



ABC Accreditation

NON-CUSTOM THERAPEUTIC FOOTWEAR

Non-Custom Therapeutic Footwear Accreditation Standards

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

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TABLE OF CONTENTS

INTRODUCTION	About the Standards; Understanding the Standards	i
OR SERIES	Organizational, Governance and Administrative Management Standards (OR)	1-7
PC SERIES	Patient Care and Management Standards (PC)	8-23
PM SERIES	Performance Management and Improvement Standards (PM)	24-31
FS SERIES	Facility and Safety Management Standards (FS)	32-36
SC SERIES	Supplier Compliance (SC)	37-40
<i>Ancillary Assistive Devices Accreditation</i>		
INTRO TO AAD	Introduction to the optional Ancillary Assistive Devices Accreditation	41
ADD STANDARDS	Ancillary Assistive Devices Accreditation Standards (AAD)	42-50



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NON-CUSTOM THERAPEUTIC FOOTWEAR

Introduction

Non-Custom Therapeutic Footwear Accreditation is designed for organizations providing non-custom therapeutic and diabetic footwear and inserts. As required in these Standards, services provided by these organizations are overseen by health care professionals appropriately trained and qualified in the provision of these services.

The scope of services and accreditation standards for Non-Custom Therapeutic Footwear Accreditation is encompassed by the Comprehensive Orthotics Accreditation and Comprehensive Pedorthic Accreditation Standards. Thus, organizations meeting the accreditation requirements for Comprehensive Orthotics or Comprehensive Pedorthic Accreditation will automatically meet the standards for Non-Custom Therapeutic Footwear Accreditation.

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), Patient Care (PC), 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)

Organization: ABC awards accreditation to an organization. Furthermore, ABC has the right and is obligated to protect the integrity of the accreditation award by limiting it to legally operating organizations. Thus, the standards require that an organization be legally constituted, not only in the jurisdiction in which it is constituted, but 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 as identified in Section III of these standards. Importantly, these include the reserved responsibility for appointing and privileging the organization's professional staff. The appointments and privileges must be based upon a professional staff member's competency to perform the necessary skills for the functions and procedures associated with that appointment.

Administration: Quality patient care depends on the orderly administration of the organization. The organization's policies and procedures should be designed to promote the provision of high-quality patient care and to enable the administration to fulfill the organization's mission, goals and objectives. These standards also address requirements for personnel management, including provisions for adequate orientation and training and performance evaluations.

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 orthotic 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 organizations 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 customers and patients.

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

OR.2

Standard: The organization makes full disclosure of ownership through the Application for Accreditation process, in accordance with 42 CFR parts 420.201 through 420.206.

Intent: ABC limits its accreditation award to organizations whose owners or participants are clearly identified and who are eligible to participate in Medicare or other Federal programs.

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. 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.3.1

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

Intent: 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.

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.

Notes

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 quality assessment and improvement; 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 orthotic 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.

OR.3.3

Standard: The governing body is responsible for documenting the appointment of staff members and permitting the delivery of patient care services. The appointment process shall include 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, if licensure or credentials are required, 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 only qualified and competent professional staff members provide or supervise the provision of non-custom therapeutic footwear. 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 quality assessment and improvement information be included within those criteria.

Notes

OR.3.3.1

Standard: The appointment process includes a mechanism for qualifying staff to provide patient care. This will include attendance at appropriate non-custom therapeutic footwear education or equivalent and at least 1,000 hours of documented work experience.

Intent: The governing body has an obligation to assure that only qualified and competent professional staff members provide or supervise the provision of non-custom therapeutic footwear. 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 quality assessment and improvement information be included within those criteria.

OR.3.4

Standard: The organization shall provide only non-custom therapeutic footwear and other items as disclosed on their current 855S application and that meet applicable Food and Drug Administration (FDA) regulations and medical device effectiveness and safety standards. The organization shall obtain from the manufacturer copies of the features, warranties, and instructions for each type of non-custom fabricated item.

Intent: The governing body has an obligation to assure that only appropriate services are provided and that the non-custom therapeutic footwear supplied as a part of those services are compliant with all applicable manufacturing and other standards.

Notes

OR.4

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

Intent: The Healthcare Insurance Portability and Accountability Act (HIPAA) has profound implications for non-custom therapeutic footwear 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 noncustom therapeutic footwear is such that practitioners and 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 orthotics and prosthetics 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 O&P profession.

OR.5

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.

Notes

OR.6

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 items 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.

Notes

PATIENT CARE AND MANAGEMENT STANDARDS (PC)

Patient care and management standards are organized into seven 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 staff member 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 Records: The central, coordinating link in any patient care organization is the patient record system. Thus, the quality of an organization's patient record system and records directly contributes to the quality of patient care.

The standards require that a record system be in place. While its complexity depends on the size and complexity of the organization, certain common characteristics of any record system or patient record exist. These standards address those common attributes: uniformity of format, maintenance of confidentiality, essential content and ready availability of these records to professional staff members.

Notes

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 quality assessment and improvement 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.

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

Patient and Family Education: The success of non-custom therapeutic footwear care depends not only upon the competency of the practitioner and the quality of the footwear, 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 footwear.

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 footwear care, or recommendations of an appropriate legal referral.

Notes

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 care for its patients. This standard requires the organization to establish a mechanism by which the education, training and competence of each professional staff member 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: Staff responsibilities include, but are not limited to (1) communication with and receipt/provision of patient care documentation between staff members and physicians and other referral sources; (2) documentation of patient care information by the staff in patient-specific, permanent records of orthotic care; and (3) communication between management personnel and staff and administrative support personnel.

Intent: The organization has a responsibility to ensure that quality care is delivered to its patients. To fulfill this responsibility, policies and procedures must be established that govern how such care is to be delivered, by whom, and according to generally accepted practices. These policies and procedures must address at least three key components of patient care. First, the organization needs to establish mechanisms that govern communication between its staff, the patient's physician and/or other referral sources. Second, organizations must establish processes to document, in permanent records the care rendered to a specific patient. This includes business records as well as patient care records (medical records). Finally, the organization must address communication between organizational management and staff members. This ensures appropriate coordination of care and supports the role of the staff member as the primary person responsible for the patient's care.

Notes

PC.1.2

Standard: The organization's staff shall perform a diagnosis-specific clinical examination for the use of the prescribed non-custom therapeutic shoes.

Intent: The organization's professional staff has the responsibility to perform a clinical examination to validate the need and appropriateness of the prescribed item/service. In the event that the clinical examination indicates a treatment other than that specified by the referral source, the professional staff must initiate a dialogue between him/herself and the referral source until such time as there is agreement with respect to the appropriate course of action.

PC.2

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 non-custom therapeutic footwear care. 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.

PC.2.1

Standard: Policies and procedures are established concerning the time between notification of patient referral and the initial patient contact and subsequent care.

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 foot care 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.

Notes

PC.3

Standard: Patient care service is the responsibility of and is provided under the direction and appropriate level of supervision of a credentialed and/or licensed staff member, practicing within their defined scope of practice.

Intent: The underlying foundation of quality non-custom therapeutic footwear patient care is the provision of care by qualified professional. Thus, PC.3 requires that all such care be the responsibility of a credentialed or licensed staff member practicing within their scope of practice.

PC.3.1

Standard: When a patient evaluation indicates that an intervention or treatment is beyond the supplier's Scope of Practice, the organization shall refer the patient back to the referral source.

Intent: The underlying foundation of quality patient care is the provision of care by qualified providers. Thus, PC.3.1 requires that all such care be performed at the direction of a properly qualified supplier.

PC.3.2

Standard: Notwithstanding PC.3, all staff providing non-custom therapeutic footwear services will be qualified according to objective criteria.

Intent: The underlying foundation of quality non-custom therapeutic footwear care is the provision of care by qualified staff members. Thus, PC.3 requires that all such care be the responsibility of a certified or licensed staff member practicing within their scope of practice.

Notes

PC.4

Standard: All federal, state, local and third party payor required communications regarding the patient are documented in the patient's clinical record.

Intent: Orthotic care should not be rendered to a patient 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.4.1

Standard: Uniform documentation includes but is not limited to: (1) professional staff member evaluation(s) of the patient, which should contain diagnosis, request for care, relevant patient history, assessment, patient education, and medical necessity; (2) pre-treatment photographic documentation as appropriate for the item; and (3) the name of the attending staff member, their findings, recommendations and treatment plan for a specific course of care and management as well as the appropriate follow-up schedule.

Intent: Non-custom therapeutic footwear care should not be rendered to a patient without the appropriate support of a referring physician. These two standards (PC.4 and PC.4.1) require the organization to document, within the patient's record, information such as referrals and prescriptions for services along with other pertinent information.

PC.4.2

Standard: The organization documents patient specific goals and expected outcomes for the use of the footwear.

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, provide joint stability, prevent deformity, increase range of motion, address cosmetic issues and/or promote healing.)

Notes

Standard: The organization maintains a 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.

Intent: The clinical record is the principle support tool for the health care professional staff member. 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.

Standard: The organization develops and maintains a secure system for the collection, processing, maintenance, storage, retrieval and distribution of patient records.

Intent: The clinical record is the principle support tool for the health care practitioner. 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.

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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 practitioner. 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.

PC.5.2

Standard: Prior to final delivery, the organization assesses the device for structural safety and ensures that manufacturer guidelines are followed.

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. beneficiary weight limits, ensuring proper function of closures, no defects in materials and workmanship).

PC.5.3

Standard: The organization investigates any patient incident or injury in which non-custom footwear may have contributed, when the supplier becomes aware. The investigation should be initiated within 24 hours after a supplier becomes aware of an injury or incident resulting in a beneficiary's hospitalization or death. For other occurrences, the supplier shall investigate within 72 hours after being made aware of the incident or injury. The investigation includes all necessary information, pertinent conclusions about what happened, and whether changes in systems or processes are needed. The supplier should consider possible links between the items and services furnished and the adverse event and assess the incident through the Performance Management program.

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.

Notes

PC.5.4

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.

PC.5.5

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 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.

Notes

PC.6

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.

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 be a substitute for the sound judgment of the staff member. However, patient participation can strengthen commitment to accepting and complying with non-custom therapeutic footwear care.

PC.6.1

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: 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.

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 therapeutic foot care.

Notes

Standard: The organization makes information available to patients concerning their rights which includes but is not limited to: (1) its policies for after-hours and emergency coverage; (2) its fees for services and policies concerning payment of fees; 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.7

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 quality assessment and improvement 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 non-custom therapeutic footwear. 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.7

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 non-custom therapeutic footwear, including its clinical function.

Intent: The organization must monitor patient satisfaction as part of its overall quality assessment and improvement 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 footwear. 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.

Notes

PC.7.2

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

Intent: The organization must monitor patient satisfaction as part of its overall quality assessment and improvement 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 footwear. 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

Standard: The organization provides the patient and caregiver(s) with education that can enhance the benefits of therapeutic foot care and management. Evidence of patient education is recorded in the patient's clinical record and includes at least: 1) the purpose and function of the therapeutic footwear; 2) the proper care and use of the footwear; (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: An improperly or uninformed patient increases the opportunity for a device to be mishandled or improperly cared for. 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.

Notes

PC.8.1

Standard: The organization shall provide necessary supplies (e.g. adhesives, solvents, lubricants) to attach, maintain, and clean the items provided, as applicable, and information about how to subsequently obtain necessary supplies.

Intent: Patients should leave the organization's facility with the supplies they need to enable themselves to care for their new items, in the short term. The organization should inform the patient about the procurement of additional supplies.

PC.9

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 non-custom therapeutic footwear 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.

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 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.

Most clinical, support and managerial staff are 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.)

Notes

PM.1

Standard: There is an ongoing quality assessment and improvement program designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve therapeutic foot care, 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, quality assessment and improvement 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 therapeutic foot 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 quality assessment and improvement 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.

Notes

PM.1.1.1

Standard: The governing body participates in the quality assessment and improvement 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: The standards address the role of the organization's participation in 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.1.2

Standard: There is a written plan for the quality assessment and improvement 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.

Notes

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.

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 to 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.

Notes

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 clinical function of the non-custom therapeutic footwear.

Intent: This standard is designed to help assess the level of patient satisfaction with the services provided and with the fit and function of any devices provided in the performance of those services. Assessing and understanding patient satisfaction will give the organizations 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.

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.

Notes

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 non-custom therapeutic footwear 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 reoccurrence, and whether systems or processes should be adjusted.

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.

Notes

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.

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.

Notes

PM.6

Standard: There is a minimum of an annual written reappraisal of the organization's quality assessment and improvement 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.

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, organizations are expected to comply with appropriate provisions of the Safe Medical Devices Act.

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 non-custom therapeutic footwear suppliers care for patients with unique physical challenges, it is important that its facilities and grounds be configured to meet the needs of the patient.

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.

Notes

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.

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.

Notes

FS.3.1

Standard: There is an emergency preparedness program designed to manage the consequences of natural disasters (especially those that may be experienced in the facility's geographic region) or other emergencies that disrupt the organization's ability to provide care and treatment.

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 following list is a suggestion and should not limit the facility's plans in any way. Facilities in the south and southeast should have hurricane, tornado, flood, fire and other relevant plans. Middle and upper east coast should have hurricane, ice, earthquake, fire, flood and other appropriate plans. Midwest facilities should have wildfire, flood, ice, tornado, fire and other plans; while the west coast would want wildfire, mudslide, earthquake, flood, fire and other types of plans.

FS.4

Standard: The organization establishes policies and procedures that discourage the use of smoking materials. However, where smoking is permitted, there are appropriate policies to control the use of smoking materials.

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

It is recognized, however, that a completely non-smoking environment may not be a practicable requirement. However, the organization must establish policies and procedures, which discourage the use of smoking materials, particularly when such activity may expose non-smoking staff and patients to second-hand smoking in areas where fire hazards are particularly acute.

Notes

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 with suspected infectious diseases. As appropriate, these include procedures to comply with OSHA blood borne pathogen regulations.

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 with suspected infectious diseases 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.

Notes

SUPPLIER COMPLIANCE (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.

Notes

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 and uniformly followed for all patients regardless of the site of care or service delivered.

Notes

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.

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.

Notes

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.

Notes



ABC Accreditation

Ancillary Assistive Devices

Introduction

The Ancillary Assistive Device (AAD) Accreditation is designed for organizations providing certain items of Durable Medical Equipment in addition to orthotic, prosthetic, pedorthic or post-mastectomy 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 AAD accreditation is predicated on the awarding and/or maintaining of ABC accreditation in another discipline, such as Non-Custom Therapeutic Footwear Accreditation.

The scope of services for AAD Accreditation includes any item of durable medical equipment or supplies that is used to support activities of daily living, facilitate independence, or for monitoring or treating conditions that impact ongoing care.

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

About the Standards: ABC accreditation standards create a baseline of minimal expectations for 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.

Understanding the Standards: ABC Ancillary Assistive Devices Accreditation standards are comprised of the standard itself, a statement of intent and a compliance measurement.

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.

Compliance: The compliance statement lays out the measures an organization is advised to take to become compliant with the standard.

AAD.1

Standard: The governing body documents the appointment of staff members delivering patient care services. The appointment process must include a monitoring function designed to at least annually verify the completion of continuing education consistent with the ancillary assistive devices and services (AAD) provided to patients. If licensure or credentials are required, the current good standing of staff members with their respective licensure/credentialing organization(s) is verified.

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

Compliance: There is documented evidence that professional staff member maintain good standing with their respective credentialing organizations on an annual basis. All credentials and licenses are to be publicly displayed.

In addition, the governing body (or personnel to whom this task has been delegated) must develop a mechanism to objectively identify and document each member's level of competence as it relates to the delivery of durable medical equipment. The governing body must implement an oversight mechanism to assure that the process is consistently implemented for each professional staff member.

AAD.1.1

Standard: The competency of staff to provide appropriate care is documented. The documentation will include qualifications, training, experience and continuing education requirements consistent with the specialized AAD they provide to beneficiaries.

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.

Compliance: The organization has implemented a process for documenting staff competency based on training and experience.

Notes

AAD.1.2

Standard: At least annually, relevant indicators are used to assess and document continuing competency.

Intent: 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.

Compliance: The organization annually evaluates and documents the continuing competency of staff members.

AAD.2

Standard: The organization shall provide only those items as disclosed on their current CMS-855S application and that meet applicable Food and Drug Administration (FDA) regulations and medical device effectiveness and safety standards. The organization shall obtain from the manufacturer copies of the features, warranties, and instructions for each type of AAD.

Intent: The governing body has an obligation to assure that only appropriate services are provided and that the AAD supplied as a part of those services are compliant with all applicable manufacturer’s guidelines and all applicable standards.

Compliance: A review of charts indicates that all services rendered and devices supplied are consistent with the statements made on the organization’s CMS-855S form.

Notes

AAD.3

Standard: Policies and procedures are established concerning the time between notification of patient referral and the initial patient contact and subsequent care.

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 AAD 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.

Compliance: Policies and procedures have been established and are consistently followed concerning the time between patient referral notification and initial patient encounter for similar patient conditions.

AAD.4

Standard: The provision of AAD is the responsibility of and is provided under the direction and appropriate level of supervision of a qualified, and when appropriate, licensed or credentialed staff member practicing within their scope of practice.

Intent: The underlying foundation of quality patient care is the provision of care by qualified staff members. Thus, ABC requires that all such care be the responsibility of a qualified staff person.

Compliance: On the basis of a sample of patient care records, provision of all AAD is the responsibility of and is provided under the direction of a qualified staff person.

AAD.4.1

Standard: When a patient evaluation indicates that an intervention or treatment is beyond the supplier's scope of practice, the organization shall refer the patient back to the referral source.

Intent: The underlying foundation of quality patient care is the provision of care by qualified providers. Thus, ABC requires that all such care be performed at the direction of a properly qualified supplier.

Compliance: No evidence is found during the survey process to indicate that the organization provides services beyond its defined scope, or, evidence of referrals indicated in this standard is found in patient charts.

Notes

AAD.4.2

Standard: All staff providing AAD services will be qualified according to objective criteria.

Intent: The underlying foundation of quality patient care is the provision of care by qualified professionals. Thus ABC requires that all such care be the responsibility of a properly qualified professional practicing within their defined scope of practice.

Compliance: All non-credentialed or non-licensed staff providing AAD services are qualified according to objective criteria, e.g. education, training and work experience.

AAD.4.5

Standard: All federal, state, local and third party payor required documentation regarding the patient are recorded in the patient's clinical record.

Intent: AAD services should not be provided to a patient without a prescription. This standard requires the organization to document, within the patient's record, 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.

Compliance: On the basis of a sample of patient care records, all AAD services are supported by documented physician referrals, which includes the patient's diagnosis and a specific request for services.

AAD.5.1

Standard: Uniform documentation includes, but is not limited to: (1) professional staff member evaluation(s) of the patient, which should contain diagnosis, request for care, relevant patient history, assessment, patient education, and medical necessity; and (2) the name of the attending staff member, their findings, recommendations as well as the appropriate follow-up schedule.

Intent: Uniform documentation is an element of consistent patient care and can be an indicator of the effectiveness of internal policies and procedures.

Compliance: On the basis of a sample of patient care records, documentation includes professional staff member's patient evaluation(s), which should include diagnosis, request for care, relevant patient history, assessment, and patient education. All charts should be uniformly maintained.

Notes

AAD.6

Standard: Prior to final delivery, the organization assesses the AAD for structural safety and ensures that manufacturer guidelines are followed.

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. beneficiary weight limits, no defects in materials and workmanship).

Compliance: Patient records indicate that, prior to delivery, the AAD has been checked for workmanship and appropriateness.

AAD.6.1

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

Intent: Suppliers should strive to provide the needed AAD items as expeditiously as practical.

Compliance: Evidence indicates that the supplier delivers and sets up (or coordinates set up with another supplier) all equipment and items in a timely manner as agreed upon by the beneficiary/caregiver, supplier, and prescribing physician.

AAD.6.2

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: Suppliers should strive to provide the needed AAD items with all items necessary to operate or adjust the equipment provided.

Compliance: Evidence indicates that the supplier provides all items that are necessary to operate the equipment or item(s) and perform any further adjustments as applicable.

Notes

AAD.6.3

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

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

Compliance: Evidence indicates that the supplier provides, or arranges for, loaner equipment equivalent to the original equipment during any repair period.

AAD.7

Standard: The organization investigates any patient incident or injury in which the AAD may have contributed, when the supplier becomes aware. The investigation should be initiated within 24 hours after a supplier becomes aware of an injury or incident resulting in a beneficiary's hospitalization or death. For other occurrences, the supplier shall investigate within 72 hours after being made aware of the incident or injury. The investigation includes all necessary information, pertinent conclusions about what happened, and whether changes in systems or processes are needed. The supplier should consider possible links between the items and services furnished and the adverse event and assess the incident through the performance management program.

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.

Compliance: The organization conducts an investigation, documents the results, and when indicated, initiates corrective action and takes steps to minimize the likelihood of recurrence of similar events as specified in this standard.

Notes

AAD.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 quality assessment and improvement 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.

Compliance: The organization periodically assesses patient satisfaction with its performance and service.

AAD.9

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

Intent: The organization must monitor patient satisfaction as part of its overall quality assessment and improvement 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 AAD. 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.

Compliance: The organization documents and, not less than annually, evaluates the results of patient satisfaction assessments as part of its quality assessment and improvement program.

Notes

AAD.10

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 purposes 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.

Compliance: The organization provides patients and appropriate caregivers with education that includes the purpose, function, risk, proper care and use of the device. Furthermore, evidence of patient education is to be recorded in the patient's clinical record.

AAD.11

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

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

Compliance: Evidence indicates that the supplier provides beneficiaries with essential contact information for rental equipment and options to rent or purchase ancillary assistive devices, when applicable.

Notes

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.

Compliance: The organization provides appropriate follow-up care that is consistent with the patient's diagnosis, care rendered, or follow-up recommendations of an appropriate legal referral; and, in the sample of records reviewed, all follow-up care is recorded in a patient's clinical record.

Notes