**Intent:** Organizations must institute preventive measures to control the transmission of infections and to minimize opportunities for staff and patients to be exposed to hazardous health risks. Thus, organizations must establish procedures to properly manage the delivery of care to patients and to minimize human exposure to hazardous waste and materials. An adequate infection control program will also address the suitable cleaning (and appropriate disinfecting) of the facility and patient equipment.

#### FS.6

**Standard:** Written procedures are established for, and documentation verifies, the organization's compliance with Universal Precautions addressing the transmission of airborne and blood borne pathogens.

**Intent:** Organizations must institute preventive measures to control the transmission of infections and to minimize opportunities for staff and patients to be exposed to hazardous health risks. Thus, organizations must establish procedures to properly manage the delivery of care to patients and to minimize human exposure to hazardous waste and materials. An adequate infection control program will also address the suitable cleaning (and appropriate disinfecting) of the facility and patient equipment.

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Notes

## SUPPLIER COMPLIANCE STANDARDS (SC)

The following Supplier Compliance standards are designed to support organizational activities toward meeting the requirements established by the Centers for Medicare and Medicaid Services (CMS) Office of Inspector General's (OIG) Compliance Guidance for Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry, "Report." Depending upon the organization's size and scope of services provided, the organization is expected to develop a compliance program that encompasses the spirit of the OIG's Report. The standards parallel the basic elements present in the OIG's Report organized into five essential standards including:

1. The organization adopts a program based upon formal policies and procedures. The compliance program should be based upon formal processes that clearly guide the organization in preventing inappropriate billing.
2. A qualified and trained individual is responsible for maintaining the compliance program. Although these duties may be vested in an existing position, the purpose is to assure that a designated person oversees a consistently administered program.
3. Appropriate staff are properly trained and educated on claims development and billing procedures. Such 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 ensures that the compliance program is followed but it will also help identify those elements of the program that may need improvement.
5. Written employment criteria and disciplinary guidelines are implemented. The organization 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.

As indicated, these standards are designed to reflect the primary elements of the Report and encourage organizations to establish procedures to minimize the occurrence of fraud and abuse and ultimately protect the organization from its effects. However, to understand fully the intent and details of the Report, it is strongly recommended that all organizations seeking accreditation and compliance with these specific standards obtain a copy of the 2000 Report in its entirety. In addition, available from various organizations are a variety of supplemental materials to assist organizations in compliance with the guidelines.

## SC.1

**Standard:** The organization administers a compliance program, applicable to all organization personnel, that addresses the critical elements of appropriate reimbursement practices and reduces the risks associated with these activities.

**Intent:** To assure that the organization is reasonably protected from the risks associated with third party payor billing practices, policies and procedures must be established to guide the organization. These policies and procedures may address, but not be limited to: personnel assignments and responsibilities, appropriate standards of conduct in claims development and submission, patient billing, training and an audit and monitoring process. Organizations must ensure that these policies and procedures are available, understood by staff and uniformly followed for all patients regardless of the site of care or service delivered.

## SC.1.1

**Standard:** The program includes written policies, procedures and standards that articulate the organization's compliance with federal and state policies.

**Intent:** To assure that the organization is reasonably protected from the risks associated with third party payor billing practices, policies and procedures must be established to guide the organization. These policies and procedures may address, but not be limited to: personnel assignments and responsibilities, appropriate standards of conduct in claims development and submission, patient billing, training and an audit and monitoring process. Organizations must ensure that these policies and procedures are available, understood by staff followed for all patients regardless of the site of care or service delivered.

## SC.2

**Standard:** A qualified and trained individual is designated by the governing body to be responsible for maintaining the organization's compliance program.

**Intent:** The organization may include this responsibility within the scope of responsibilities of an existing staff member; however, it is expected that this staff member will be properly qualified and accountable for the functions of this position within the organization.

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Notes

### SC.3

**Standard:** The organization conducts claims development and billing education for appropriate staff.

**Intent:** All appropriate employees should attend, at least annually, in-service or otherwise sponsored training sessions on compliance issues relating to claims development and submission. New employees should be scheduled for training at the onset of employment. Training should be documented and maintained in organizational personnel files to be considered during annual performance evaluations.

### SC.4

**Standard:** The organization establishes auditing and monitoring procedures to ensure consistent compliance with appropriate reimbursement issues.

**Intent:** As suggested in the standard, an annual reappraisal of the organization's compliance program should be conducted. The organization may decide to use its existing Performance Management program to determine the effectiveness of its compliance policies and procedures or establish an alternative system to accomplish this objective. The end result should establish an oversight of the compliance measures that enable the organization to establish tracking mechanisms and reduce the risk of errors.

### SC.4.1

**Standard:** Monitoring procedures are on-going and the written results are evaluated at least annually. Subsequent reviews are carried out as needed to ensure corrective action has been undertaken and is successful.

**Intent:** As suggested in the standard, an annual reappraisal of the organization's compliance program should be conducted. The organization may decide to use its existing Performance Management program to determine the effectiveness of its compliance policies and procedures or establish an alternative system to accomplish this objective. The end result should establish an oversight of the compliance measures that enable the organization to establish tracking mechanisms and reduce the risk of errors.

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Notes