PATIENT CARE FACILITY ACCREDITATION GUIDE

Getting Started
Standards
Resources and Tools

BOARD FOR CERTIFICATION
PROSTHETICS PEDORTHICS
ORTHOTICS
AMERICAN
SINCE 1948

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Effective January 1, 2019

ABOUT ABC

Thank you for choosing ABC for your accreditation. The information contained in this comprehensive guide will provide you with everything you need to successfully understand and satisfy ABC's Patient Care Facility Accreditation Standards and ensure that your facility is ready for accreditation. ABC's Patient Care Accreditation program recognizes patient care facilities that promote the best business and patient care practices in the O&P profession. Are you the best at what you do? Prove it with ABC Accreditation!

Who We Are

The American Board for Certification in Orthotics, Prosthetics and Pedorthics, Inc. (ABC) is an independent, nonprofit, standard-setting organization for the accreditation of orthotic, prosthetic, pedorthic and mastectomy patient care practices as well as the certification of practitioners in these disciplines. Our Patient Care Accreditation Program is designed for facilities that provide orthotic, prosthetic, pedorthic and mastectomy services to patients. Your business must employ board certified or licensed personnel appropriate to the scope of services you provide. ABC also provides accreditation for non-patient care, central fabrication facilities. For more information on this program, please visit the ABC website.

ABC is governed by a voluntary board of directors composed of orthotic, prosthetic and pedorthic health care professionals and consumers. In coordination with the board, ABC accreditation policy is administered by the Facility Accreditation Committee. ABC's mission is to establish and promote the highest standards of organizational and clinical performance in the delivery of orthotic, prosthetic and pedorthic services. Our high standards and affordability are what make ABC the premier choice for O&P Accreditation.

In 2003, CMS implemented standards of patient care and fraud protection over the orthotic, prosthetic, pedorthic, mastectomy and durable medical equipment professions and relies on non-governmental accrediting organizations, such as ABC, to evaluate all patient care centers against the established Medicare Quality Standards.

In 2006, ABC was awarded Deemed Status from CMS. With this status, facilities accredited by ABC are in compliance with CMS's mandatory accreditation requirement. Deemed Status from CMS is a validation of ABC's high standards and serves as the highest public recognition of orthotic, prosthetic, pedorthic and mastectomy care centers.

Accreditation is a privilege, not a right. We have the legal authority to award accreditation and may withhold, suspend or revoke accreditation if your facility violates ABC's policies, rules or regulations. Once you submit an application for accreditation, you agree to abide by the Terms of Agreement and Business Associate Agreement (found within the application), the ABC *Code of Professional Responsibility* and the policies and standards outlined in the Patient Care Facility Accreditation Guide.

ELIGIBILITY CRITERIA

The following criteria will help you determine if you are eligible for accreditation. While not a comprehensive list, it covers the basic requirements that you must have in order to be eligible to apply to ABC. The remaining eligibility requirements are identified throughout the Standards and are relevant to specific products and services your organization provides.

Your organization must be:

- Located within the United States, one of its territories or possessions or be a Department of Defense medical treatment facility or program.
- A formally organized and legally established business that is currently providing the Durable Medical Equipment, Prosthetics, Orthotic, and Supplies (DMEPOS) services for which you are applying.
- Licensed according to applicable state and federal laws and regulations and maintains all current legal authorizations to operate.
- Operational and have a minimum of 10* complete patient charts per patient care provider available at the time of the onsite survey.
- Applying for ABC Accreditation for all of the services provided, regardless of whether Medicare or another payer is billed for these services. This requirement extends only to those services for which ABC offers accreditation.
- Applying for ABC Accreditation for all patient care locations. Each location must be in an appropriate clinical setting. The decision of what is an appropriate clinical setting is solely within ABC's discretion.
- Compliant with state licensure requirements.

In addition, you must:

- Clearly define the items and services you provide to patients, insurance companies, referral sources and regulatory bodies, including Medicare.
- Comply with the ABC *Code of Professional Responsibility*.
- Agree to the Terms of Agreement in the application and policies listed in this Guide.
- Not falsify or misrepresent your accreditation status.
- Apply for ABC accreditation of any new facility that you have opened or acquired.

Note: If allowed by state law, pharmacists are exempt from Standard HR.4.1.

**If the facility is newly established and has a limited patient care history, ABC may determine that a minimum of five complete patient charts per patient care provider is acceptable.*

APPLICATION INFORMATION

Once your facility has met the eligibility criteria and is compliant with the Standards, you are ready to begin the online application process. New applicants must submit a request to create an account in order to begin the application process. Renewing applicants must use their existing login information in order to access the renewal application.

You must apply for all products and services your facility *currently* provides as well as apply for all operational facilities within your organization. All fields must be completed, and the non-negotiable, non-refundable accreditation application fee must be included in order to submit your online application. An incomplete application or missing documentation will delay your accreditation process.

Do not submit your application until you have met the eligibility criteria and become compliant with the Facility Accreditation Standards. Submitting your application signifies that your facility is available for an onsite survey.

The following items are required with your completed application:

- Application fee (non-negotiable and non-refundable)
- Good standing of annual fees for existing accredited facilities (any outstanding annual fees must be paid before application can be submitted)
- Valid email address to receive communication from ABC
- Proof of certification and/or state licenses of staff providing patient care services. It is NOT necessary to submit copies of certifications for ABC credentialed individuals.
- Legal documentation of ownership (e.g. Articles of Incorporation, Transfer of Shares Certificate)
- Narrative of your criminal history (if applicable)

If necessary, we may require additional information or clarification in order to finalize the review of your application. All information and application materials are solely used by ABC and its surveyors or as required by law. All submissions are handled in accordance with HIPAA regulations.

After you have submitted your application, you will receive email confirmations throughout each step of the accreditation process.

Incomplete Applications

If your application is missing information or if staff needs additional clarification regarding your submission, we will contact you via email. If no response is received, we will send the request by certified mail to the primary contact listed on your application. We must receive all requested materials by the final deadline indicated in the letter. If your application is still incomplete by the deadline, your application will be denied, and your application fees will be forfeited. If your application is denied, you must resubmit a new application and fees. Incomplete applications will only be processed after all required documents

and/or fees are received. Any delay in completing your application could result in a delay in your survey and accreditation decision.

Falsification of your Application

If we discover that you have provided false or misleading information on your application or that you have misrepresented your accreditation status to outside parties, ABC may take any or all of the following actions:

- Deny the application
- Deny reapplication for accreditation
- Revoke any existing ABC accreditations for all related primary or affiliate facilities
- Revoke any existing ABC credentials from individuals found to be responsible for the falsification
- Refer the incident to the Professional Discipline Committee (PDC)
- Pursue legal action against your facility

Office Hours

Your onsite survey will occur during the days and hours of operation listed on your application, which must accurately reflect the days and hours that you have posted for the public. If your facility is by appointment only, you must note this in your online application by selecting the days you are available for appointments.

If key personnel such as an administrative or clinical manager have a schedule that differs from your hours of operation, their schedule must also be included with your application. It is very important that you inform us of all schedule changes while you are awaiting an onsite survey, as all surveys are unannounced.

Application Hold Request Policy

If your facility is not ready for the survey, is undergoing a major change (such as an ownership change, location move, opening another facility within the next 90 days) or will be unavailable for more than 14 total or consecutive days, you must put your application on hold. This will remove your application from the survey queue. Your application will remain on hold until you notify us in writing or for up to six months. The six-month period begins on the date the application was initially received. **All requests for holds must be submitted in writing, at least 30 days in advance;** any request for hold periods not received at least 30 days in advance will not be accepted. These requests must be on company letterhead, signed and dated by the accreditation contact, CEO or owner of the company or email from one of the aforementioned personnel to accreditation@ABCop.org. **You must notify us in writing when you wish to reactivate your application.** If a request to reactivate your application is not received at the end of the six months, the application will be denied and the facility will need to resubmit all application materials, including the appropriate fees.

Affiliate Locations

Affiliates are secondary patient-care locations that meet the following criteria:

- Share the corporate structure and utilizes the same policies and procedures of the primary practice
- Share the same Federal Tax ID number as the primary facility
- Maintain separate NPI and PTAN numbers
- Are located within a 100-mile driving distance of the primary facility

Designating affiliates allows organizations to apply for multiple locations at once while reducing overall accreditation fees. **Affiliate accreditation always expires with the primary location, including any affiliates that are added mid-accreditation of the primary site. Each primary location may designate up to four affiliates.** Facilities, including renewals, with more than four affiliates must make the fifth affiliate a primary location, which then can list four additional affiliates. Secondary locations that do not meet the criteria for affiliates as outlined above must submit an application as a primary location with the appropriate fees.

Administrative Offices and Warehouse Locations

You must list all related administrative locations and product warehouses on your application and include a detailed statement describing what activities or items are at those facilities. These are locations that do not provide patient care services but are integral to your practice.

As such, an onsite survey is required for all warehouse and administrative offices and the base affiliate fee will be assessed if within a 100-mile distance. Those located more than 100 miles from the primary location will be assessed the base primary survey fee. Warehouse and administrative office accreditation fees must be submitted with the application. Accreditation is not award to these types of locations; annual fees are not assessed for administration offices or warehouses.

ACCREDITATION PROGRAMS

ABC offers different accreditation programs tailored to the type of patient care services provided at each of your patient care locations. Your main service should be the accreditation program that most fully encompasses your facility's patient care services. All other services can be indicated on your application as additional services. Remember that you must apply for ABC Accreditation in all of the services provided regardless of whether you are billing CMS or another payer for those services.

Main Accreditation Programs

ORTHOTICS & PROSTHETICS

These services must be provided by a certified or licensed orthotist and prosthetist. Orthotic & Prosthetic Accreditation includes all services outlined in both the Orthotic and Prosthetic Accreditation descriptions below.

ORTHOTICS

These services must be provided by a certified or licensed orthotist. Orthotics Accreditation includes custom fabricated, prefabricated, off-the-shelf orthotic devices, pedorthics and non-custom therapeutic footwear.

PROSTHETICS

These services must be provided by a certified or licensed prosthetist. Prosthetics Accreditation is a stand-alone accreditation and does not encompass any other services, such as mastectomy or ocular prostheses.

PEDORTHICS

These services must be provided by a certified and/or licensed orthotist or pedorthist. This program is designed for facilities that provide pedorthics, therapeutic and diabetic footwear items and services. The scope of service includes the assessment, treatment and education of patients and the ability to provide non-custom therapeutic footwear and non-custom diabetic multi-density inserts.

PREFABRICATED ORTHOTICS

These services must be provided by a certified or licensed orthotist or orthotic fitter. This program is designed for facilities that **only** provide prefabricated custom fit. **Pedorthic, therapeutic and diabetic footwear services are not covered under the scope of services for this accreditation program.**

OFF-THE-SHELF ORTHOTICS

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

NON-CUSTOM THERAPEUTIC FOOTWEAR

These services must be provided by a licensed or certified orthotist, pedorthist, therapeutic shoe fitter or appropriately licensed professional. This program is designed for facilities that **only** provide non-custom therapeutic footwear and non-custom diabetic multi-density inserts.

MASTECTOMY

These services must be provided by a certified or licensed mastectomy fitter. This program is designed for facilities that provide patient care services related to post mastectomy prostheses and accessories. This program does not include pneumatic compression devices (lymphedema pumps). If your facility is only providing Mastectomy, please review our Mastectomy Patient Care Guide, which is available on our website, ABCop.org.

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

OCULAR PROSTHETICS

The services provided by these facilities must be provided by a board certified or licensed ocularist or an ocular Diplomate or Associate of the American Society of Ocularists. This program is designed for facilities that provide fitting, shaping, painting and maintenance of ocular prostheses.

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

Additional Accreditation Programs

DURABLE MEDICAL EQUIPMENT (DME) AND ANCILLARY ASSISTIVE DEVICE (AAD)

NOTE: ABC does not provide DME or AAD as a stand-alone accreditation program. **To be eligible for DME or AAD Accreditation, you must also apply for one of ABC's main accreditation programs and maintain that accreditation.** If your facility is providing any of the items listed in either or both programs, your facility **must** obtain additional accreditation in DME or AAD.

DME or AAD Accreditation is necessary for all facilities that provide durable medical equipment in addition to orthotics, prosthetics, pedorthics, non-custom therapeutic footwear, prefabricated orthotics, off-the-shelf orthotics, mastectomy and ocular prostheses. AAD is considered a sub-category of DME; therefore, all AAD services are covered in the DME Accreditation. If you are providing services that span both categories, it is only necessary to apply for DME. If you are renting any products listed in the following charts, you must apply for DME Accreditation.

The chart will provide you with guidance on the products covered by each of the accreditation programs.

DURABLE MEDICAL EQUIPMENT
All Ancillary Assistive Devices
Continuous Passive Motion (CPM)
Continuous Positive Air Pressure (CPAP) Devices and/or supplies
Contracture Treatment Devices: Dynamic Splint
Enteral Equipment and/or Supplies
External Infusion Pumps
External Infusion Pump Supplies
Gastric Suction Pumps
High Frequency Chest Wall Oscillation (HFCWO) Devices) and/or supplies
Hospital Beds–Electric
Hospital Beds–Manual
Implanted Infusion Pumps and Supplies
Infrared Heating Pad Systems and/or supplies
Insulin Infusion Pumps
Insulin Infusion Pump Supplies
Intermittent Positive Pressure Breathing (IPPB)
Intrapulmonary Percussive Ventilation Devices
Mechanical In-Exsufflation Devices
Nebulizer Equipment and Supplies
Negative Pressure Wound Therapy Pumps and Supplies
Neurostimulators and/or supplies
Oxygen Equipment and Supplies
Parenteral Equipment and/or Supplies
Respiratory Assist Devices
Respiratory Suction Pumps
Ventilators: all types–Not CPAP or RAD
Wheelchairs-Complex Rehab. Manual Chair
Wheelchairs-Complex Rehab. Manual Chair Accessories
Wheelchairs-Complex Rehab. Power Chair
Wheelchairs-Complex Rehab. Power Chair Accessories

ANCILLARY ASSISTIVE DEVICES
Automatic External Defibrillators (AEDs)
Blood Glucose Monitors and Supplies (mail order)
Blood Glucose Monitor and Supplies (non-mail order)
Canes and Crutches
Enteral Nutrients
Heat and Cold Applications
Neuromuscular Electrical Stimulators (NMES) and/or supplies
Osteogenesis Stimulators
Ostomy Supplies
Patient Lifts
Penile Pumps
Parenteral Nutrients
Pneumatic Compression Devices
Power Operated Vehicles (scooters)
Seat Lift Mechanisms
Speech Generating Devices
Support Surfaces: Pressure Reducing Beds/ Mattresses/Pads–New
Support Surfaces: Pressure Reducing Beds/ Mattresses/Pads - Used
Surgical Dressings
Tracheostomy Supplies
Traction Equipment
Transcutaneous Electrical Nerve Stimulators (TENS) and/or supplies
Ultraviolet Light Devices and/or supplies
Urological Supplies
Walkers
Wheelchair Seating/Cushions
Wheelchairs–Standard Manual
Wheelchairs–Standard Manual Related Accessories and Repairs
Wheelchairs–Standard Power
Wheelchairs–Standard Power Related Accessories and Repairs

If your facility is renting any of the above items, regardless of your main accreditation category, your facility must apply for DME Accreditation.

ACCREDITATION SURVEY

The Basics

All applicants must meet the basic eligibility criteria as well as become compliant with the Standards listed in this Guide. Your compliance is determined by a review of your application materials, an onsite survey, and a final validation of your surveyor's findings. The onsite survey is conducted by professionally trained and qualified surveyors. **As required by CMS, all surveys for patient care accreditation are unannounced and unscheduled** and occur during your posted business hours**.** By submitting your application, you declare yourself ready for an onsite survey at any time. Surveys will not be rescheduled due to emergency closure, staff unavailability or lack of readiness. If you deny the surveyor access to your facility and/or essential paperwork or if your facility is closed during posted business hours, you must resubmit an online application and include all accreditation fees. If your facility will be closed for any reason, you will need to inform us in writing—please refer to the section *Requesting Blackout Dates*.

Types of Surveys

INITIAL SURVEY (FIRST-TIME APPLICANTS)

If you are considering accreditation for your facility, we encourage you to review this Guide and complete the Pre-Application Checklist located in the back of this Guide or on our website, ABCop.org, to help you determine if you are eligible for ABC Accreditation. To be placed in the queue for the initial survey, you must submit a request to create an account/login and then submit a completed online application and fees.

REACCREDITATION SURVEY

Most accreditations are valid for up to three years. Your facility's primary contact will receive a letter and email notifications about renewing your accreditation beginning approximately seven months prior to your expiration date. However, ultimately it is your responsibility to submit your reaccreditation application on time. Reaccreditation applications are due no later than five months prior to your expiration date. If you submit your application late or place it on hold after submission, we cannot guarantee that the onsite survey will take place before your expiration date. The reaccreditation survey will be conducted in a manner similar to your initial survey; the surveyor will also review any previous deficiencies and evaluate your corrections. In order to be assigned a reaccreditation survey, you must submit a completed renewal application and all fees as well as be current with your facility's annual fees.

RESURVEY

Additional surveys may be required when there are significant changes such as a location move, change of ownership or addition to your facility's scope of services. Resurveys are also required if we are unable to conduct an initial or reaccreditation survey due to unavailability at your facility or if the surveyor is denied access. To begin the resurvey process, you must submit an online application and fees.

VERIFICATION SURVEY

Verification surveys allow ABC to confirm various elements associated with your facility. Verification surveys are most often used to confirm that changes documented in your Corrective Action Plan (CAP) have been implemented. (For an explanation of the CAP process, please see *Accreditation Decisions.)* We will inform you in writing if we require a verification survey. You are responsible for the fees associated with a verification survey.

QUALITY CONTROL SURVEY

We reserve the right to randomly visit any ABC accredited facility to conduct a quality control survey. We use these surveys to determine consistency among ABC accredited locations and to evaluate surveyor performance. Additionally, we reserve the right to conduct a quality control survey to determine ongoing compliance with the ABC Standards. These surveys are random and unannounced and may be initiated in response to consumer or professional complaints. We do not charge for these surveys.

Surveyors

Surveys are conducted by either a single surveyor or a team of surveyors. On occasion, we will send a surveyor apprentice as part of the survey team, at no additional charge to you. All surveyors and surveyor apprentices have a photo identification badge issued by ABC. Surveyors are assigned based on the programs indicated on your application.

Once your facility's survey has been picked up by a surveyor, you will receive an email with your surveyor's name. All ABC surveyors/apprentices must disclose any potential conflict of interest with the applicant/facility to us before they are assigned to conduct the survey. If you have a conflict of interest with your assigned surveyor, please email accreditation@ABCop.org with your name, facility's contact information, and reason within five days of receiving your assigned surveyor email. Requests made after the five days will be denied. The following constitute as valid conflict of interest:

- The surveyor has provided consulting services or accreditation guidance of any kind to your facility.
- The surveyor has a personal relationship with owner, shareholder, or other individual working at the facility.
- The surveyor enters into employment or contract with the facility.
- The surveyor was employed or contracted or currently employed or contracted with a competing business in your local area.

Surveyors/apprentices with a confirmed conflict are not assigned that survey.

Your surveyor is not available to you after your onsite survey and we cannot provide you a surveyor's personal contact information. ABC staff is available to you throughout your accreditation process for any questions you might have. Simply call or email us at accreditation@ABCop.org.

About Our Surveyors:

BACKGROUND

ABC surveyors have the necessary education and training to form a solid foundation for program evaluation. The amount and kind of education and training depends upon the type and level of program to be evaluated.

SITE SURVEYOR TRAINING

Our surveyors receive formal, organized training through workshops conducted by experienced evaluators representing numerous aspects of the provision of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS). In addition, we have developed training materials on the ABC Accreditation Standards, their structure and the relationship between ABC and the Centers for Medicare and Medicaid Services (CMS).

APPROACH

ABC surveyors demonstrate maturity, objectivity, diplomacy and dedication. They project an image of professionalism in both behavior and appearance. In addition, our surveyors appreciate the confidential nature of the task and understand the need for self-initiative, a cooperative attitude, an analytic approach to the task and the necessary degrees of flexibility.

KNOWLEDGE

Our surveyors are knowledgeable in the disciplines in which we accredit and of the entire accrediting process. They have sufficient general and specific experience to be able to exercise appropriate judgment. In addition, our surveyors thoroughly understand the standards as well as what constitutes deviation from or noncompliance with those standards. It is imperative that surveyors be very familiar with the content of your application and all related materials provided to them prior to the site visit.

SKILLS

Our surveyors are skilled in interviewing, interpersonal communications, self-expression, note-taking and maintaining objectivity. Through experience and education, surveyors have developed capacities for deductive reasoning and logical analysis. They are skilled in writing and accurate in recall.

ACCREDITATION SURVEY PROCESS

Our goal is to make the accreditation process as effective and uncomplicated as possible. The following information will help you understand what you can expect from the process.

Preparing for your Survey

Before applying, you should make sure your facility is compliant with the eligibility criteria and the Standards. We offer a variety of accreditation tools on our website, ABCop.org. The **Relevant Standards** tool is one important tool that will assist you in determining which Standards apply to the product categories you are providing. Accredited facilities also have access to our online Compliance Kit Resource Pack. Additional preparation resources can be found in the **Resources & Links** section of this Guide or on our website.

Survey Structure

INITIAL INTERVIEW

Your surveyor(s) will conduct an initial meeting with your facility's survey contact or designated representative. At this time, the lead surveyor will:

- Briefly introduce him/herself, along with other members of the survey team (if applicable)
- Discuss the survey objectives and the day's schedule
- Answer any questions you may have regarding the survey
- Ask for the general layout of your facility and a description of any other details about your facility and your staff that should be noted

INFORMATION GATHERING

To verify that you have met the requirements of ABC's Accreditation Standards; your surveyor will review many areas, including:

- Personnel files
- Patient records
- Accounting and bookkeeping records
- Contracts with vendors, staff members
- Agreements with physician's offices
- Fire safety and emergency management plans and documentation
- Patient satisfaction surveys and results
- Business policies and procedures
- Product delivery information

By applying for accreditation, you authorize ABC and our surveyors access to all records (including patient, personnel, financial management, risk management, operational review, quality assurance and quality improvement) and physical areas necessary to determine your facility's compliance with the ABC Standards. Your surveyor will also conduct staff and patient interviews and may look at other areas as they relate to the Standards. All Protected Health Information (PHI) is treated in accordance with Health Insurance Portability and

Accountability Act (HIPAA) regulations. Per CMS, surveyors are required to call a sampling of your facility's Medicare patients and ask the patient or caregiver a few questions about the device, education, and follow-up they received. We recommend that a staff member be present while your surveyor makes these calls.

CLOSING INTERVIEW

During the closing interview, your surveyor(s) will discuss general survey findings. This interview provides you with a final opportunity to clarify any information or present documentation that may not have been available to your surveyor during the course of the survey. All significant recommendations and deficiencies will be discussed with you.

Your surveyor **cannot** provide judgment as to whether your facility will be granted accreditation and is not permitted to discuss whether your facility has passed or failed. Your surveyor's role is to review the information presented and to clarify, observe and verify that the data supports your compliance with the applicable standards. Your surveyor may also provide suggestions that could help improve your business practice.

In the event that the ABC Patient Care Facility Accreditation Standards are revised, we will establish a time frame for you to achieve compliance. Remember, it is your responsibility to ensure that you are in compliance with the ABC Standards at all times.

After the Survey—Results

SCORING PROCESS

Your surveyor will submit their initial findings to ABC. They cannot give you the final survey score during the onsite survey, as all results must be validated and finalized by staff. Finalized results will be emailed and mailed to your primary contact within four to six weeks of your survey date. Results for reaccreditation surveys are not processed if there are any outstanding invoices, such as annual fees. Any questions regarding accreditation status should be directed to the ABC Facility Accreditation staff at accreditation@ABCop.org.

ACCREDITATION DECISION

Once your survey results have been validated and processed, you will receive an email decision with access to your facility's decision letter, survey report, and certificate (if applicable). Your facility's decision letter and certificate (if applicable) will also be mailed to your facility. The report will indicate a score of **Compliant**, **Partially Compliant** or **Non-Compliant** for each standard for which your facility was surveyed. Standards marked Partially Compliant or Non-Compliant will include comments to assist you in taking corrective action to meet the standard. Your decision letter will inform you of your accreditation status and any additional action necessary, including if you need to submit a Corrective Action Plan (CAP). Accreditation certificates are the property of ABC and must be returned upon request.

ACCREDITATION DECISIONS

Full Approval

ABC Facility Accreditation is awarded when the overall score is within a passing range and no significant compliance issues are found. Facilities with full approval will receive an emailed decision with access to an electronic letter, survey report, and certificate. A decision letter and certificate with a three-year accreditation will be mailed to your primary facility.

Corrective Action Plan (CAP) Decisions

If your surveyor found deficiencies and/or if your facility's overall score is not within a passing range, your facility may be given the opportunity to submit a Corrective Action Plan (CAP). A CAP is a document that is submitted to ABC demonstrating your facility's compliance with the standard(s) in question. CAPs are reviewed and approved on a case-by-case basis; submitting a CAP does not guarantee accreditation. The length of accreditation awarded with a CAP requirement may vary from one to three years, dependent on review of the survey results. Failure to submit an approved CAP within the allotted time period will result in revocation of any existing accreditation or denial of accreditation. There are no fees associated with CAP submission and they may be mailed, emailed to accreditation@ABCop.org or faxed to the Accreditation Department's secure fax, 703-842-8027. It is strongly recommended that you make copies of your CAP documents, as any items submitted to ABC will not be returned.

This icon indicates each of the standards that, if marked P or N, will require a CAP.

Pass with a Corrective Action Plan requirement

If your facility's overall score is within a passing range but had deficiencies, you will be issued an accreditation that is contingent on an approved CAP. During the time of review, your facility is considered accredited.

Fail with a Corrective Action Plan requirement

If your facility's overall score is not within the passing range, you may be given the opportunity to submit a CAP. During the time of review, your facility is not considered accredited. After the review of your CAP, you may be granted accreditation.

Corrective Action Plan Timeline

CAPs are due within 60 days of the decision email date. Your accreditation decision, containing your CAP request, will be emailed and mailed to you. Failure to submit a CAP by the deadline will result in denial or revocation of accreditation. Due to the intensive nature and volume of CAP reviews, it takes approximately eight weeks to review each CAP.

Incomplete Corrective Action Plans

If your initial CAP does not adequately demonstrate compliance with missed standard(s), we will inform you via email and/or letter. If additional information is necessary in order for us to make an accreditation decision, we will make one additional request for follow-up materials within a specified timeframe. All materials are due by the deadline stated in the correspondence.

Supporting Corrective Action Documentation and Format

Your CAP must include supporting evidence that shows how changes have been implemented to address each missed (P or N) standard. This can include completed forms, logs, training notes, annual reports, patient notes (with patient identifying information removed) and meeting minutes. Your facility's Policy and Procedure manuals will not be accepted as a CAP; policies should only be submitted when directly relevant to the surveyor comment or the standard being addressed. All documentation is treated in accordance with HIPAA, privacy and security regulations. For each missed (P or N) standard, please use the format shown in the example below:

1. Standard: FS.3.2.2
2. Description of corrective action: We have now completed a yearly fire drill. In the future, these will be completed on the first Monday of December.
3. Documentation: (Include a copy of the completed fire drill report, including signatures of employees in attendance and analysis of the drill.)

Denial

A facility may be denied accreditation for multiple reasons. Some of the most common causes for accreditation denial are:

- The surveyor was denied access to the facility and/or documentation
- Facility was closed or otherwise unavailable for the onsite survey
- Submission of two CAPs that did not adequately address the issues in question or the CAP was not submitted by the deadline

If your accreditation is denied, you must reapply and be resurveyed in order to attain ABC Accreditation. When you reapply, you must submit a new application with the appropriate fees.

Accreditation Effective Dates

Accreditation effective dates for new and renewing facilities are determined as follows:

- First day following your survey, if your facility passes the initial survey
- Date reaccreditation application was received by ABC, if your facility is accredited and passes the reaccreditation survey
- Date that the CAP was received, if the plan satisfies the deficiencies identified

The accreditation effective date for service or affiliate add-ons is the date the application was received by ABC, if your facility passes the respective add-on survey.

Reporting to Medicare and Other Third Parties

ABC notifies CMS weekly of all accreditation decisions once they are finalized. Additionally, we may notify other payers or interested parties of the status of your facility's accreditation as well as issue public statements concerning the accreditation of applicants. Facilities that are past-due on annual or accreditation fees are not reported to Medicare, verified with other third parties and are not considered in good standing.

Accreditation Decision Review

All onsite survey findings that result in a limited, denied or revoked accreditation are automatically reviewed by the ABC Facility Accreditation staff. ABC staff has the authority to request additional information from you or your surveyor before reaching a final decision. If you believe your facility's accreditation is limited, denied or revoked as a result of incorrect information, you may formally appeal the decision.

Appeals Process

You have 15 days from the receipt of the accreditation decision to submit a written appeal to the Facility Accreditation Committee. Your appeal must be mailed via certified mail, return receipt requested or by verifiable overnight express mail service to:

American Board for Certification in Orthotics, Prosthetics & Pedorthics, Inc.
Attn: Facility Accreditation Department
330 John Carlyle St.
Suite 210
Alexandria, VA 22314

Your appeal must include the necessary evidence or relevant documentation supporting the basis of your appeal. If you do not appeal the decision within the 15-day time period, the accreditation decision will be final.

You will receive notification of the Committee's decision on your appeal within 45 days of its receipt by ABC. Should you not be satisfied with the decision, you may submit a second appeal to the ABC Board of Directors by sending another certified, written appeal to the ABC offices within 15 days of receipt of the Committee's decision. You will be notified of the board's decision within 60 days of receipt of your request. The decision of the board is final.

ACCREDITATION FEES

Current accreditation fees may be found by visiting the Patient Care Accreditation section of the ABC website. **All accreditation fees are non-negotiable and non-refundable.**

Accreditation fees are set by the ABC Board of Directors and reviewed annually. ABC reserves the right to adjust accreditation fees and establish the effective date of change. ABC also reserves the right to adjust accreditation fees based on new or validated information obtained during the survey process, which may affect the type of survey, the type of accreditation awarded and/or the number of survey days required. Final accreditation determination is contingent upon receipt of all fees.

Application Fees

The accreditation application can be accessed by logging into your facility's account on the ABC website, ABCop.org. Application payment for all programs and primary and, if applicable, affiliate and/or warehouse/administrative locations must be provided in order to submit your application to ABC. Additional fees are required for any accreditation program that is added to your main accreditation. Full payment must be submitted with your application. Your facility will only be added to the survey queue if your application is complete and fees are received in full. The fees associated with the application encompass application processing and the onsite survey. We do not charge fees for any travel expenses incurred by surveyors.

ANNUAL FEES

All accredited facilities are assessed annual fees. Notifications are emailed in September and mailed in October of each year. Your annual fees are due on December 1st. Your current accreditation status is dependent on the timely receipt of these fees. Failure to submit annual fees may incur any or all of the following:

- Removal from ABC's weekly Medicare report
- Removal from ABC's Directory
- Inability to verify your facility's accreditation with all third-party payers
- Revocation of facility accreditation

Certificate Reprint Fees

If you wish to obtain an additional accreditation certificate, a $25 fee is required per certificate. Your facility's fees and accreditation must be current in order to process your reprint request.

MAINTAINING YOUR ACCREDITATION

Accreditation requires that you continue to comply with the ABC Standards, abide by all policies and procedures and submit your annual fees on time. Failure to fulfill any of these requirements may result in the revocation of your facility's accreditation.
Facilities must notify ABC of any and all changes within 30 days of the effective date of change. Such changes include:

Moving a Location

You are required to reapply for your facility should you change addresses as ABC is required to visit your new address. ABC cannot update our facility records without the completion of the accreditation application and associated fees with the updated address.

Adding a Location

You are required to apply for ABC accreditation for all operational patient care sites as well as related administrative and warehouse locations. Administrative, warehouse and patient care sites that are within 100 miles driving distance of your primary location and under the same Tax ID must apply as affiliate locations (not to exceed four affiliates per primary); those outside of 100 miles or that do not meet the affiliate definition must apply as a primary.

Any affiliate or related office that opens after the primary location has been granted accreditation cannot advertise or otherwise consider itself an accredited patient care center until you have applied for and been granted accreditation status by ABC. You must submit a new application, including all appropriate fees, upon the opening /acquisition/merger of an affiliate location. Once your application has been approved, ABC will determine if the location is eligible for a 90-day accreditation, with full accreditation contingent on passing your onsite survey with no significant compliance issues. If approved for full accreditation, this accreditation will be valid for the length of your primary location's current accreditation.

Changing Corporate Structure

If you are changing your corporate structure, you must submit written details of the change, effective date, legal documentation (i.e. new business license, Articles of Incorporation) and ownership information to ABC. If you are changing ownership in addition to the corporate structure, please see the *Ownership Changes* section.

Adding Services or Products

ABC can only issue accreditation for services currently being offered. If you do not currently provide a service but wish to provide it in the future, you must wait until you are actively providing that service at your facility to apply for accreditation. To add services or products that are not covered under your current accreditation, you must submit an application and all fees.

If a new product is currently covered in your facility's accreditation and does not require an additional survey, you can submit a detailed statement on your company letterhead that specifies the items that are being provided and the effective date.

Accreditation for the additional scope or product category will be valid for the length of your primary location's current accreditation period; no additional time is granted.

Discontinuing a Service

You must notify ABC in writing if you discontinue any patient care service or discontinue offering a specific item or device. If you add the service at a later date, please see the instructions for adding additional scopes of services, items or devices. If the removal of the service or item/device results in a change to your accreditation programs, you will be required to mail ABC your original certificate so an updated certificate can be reissued.

Closing or Selling Your Facility

You must notify ABC in writing if you close or sell your facility; notification must be sent within 30 days of the sale or closure. You must also mail ABC the original active accreditation certificate. If you reopen your facility at a later date, you must submit a new online application and all related fees. If your facility is sold, your accreditation is not transferrable to another owner, and the new owner of your facility will need to reapply (see Ownership changes).

Lawsuits and Disciplinary Actions

You must notify ABC if there are pending lawsuits and/or disciplinary actions against any staff members or locations when you apply for accreditation. A detailed written statement that includes the following must be submitted with your application and fees:

- A description of the incident
- The date and where the incident occurred
- The verdict of the charge(s) that were filed against the individual
- Any penalty/sentence associated with charges
- When the sentence was, or will be, completed
- Court case summary of the incident

Copies of court documents are also required. If the documents are not available, indicate the jurisdiction in which the charge(s), conviction or plea occurred and why the documents are not available. If all the appropriate information is not provided, the processing of your application will be delayed and your application may be considered incomplete.

You must also inform ABC in writing if any legal or disciplinary action is taken against the facility or its employees at any time during the accreditation period.

Ownership Changes

ADDING OWNERS TO EXISTING OWNERSHIP

ABC requires that you submit a renewal application for resurvey with a detailed letter, accreditation fees and legal documentation of the changes. When completing your application, please make sure you select the option for *Ownership Change*. If you are adding owners to your facilities, you will maintain your current accreditation cycle while waiting for an onsite survey.

COMPLETE CHANGE OF OWNERSHIP

ABC Accreditation is not transferrable between two different owners. A complete change in ownership requires the facility to be resurveyed. If no existing owners are remaining at the facility, the new ownership must submit an online application, application fee, and upload a letter detailing the changes as we as supporting legal documentation of the sale. ABC is authorized to issue a 90-day accreditation if your facility is accredited and in good standing under a different owner. To be issued a 90-day accreditation based on an ownership change, you must make your request in writing, along with your application, legal documentation of the sale and all fees. In order to issue a 90-day accreditation, your application must be approved and accreditation must be verified. We will approve the product categories based upon your facility's previous accreditation and in accordance ABC's Scope of Practice.

REMOVING AN OWNER FROM EXISTING OWNERSHIP

If you are removing an owner from your facility's existing ownership, you must submit a letter detailing the change, the effective date and provide legal documentation (i.e. Transfer of Shares evidence, Articles of Incorporation). A resurvey is not required as long as an existing owner remains.

PERSONNEL CHANGES

You are responsible for notifying ABC of employment status changes for all certified and licensed personnel within 30 days of the effective change date. All notifications must be made in writing. In the event that a personnel change leaves your facility without a qualifying professional, you have a maximum of six months from the last day of employment to replace the professional. Failure to do so will result in loss of accreditation for that discipline. **This six-month grace period is allowed once per accreditation cycle.** During this time, your facility must still operate within the ABC Scope of Practice and in accordance to state and federal laws.

COMPLAINT PROCESS

ABC's Professional Discipline Committee (PDC) will investigate all complaints involving an ABC accredited facility or any accreditation applicant that appears to be out of compliance with the Accreditation Standards or *Code of Professional Responsibility*. You must provide ABC's contact information to clients/patients for the purpose of reporting a complaint.

ABC will notify the appropriate regulatory authorities if an alleged complaint involves:

- Possible abuse, neglect or exploitation
- Professional misconduct
- Noncompliance with state or federal laws

You will be informed of all allegations and provided with copies of all complaint-related materials.

If a review of the complaint determines that there is immediate risk to patients, we will notify the appropriate governmental and investigative agencies. If the situation does not pose immediate risk, the complaint will be investigated in accordance with the *Code of Professional Responsibility*.

Depending upon the nature of the complaint, the following actions may be taken:

- ABC will follow the guidelines outlined *Code of Professional Responsibility* and may also:
  - Request your cooperation in resolving the complaint
  - Request that you respond to the complaint within an identified time frame
  - Determine if you are aware of the complaint and if you have taken action

ABC will review all the information collected about the complaint, including any information gathered in a re-survey. If the investigation reveals the complaint or allegations are valid and a patient's health, safety and welfare are at risk, accreditation may be revoked or suspended. You may appeal the committee's decision by following the appeals process.

If the ABC Professional Discipline Committee makes the decision to revoke your accreditation, we will notify the appropriate regulatory agencies of our decision.

ANNOUNCING AND PROMOTING YOUR ACCREDITATION

We know that once you gain your ABC Accreditation, you'll be proud to announce your achievement to your patients, referral sources and insurers. Check out the following tools, all designed to help you show your ABC pride.

Logo/Advertising Language

Once you are accredited, we encourage you to use the ABC logo on your facilities' business cards, letterhead, invoices, website and marketing materials. It's easily accessible through your facility's MY ABC account. Just log in to your account and download either a hi-res or a lo-res version of the ABC Accreditation logo.

Press Releases

We encourage you to publicize your accreditation status and provide a sample press release in your accreditation notification packet. You can also download a copy of the sample press release by logging on to your facility's MY ABC account and accessing the online Resource Pack.

Public Information Requests

Upon request, ABC will release your accreditation status, accredited programs, and accreditation dates to the public. This information is released without written authorization or notification. Accredited facility information is also available online in the ABC Directory.

You must take care to accurately describe the program(s), service(s) and affiliate office(s) for which your facility is ABC accredited. You must abide by the ABC Logo Guidelines when using the logo to advertise your accreditation status to the general public. Any false or misleading advertising indicates noncompliance and will result in penalties up to and including revocation of your accreditation. The Logo Guidelines will be sent to you in your accreditation notification packet. Any location that has not yet received accreditation (new affiliate locations or locations still in the application process) must state in all forms of advertising and marketing that they are NOT ABC Accredited.

ACCREDITATION STANDARDS AND COMPLIANCE TIPS

ABC Accreditation Standards represent baseline expectations of your facility's physical environment and the functions of patient care. Accreditation decisions are based on the degree of compliance with the Standards. Compliance is assessed as appropriate to the size of your facility and services provided. However, all facilities are evaluated on the same set of Standards.

The Standards for patient care facilities are grouped into the following eight categories:

- **Administrative**
- **Human Resources**
- **Patient Care and Management**
- **Product Safety**
- **Patient Records**
- **Performance Management and Improvement**
- **Facility and Safety Management**
- **Claims and Billing Compliance**

We are committed to providing you with useful resources to guide you through the accreditation process. The following Standards and Compliance Tips is a valuable resource for those who are planning to apply for accreditation or for current accredited facilities looking toward reaccreditation. For many of the Standards there is an accompanying tip that provides suggestions for complying with that standard. The guidance offered in each tip is meant to further clarify the expectations of the Standards. Following the tips does not automatically ensure compliance or guarantee that you will pass the accreditation survey. The tips are suggestions and we recommend that you expand on them as you deem necessary.

Administrative Standards (AD)

The Administrative Standards address the legal status and legitimacy of the business, compliance with Medicare and HIPAA requirements and establishment of the internal policies and procedures of the business. ABC awards accreditation only to a legal entity.

The Standards require that your business be legally constituted, not only in the jurisdiction in which it is based, but also in those localities in which you provide services. Full disclosure of ownership is required at the time of application and all financial records must be complete. Your business must have a physical location accessible to the public and make reasonable physical accommodations for your employees and patients. All licenses, certificates and permits must be displayed in an area accessible to the public.

In addition, written policies and procedures which address the clinical and business aspects of your business are required.

Your policies and procedures must include but are not limited to:

- Professional qualifications and continuing competency
- A mechanism to facilitate professional staff communication with the governing body
- Patient care and management, including patient and family education and patient rights
- Maintenance and confidentiality of patient records
- The protection of private healthcare information
- Patient billings, collections and complaint resolution
- Performance management
- Facility and safety management

AD.1

Your business has documentation that it is a legal entity in the state(s) in which it is located and is authorized to provide the services for which you seek accreditation.

TIP

You will need to provide legal documentation of proof of ownership, including evidence of your:

- Tax Identification Number (TIN)
- Articles of Incorporation (Corporation) or
- Articles of Organization (LLCs)

You must provide your surveyor with evidence that you have a business license and the necessary permits from federal, state and local governments. Since licensing and permit requirements vary among jurisdictions, it is critical that you contact your state and local government to determine the specific requirements for your business, such as:

- Business license from your city or county
- Zoning or occupancy permit
- Fictitious business name permit (also called dba or doing business as permit)
- Sales tax license
- Fire department permit
- Special state-issued occupational or professional licenses

AD.1.1

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

TIP

Some of the same issues mentioned in AD.1 apply to this standard as well. You will need to show proof of compliance with all federal, state and local laws. In states where professional licensure is required, you must provide a current copy of your valid license(s).

AD.1.2

Your business has a physical location accessible to the public.

TIP

ABC does not accredit businesses without a physical location, such as those operated by Internet or mail order. Your business must have a physical location that is accessible to the public.

AD.1.2.1

You must display all current licenses, certificates and operation permits in a location accessible to the public.

TIP

Licenses, certificates and permits must be current and displayed in an area that is accessible and viewable by your patients such as the patient waiting area, reception area or a hallway accessible to the public. Although requirements vary among jurisdictions, it is critical that you contact your state and local government to determine the specific requirements for your business, such as:

- Business license from your city or county
- Zoning or occupancy permit
- Fictitious business name permit (also called dba or doing business as permit)
- Sales tax license
- Fire department permit
- Special state-issued occupational or professional licenses

AD.2

Your business has designated at least one person who has the authority, responsibility and accountability to direct the business's operations.

TIP

Your business must have one or more individuals who are identified as the business's leadership. All specified individuals share the authority to direct key aspects of the business. You may identify them on business organizational charts, written job descriptions or meeting minutes.

AD.3

Your business must have a mission statement that describes the services you provide, as well as the goals and objectives of the business.

TIP

This mission statement could be part of your Policy Manual, displayed in your patient waiting area, included in your marketing/promotional materials or posted on your company website.

AD.3.1

Your business must have written policies and procedures for the performance of clinical and business operations. Your staff must be made aware and have access to current policies.

TIP

Your policies and procedures need to describe how your clinical and business activities are perwormed. You must inform your staff of these policies and procedures and ensure that all staff members have access to them. This information can be relayed during staff meetings and/or by providing your staff with printed or electronic copies of the policies and procedures. Staff must be notified of any changes or additions made to company policies and procedures. All changes, additions and notifications must be clearly documented.

AD.3.1.1

You must annually review your written policies and procedures for the performance of clinical and business operations. Your review must be documented.

TIP

Your documentation can be in the form of annual notes, corporate minutes, and staff meetings.

This can be documented in annual notes, corporate minutes, staff meetings, policy and procedure manual.

AD.4

Your business may provide only the services and items listed on your most current ABC accreditation application.

TIP

When we review your patient charts and other records, we must be able to confirm that all services and items supplied to patients are consistent with your current ABC accreditation application.

AD.5

Your business must comply with the applicable provisions and requirements of the current CMS DMEPOS Supplier Standards, Regulations and Medicare Contractor policies and articles.

TIP

You are responsible for being knowledgeable about all of the current CMS (Medicare) Supplier Standards, regulations and policies. You can read about them on the CMS website (cms.gov) or take seminars or courses to become more knowledgeable. You must disclose the current CMS Supplier Standards to your Medicare patients and have those patients provide signature of receipt. You do not have to give each patient a copy to take home but they must sign off that the standards were disclosed to them. You must have proof of your liability insurance and surety bond, if applicable. The Medicare Supplier Standards and a Patient Acknowledgement form are available in the online Resource Kit.

AD.5.1

Your business must have written policies and procedures, which require you to annually verify and document that all employees, contractors and new hires are not on the Office of Inspector General (OIG) List of Excluded Individuals and Entities (LEIE).

TIP

The Office of Inspector General (OIG) and ABC require health care entities to check the OIG List of Excluded Individuals and Entities (LEIE) to ensure that individuals or entities, including but not limited to employees (W-2) and contractors (1099), are not listed. Use the OIG Exclusion Checklist in the online Resource Kit to document this review.

As part of the hiring process, you must verify and document that prospective new hires are not on the OIG List of Excluded Individuals and Entities (LEIE). You must document the date of the search, the names of the individuals or contractors checked and whether the individuals or contractors were on the list.

The business must have policies and procedures in place that address the frequency of these checks and the protocol if a current employee or a prospective new hire is on the list. ABC requires that these checks be done annually and documented in your written policies and procedures.

AD.6

Your business must comply with the relevant requirements of the Health Insurance Portability and Accountability Act (HIPAA).

TIP

The Health Insurance Portability and Accountability Act (HIPAA) has many sections and requirements. You should be knowledgeable about the Act and its applicability to your business. Make sure you stay up to date on any changes and/ or updates to HIPAA.

Examples of compliance include:

- You have a designated and trained HIPAA officer
- Business Associate Agreements are in place
- Patient Acknowledgements are required and filed
- HIPAA Privacy Rules are in place
- Notice of privacy practices are displayed, distributed or accessible to patients
- HIPAA Security Regulations are in place, as applicable
- Patient records are stored appropriately
- Access to Protected Health Information (PHI) is properly restricted
- Computer and other system passwords are in place
- Documentation of staff education

Use the Patient Acknowledgement form in the online Resource Kit to document that information has been provided to patients.

AD.7

Your business must make reasonable physical accommodations for your employees and patients.

TIP

Your business must comply with applicable requirements of the Americans with Disabilities Act (ADA) ada.gov. You should seek out ways to become knowledgeable about how ADA applies to your business. You need to make reasonable physical accommodations for your employees and patients.

Examples include:

- Ramps, entrances and exits must be appropriate for the business and the population of patients being served
- Patients and staff using wheelchairs, walkers, crutches or other mobility aids must be able to access the facility
- Restrooms must be accessible by your patients and staff
- Doorway width must be appropriate for your patients and staff

AD.8

Your business must have financial records that are accurate, complete, current and reflect either cash or accrual accounting practices. You must have an operating budget appropriate to your business size and scope of services.

You must maintain financial information or accounts that:

1. Manage revenues and expenses on an on-going basis

2. Link items and supplies to the patient

3. Reconcile charges to the patient for services, items and supplies with invoices, receipts and deposits

4. Have a mechanism to track actual expenses and revenues

TIP

Accurate, complete and current financial records are an indication of the health of an organization.

- Your surveyor must see evidence that:
- You have an operating budget that meets the needs of your patients and your business operations
- You manage revenues and expenses as they relate to patient services on an ongoing basis
- Your business uses either cash or accrual based accounting practices
- Your records or financial accounts allow you to identify which specific items or equipment were provided to specific patients
- Your records or financial accounts allow you to reconcile charges to patients with invoices, receipts and deposits.

Human Resources (HR)

The Human Resource Standards applies to all personnel at the facility's physical location, whether directly employed, contracted or those serving in a volunteer capacity providing patient care services or supporting activities.
The terms *staff* and *staff member* (and their derivatives) as used in these Standards are intended to refer to the facility's various types of care providers and support staff. The facility ownership/leadership has the responsibility for appointing and privileging its staff. The appointments and privileges must be based upon the staff member's competency to perform the necessary skills for the functions and procedures associated with that appointment. You must manage the competencies and qualifications of contracted services and personnel in the same manner that you manage the competencies and qualifications of direct employees and volunteers.

You can define in the contract, or in written policy, criteria for performance of the contracted service; or, you can review and adopt the contracted business's policies and practices. The contract should specify that the contracted business would provide only qualified staff based on their education, training, licensure and competence as defined by the business. Contracted entities are subject to the same eligibility requirements as employees and volunteers. Facility management will be held ultimately accountable for the actions of its contractor's staff and volunteers.

The Human Resource Standards are applicable to any contracted service that provides any element of care or service, which is eligible for survey. They do not apply to delivery of home

medical equipment and pharmaceutical products via a contracted common carrier (i.e. UPS, FedEx, US Postal Service, local courier companies), where there is no education or set-up involved. The Standards, however, do apply when delivery is provided by a direct employee of the business or a contractor of the business not excluded in this paragraph.

HR.1

Your business must have human resource policies and procedures that address employee duties and responsibilities.

These policies must include:

1. Detailed job descriptions that list personnel qualifications and training requirements

2. Required certifications and/or licenses

3. Required experience

4. Continuing education requirements that are consistent with the items and services you provide

HR.2

You must annually document that you have verified current licenses and certifications held by all staff members who provide patient services.

TIP

The licenses and certifications held by all patient care providers must be verified annually. You can do this by contacting the issuing agency (licensure or certification board) and requesting verification that the individual's credentials are still valid. This can be done via phone, email or by checking the agency's website. Once acquired, the verification should be documented in the employee's personnel file or another file specifically for this purpose. You should document the date and method by which verification was received. Use the Employee Verification form in the online Resource Kit to document your review.

HR.3

You must have orientation and training programs to familiarize all staff with your facility and procedures. This includes having appropriate reference materials and educational information available to all personnel.

TIP

It is important that you document staff participation in initial orientation or training as well as all ongoing and remedial training programs. Documentation could include a signed and dated list of participants and a copy of the agenda for the orientation or training session.

The orientation or training should include information to ensure that your staff understands your emergency preparedness and evacuation programs and procedures. The orientation or training materials should be available to all personnel. You could have copies made for each staff member or have master copies in a location accessible to all staff.

HR.4

You must verify that your staff has completed continuing education consistent with the services and items they provide and are in compliance with their credentialing organization, as applicable.

TIP

You must document staff participation in continuing education that is relevant to their patient care duties. This continuing education may include in-service programs, manufacturer sponsored courses or courses provided by other sponsors. You can document participation with in-service sign in sheets and agendas, course certificates or official continuing education statements such as those provided by ABC to credentialed individuals (MCE Statement). The documentation should be kept either in staff continuing education records or each individual staff member's personnel file. Use the Assessment of Employee Continued Competency in the online Resource Kit to document your review.

HR.4.1

When required by state licensure, staff providing patient care must be licensed by the orthotic, prosthetic and/or pedorthic licensure body and function within their licensure scope of practice.

TIP

You must provide a current copy of any required state licenses. Your patient care records must indicate, with notes and signatures, that care is being provided by licensed staff.

HR.4.2

In the absence of state licensure requirements, staff providing custom fitted prefabricated or custom fabricated items and services shall be certified as appropriate and function within the ABC Scope of Practice.

TIP

Your patient records and office policies must demonstrate that personnel providing these services are certified. You must provide copies of their current certifications. Your patient care records must indicate by notes and signatures that care is being provided by the appropriate certified staff.

HR.5

You must meet all CMS (Medicare) requirements for the items and services provided and for the employment of specialty personnel.

TIP

The business must meet all requirements described on the CMS 855S form. You must have current W-2 or 1099 forms for all staff. These forms should be maintained in their personnel file or another file specific to this purpose.

HR.6

You may privilege certified or licensed staff to provide patient care beyond their defined scope of practice under the supervision of a certified or licensed individual practicing within their scope of practice. If you privilege a staff member, your process must be in compliance with applicable laws, based on Written Objective Criteria* and under the Indirect Supervision* of a certified or licensed individual practicing within their scope of practice.

*See definition of Written Objective Criteria and Indirect Supervision in the ABC *Scope of Practice*.

TIP

Certified or licensed staff can be privileged to provide items or services beyond their scope of practice. However, you must document that you have established Written Objective Criteria to assess the competency of each person. Use the Individual Privileging Record template and the Instructions for Establishing Privileging Criteria in the online Resource Kit for help with this standard.

This documentation may take different forms, including but not limited to, proof of completion of continuing education courses related to particular devices, documented in-house or in-service training that is specific to the items or services that the patient care provider is being privileged to provide and/or documented specific work experience participating in patient care activities.

You will need written documentation for each privileged patient care provider describing what criteria they met and how they met it. A log of items or services the individual has been privileged to provide is not considered Written Objective Criteria. The supervisor's co-signature must appear in all patient documentation.

HR.6.1

If you utilize Support Personnel* to participate in patient care tasks related to custom fitted prefabricated or custom fabricated orthoses, prostheses and pedorthic devices, those tasks cannot include patient assessment, formulation of the treatment plan, final fitting and delivery and any follow-up care that modifies the function of the device as originally prescribed. Any tasks delegated to Support Personnel must be done under Direct Supervision*.

*See definitions of Support Personnel and Direct Supervision in the ABC *Scope of Practice*.

TIP

Only non-critical patient care tasks may be delegated to non-credentialed Support Personnel. The certified or licensed caregiver must be physically on-site while the care is being provided and is responsible for documenting the care in the patient's record.

HR.7

You must provide and document performance reviews of your staff at least annually. These reviews must provide your staff with feedback on competency and opportunities to improve performance related to the items and services they provide.

TIP

During those reviews, you will need to provide all of your staff with feedback on their competency and areas for improvement, if needed. For each staff member that provides patient care, you need a way to document their continued competency as it relates to specialized equipment, items and services.

You can measure their continued competency through patient satisfaction surveys, continuing education related to specialized equipment, items and services or other performance management data. You can document the ways in which each care provider maintains their competency through proof of completion of continuing education courses, documented in-house training, in-services and/or documented specific work experience.

These appraisals are to be documented in their personnel file or another file specifically maintained for that purpose. Use the Employee Performance Evaluation form in the online Resource Kit to document your review.

HR.8

Your delivery and set up staff must be competent to deliver and train patients on the use of specialized equipment.

TIP

You must be able to demonstrate the competency of the technical personnel who deliver, setup and train patients on specialized equipment. You must first establish Written Objective Criteria for assessing their competency. You should use the manufacturer's guidelines for delivery and setup in establishing your competency criteria.

Each technician should have a competency assessment document that lists each criteria measured for competency and how they were met. Tools for assessing competency may include ride-along supervision, patient satisfaction survey results, continuing education courses, manufacturer's training courses and/or supervised on-the-job training. Your patient records must document that delivery, setup and patient education/training have taken place. Use the Instructions for Establishing Privileging Criteria and Individual Privileging Record template in the online Resource Kit for this standard.

HR.8.1

You must have a policy that describes the qualifications and competencies of all staff that deliver specialized equipment, training and home assessment.

TIP

All delivery personnel must be qualified to provide training on the delivered equipment and to perform a home assessment. You must first establish Written Objective Criteria for assessing competency as referenced in the tip for HR.8. Each individual should have a competency assessment document as referenced in the tip for HR.8.

HR.8.1.2

You must have a policy that lists the qualifications and competencies of the staff that train patients on the proper care, use and maintenance of the specialized equipment provided.

TIP

Your policies and procedures must list the qualifications and competencies you require of all individuals who deliver equipment on your behalf. Written Objective Criteria and competency assessment must be established as outlined in the tip for HR.8.1. Patient records must document that patient education and training on the proper care, use and maintenance of the delivered equipment have taken place.

HR.8.2

If you provide complex rehabilitative technology, you must have at least one Rehabilitative Technology Supplier (RTS) available to service each location. In addition to the RTS, you may also employ other trained technicians to service each location.

TIP

A qualified RTS must have one of the following credentials:

- Assistive Technology Professional (ATP)
- Certified Rehabilitative Technology Supplier (CRTS)

A trained technician is identified by all of the following:

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

Your personnel files or other records must contain documentation of the above requirements.

HR.8.3

If you provide respiratory equipment, supplies and/or services, you must provide services in compliance with the current version of the *American Association for Respiratory Care Practice Guidelines*.

TIP

Patient care records must demonstrate compliance with the American Association for Respiratory Care Practice Guidelines (rcjournal.com/cpgs). Copies of the Guidelines must be readily available for your staff.

Patient Care and Management (PC)

Patient Care and Management Standards address essential components designed to support the delivery of appropriate, safe and effective patient care and to ensure that patient needs are met. These Standards are designed to address Physician Interaction, Patient Rights, Patient and Family Education and Patient Follow-up Care. They will also guide you in your steps to establish mechanisms to help you provide the best quality care for your patients.

1. **Physician Interaction and Communication—**To support continuity of care between your business and your referral sources, mechanisms for communication between the professional staff and a patient's referring physician or appropriately licensed healthcare prescriber must be maintained.
2. **Patient Rights—**To establish an environment that facilitates the delivery of effective care, you must create an atmosphere of mutual trust between patients and professional staff.
3. **Patient and Family Education—**The success of patient care depends not only upon the competency of the practitioner and the quality of the device, but also upon its proper and effective use and care by the patient.
4. **Patient Follow-up Care—**The Standards in this section support ongoing patient care and reflect the standards of care generally accepted by the profession. They require that you provide follow-up care, appropriate to the patient's condition and complexity of the care, in accordance with the current valid order.

PC.1

Your business must have written policies and procedures that address the responsibility of your professional staff to provide appropriate, effective and ethical patient care. All activities of your business must be in accordance with the ABC *Code of Professional Responsibility*.

TIP

Review your compliance with the ABC *Code of Professional Responsibility*.

Your facility must comply with the Code. This obligation includes, without limitation, the actions of its employees or independent contractors who provide patient care services for the facility, regardless of their individual credentialed status.

Your written policies and procedures should contain information on topics such as:

- Personnel qualifications and training
- Required certifications, and/or licenses
- Required experience
- Continuing education requirements consistent with the specialized equipment, items and services provided to patients
- Privileging and supervision policies, if applicable

Additional resource: ABC *Scope of Practice*.

PC.1.1

Your written patient management policies and procedures must be:

1. Available to all staff

2. Consistently followed at each of your locations

3. Provided upon request to ABC and government officials or their authorized agents

PC.1.2

You must have written policies and procedures that facilitate and enhance communication and coordination of patient care.

TIP

You can facilitate this communication in many ways, including staff notices, training and meetings with documented minutes or notes.

PC.1.3

You must inform your patients of the expected time frame for delivery of items and services.

TIP

You might indicate the timeframe for delivery with a note of the verbal communication in the patient record or by providing the patient with a follow-up appointment card.

PC.2

You must have a policy that requires you to notify the healthcare prescriber within five calendar days if you determine that you cannot or will not provide the items or services that are prescribed for a patient.

TIP

For example, if a patient is referred to your facility by a healthcare prescriber for a service you do not provide, your policy requires you to notify the appropriately licensed healthcare prescriber within five calendar days if you determine that you cannot or will not provide the equipment, items or services that are prescribed for the patient.

PC.2.1

You must maintain an appropriate fitting stock so that you can effectively provide your patients with properly fitting and functioning mastectomy items. You must have a minimum fitting stock of 10 mastectomy forms and 24 bras.

TIP

If you provide mastectomy products, you must have the minimum fitting stock indicated in the standard. This fitting stock must be available for the surveyor to observe.

PC.2.2

If you provide custom fabricated or custom fitted prefabricated orthoses, prostheses or pedorthic devices you must have access to the tools and equipment necessary to provide follow-up including modification, adjustment, maintenance and repair of the device.

TIP

Each patient care location must have the tools and equipment needed to provide adjustments and repairs.

PC.3

You must keep documentation of all referrals, consultations and other communication from the healthcare prescriber in the patient's record. This documentation must not be altered in any way.

TIP

Your patient records must contain all referrals, consultations and other communications from the appropriately licensed healthcare prescriber. These communications must be unaltered and include the referral or prescription, the patient's diagnosis and clinical notes

PC.3.1

You must provide patient care in accordance with the most recent prescription for the items or services provided. All patient care must be in accordance with the payer requirements.

TIP

Your patient records must document that the patient care was delivered according to the most current prescription and in accordance with payer specific requirements (e.g., written instructions are given to patients, warranty information is provided). The prescription must be in the patient chart.

PC.3.2

During each patient visit, you must review the treatment plan, verify that the patient's record contains the current prescription and document the care provided during that visit.

TIP

Clinical documentation must reflect assessment of the treatment plan and contain notes for every patient interaction. Documentation should address all of the elements listed in the standard.

PC.3.2.1

Patient non-compliance must be evaluated and documented. You must attempt to correct non-compliance through patient management activities, patient education and communication with the referral source.

TIP

Patient non-compliance with follow-up care may include situations such as not showing up for appointments, failure to follow patient instructions or failure to follow break-in wearing schedules. Any non-compliance should be documented in the patient record.

Trends of non-compliance should be included in your business's performance management activities (see PM.7 and PM.8).

PC.3.3

You must provide and document follow-up care consistent with the diagnosis and complexity of services provided.

TIP

The level and frequency of follow-up care depends on the types of services and items you have provided. You should consistently schedule follow-up appointments based on the potential risks and likelihood of changes in the fit of the device or the patient's function over time.

PC.3.4

The patient care provider must perform and document in the patient's record an in-person, diagnosis-specific, clinical examination related to the patient's use and need of the prescribed device. For example: sensory function, range of motion, joint stability, skin condition (integrity, color and temperature), presence of edema and/or wounds, vascularity, pain, manual muscle testing, functional limitations, compliance, cognitive ability and medical history.

PC.3.4.1

The patient care provider must determine and document the appropriate orthosis, prosthesis or pedorthic device. This determination must be based on the patient's need and must ensure optimum therapeutic benefits and appropriate strength, durability and function as required for the patient.

TIP

Your patient records must document your determination and rationale for the appropriate orthosis, prosthesis or pedorthic device and the appropriate materials, components and design based on the patient's need.

PC.3.4.2

The patient care provider must formulate and document a treatment plan consistent with the prescription and must consult the healthcare prescriber when necessary.

TIP

Your patient records must document that a treatment plan has been formulated for each specific patient and is consistent with the prescription. If consultation with the prescribing healthcare professional is necessary, it must be documented in the record.

PC.3.5

The patient care provider responsible for complex rehabilitative wheelchairs and assistive technology must coordinate services with the healthcare prescriber to conduct face-to-face evaluations of the patient. These evaluations must take place in an appropriate setting and include input from other members of the healthcare team.

TIP

If you provide complex rehabilitative wheelchairs or assistive technology, you must have a policy that requires that these services are coordinated with the prescribing healthcare professional. Your patient records must document that you coordinate services with the prescribing healthcare professional.

PC.4

The patient care provider must document in the patient's record the patient's goals, progress toward meeting their goals and expected outcomes related to the use of the items or services provided.

TIP

Patient records must include documentation that specific patient goals and expected outcomes were established at the initial patient assessment. Pre- and post-care surveys, interviews, evaluations, outcome measurements and other methods may be used to measure the patient's progress. This documentation is usually recorded in the clinical notes section of the record.

PC.5

Your business must have written policies and procedures that support the right of the patient to participate in decisions about the scope of treatment, including the establishment of goals and expected outcomes.

TIP

You should also document the patient's participation in these decisions in the patient record.

PC.5.1

You must demonstrate how you inform patients about their rights, including but not limited to:

1. Confidentiality

2. After hours contact and care

3. Timely complaint resolution

TIP

Patient records must indicate that the patient has been informed of their rights. There are many ways to do this, including requiring the patient's signature on a copy of the patient's rights. You can also provide them with a brochure, flyer or information sheet that clearly states patient's rights.

PC.6

Your policies and procedures must describe how you provide information related to the setup, features, routine use, troubleshooting, cleaning, infection control practices and maintenance of all equipment and items provided.

PC.6.1

You must provide the patient and/or caregiver with instructions for the proper care and use of the device. This patient education must be documented and must include:

1. The purpose and function of the item

2. Infection control, including the proper care, cleaning and use of the item

3. Disclosure of the potential risks, benefits and precautions

4. How to report any failure or malfunction

5. When and to whom to report changes in physical condition when it relates to the device

TIP

You can provide this information to your patients in a variety of ways. You can give your patients care and use information sheets, manufacturer's guidelines or verbal instructions. An information sheet would include information on how to report any failures or malfunctions of the device and when and to whom to report changes in their physical condition. No matter which method you decide to use, you must document in the patient's record that these instructions were given.

PC.6.2

You must provide the patient and/ or caregiver with instructions on how to inspect their skin for pressure areas, redness, irritation, skin breakdown, pain or edema. This patient education must be documented in the patient's record.

TIP

Patient records must indicate that the patient and/or caregiver have been educated on how to inspect their skin. Care and use information sheets or verbal instructions may be used.

PC.6.3

You must provide the necessary supplies (e.g., adhesives, solvents, lubricants) to attach, maintain and clean provided items, as applicable, and information about how to obtain replacement supplies.

TIP

Patient records must reflect that the patient was provided an appropriate amount of supplies necessary for the proper use and maintenance of the devices and/or items.

PC.6.4

For supplies provided by mail order delivery, your policies and procedures must require documentation in the patient's record that the patient and/or caregiver(s) has received training and written instructions on the use and care of the supplies.

PC.6.5

You must make sure that the patient and/ or caregiver can use all provided equipment safely and effectively in the settings the items will be used.

TIP

You must have documentation that patients and/ or caregivers have been provided with proper instructions for the safe use of all equipment. The patient record should document that this education was provided.

PC.6.6

You must adapt the training and instruction materials to the needs, abilities, learning preferences and language of the patient and/ or caregiver.

TIP

All training and instruction materials must be in a format and manner that is understandable to all patients, including those who have communication barriers such as language differences. This also includes patients with vision, speech, hearing and cognitive impairments. If a significant portion of your patient population speaks a language other than English, you should provide them with training and instruction materials in their native language.

PC.6.7

The training and instructions provided to the patient and/or caregiver must be equal to the risks, complexity and manufacturer's instructions and/or specifications for the item provided.

TIP

Patient records and instructions must reflect that the patient has been given appropriate training on any provided equipment based on the item's associated risks and the appropriate manufacturer's instructions.

PC.6.8

If you provide respiratory equipment, supplies and/or services, you must provide patient and caregiver training in accordance with the current version of the *American Association for Respiratory Care Practice Guidelines*.

TIP

Patient records must document that patient and caregiver training was provided in accordance with the *American Association for Respiratory Care Practice Guidelines* rcjournal.com.

PC.6.9

If you provide respiratory equipment, supplies and/or services you must provide respiratory services 24 hours a day, 7 days a week as needed by the patient.

TIP

You must have staff on-call for times when the office is closed and this information must be provided to your patients.

PC.7

You must have a written policy that describes how your staff will respond to evidence that a patient may be at risk from real or perceived abuse, neglect or exploitation. Your policy must address the process by which the proper authorities are notified and how you determine when to contact the appropriate community resources.

TIP

You must have a policy that addresses potential patient-at-risk issues. Your policy should include who is responsible for reporting concerns, what parties should be contacted and a listing of community resources available to your staff. An incident report should be used to document any specific situation in which real or perceived abuse, neglect or exploitation is noted. You may wish to seek legal counsel to develop this policy.

PC.8

You must have a written contingency plan that describes your response to emergencies and disasters affecting patient care in the home setting, as appropriate to the scope of services you provide. This plan must be assessed annually and the assessment must be documented.

TIP

You must document that you perform an annual review of your emergency and disaster contingency plan. You must also document any corrective actions that you have taken for any vulnerabilities identified. Corrective actions can be documented in staff meeting notes or as an addendum to the policy and procedure manual. Provide training on your emergency plan to your staff and document this training with sign in sheets and an agenda for the session.

PC.9

CAP

You must have a written contingency plan that describes your response to after-hours and emergency maintenance needs and must provide your patients with information and telephone numbers for customer service, regular business hours, after-hours access, item repair and emergency coverage. This information should be based in part on the criticality of services provided to assure the continuation of critical care throughout an emergency.

TIP

This can be done by providing patients with business cards that include after-hours numbers and company website information or a brochure that includes contact numbers for all types of identified emergencies. Staff should be trained on the contingency plan and this training should be documented.

PC.9.1

You must annually conduct and document drills to determine the effectiveness and efficiency of your plans to provide emergency maintenance, backup or replacement of equipment, devices and/or items through a disaster or emergency.

TIP

You must conduct and document disaster and emergency drills by using a sign in sheet, staff participation list and/ or drill program agenda.

Product Safety (PS)

The Product Safety Standards require that your organization affirm the safety and appropriateness of the DMEPOS items and services that you provide to patients. Your business is required to establish a product safety program to promote the safe use of items and to minimize the safety risks, infections and hazards for both your staff and patients. The Standards require you to have documented policies and procedures in place that address patient safety, equipment and device failures, repairs, product recalls and infection control. Effective product safety programs must adhere to four principles:

1. Product Safety

Your business must be able to document that all patient items being dispensed are properly labeled, if applicable and are genuine and not counterfeit or adulterated.

2. Patient Safety

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

3. Equipment and Device Failures, Repairs, Recalls and Preventative Maintenance

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

4. Infection Control

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

PS.1

You must have written policies and procedures that address the following:

1. Patient safety

2. Equipment and device failures

3. Repairs

4. Product recalls

5. Infection control

TIP

These policies are intended to promote the safe use of equipment and items as well as minimize the safety risks, infections and hazards for both staff and patients.

PS.2

You may only provide items that meet applicable Food and Drug Administration (FDA) regulations.

TIP

You may maintain a log to help you identify the equipment and supplies that are subject to Food and Drug Administration (FDA) regulations fda.gov.

PS.2.1

Before you distribute or deliver items to a patient, you must verify and document that the items are not altered, counterfeit, suspected of being counterfeit, misbranded, are appropriately labeled for their intended use or distribution and have not been obtained by fraud or deceit.

TIP

You can inspect and document that when received, all items are in their original manufacturer packaging and contain original packing slips. Verify that wholesalers and billing companies are not included on the OIG exclusion entity list.

PS.2.2

In order to document the verification of the authenticity of items purchased for use in providing patient care, you must obtain from the manufacturer copies of the features, warranties and instructions for each type of non-custom fabricated item or equipment.

TIP

You must document that all purchased items are genuine. This documentation must include copies of the features, warranties and instructions for every type of equipment or item obtained from a manufacturer that is provided to your patients. This information is often found in instruction guides or care and use materials. These copies must be maintained and easily accessible.

PS.3

You must have written policies and procedures that promote the safe use of equipment and items and minimize safety risks, infection and hazards for your staff and patients.

TIP

You must implement policies and procedures that promote facility safety that include the promotion and use of universal precautions, the minimizing of safety risks and hazards and cleaning the facility. You must document all periodic safety management training programs that you provide for your staff.

PS.3.1

You must have a record of all equipment used in the provision of patient care, as well as documentation of the appropriate maintenance of the equipment.

TIP

An equipment management program should include a comprehensive listing of all equipment, tools, analytical and measuring devices as well as other DME type equipment and their maintenance. Examples include, but are not limited to, CAD/CAM calibrations, torque wrenches, CPM machines, CPAP and oxygen equipment. Use the Equipment Maintenance Log in the online Resource Kit to document this information.

PS.4

You must have a written policy for identifying and monitoring equipment and item failures, repairs and recalls and communicating these to your staff.

TIP

Documentation of the policy may include logs to identify equipment and items that are defective, require repair or maintenance or have been recalled. Any such failures, repairs or recalls must be communicated to your staff.

PS.5

You must have a policy in place for the investigation and documentation of adverse events, including incidents, injuries and/or infections that may have been caused by the item you provided.

If an adverse event results in the patient's hospitalization or death, you must initiate an investigation within 24 hours of becoming aware of the situation. For other adverse events, you must investigate within 72 hours of becoming aware of the incident, injury or infection.

Your investigation must include all necessary information, pertinent conclusions and whether changes in processes are needed. You must consider any possible links between the items and services provided and the adverse event.

PS.6

You must implement a policy to make sure that the patient and/or caregiver can use all of the equipment and items that you provide safely and effectively in the settings the item will be used.

TIP

Patient and/or caregiver training on the safe and effective use of all provided equipment and items is essential. The patient's record must reflect the patient or caregiver's acknowledgement that they received equipment training.

PS.6.1

The items and equipment you provide may have specific physical requirements. You must determine and document how each of those requirements is met in the environment in which that item or equipment will be used.

TIP

Your home assessment process must ensure that all of the physical requirements for each type of item or equipment provided are met. For example, what type of power cord is required? Is the electrical outlet appropriate for the use of that power cord? You must follow manufacturer guidelines for all equipment provided, including the environment in which the equipment is to be used. You must have a record of the physical features of the environment in which the equipment is to be used.

PS.6.1.1

You must have written policies and procedures to deal with inconsistencies between the observed physical environment in which the item and/or equipment will be used and the physical requirements of the items.

TIP

If you observe that the physical environment is different from the requirements for the item prescribed, you must have a contingency plan to contact the healthcare prescriber to discuss the needed items. For example, is an alternative item available that would be more consistent with the actual physical environment?

PS.7

When providing equipment to patients, you must provide your contact information and options for rental or purchase of the equipment.

TIP

You must provide your patients with contact telephone numbers that allow them to reach the appropriate person. If applicable, you must have a written rental policy and patient records must reflect that equipment rental or purchase options have been explained to the patient. Include a copy of the Medicare capped rental form.

PS.8

You must store the items and supplies for patient use in accordance with appropriate infection control procedures and ensure that cross-contamination does not occur.

TIP

You must have procedures that address the storage of patient equipment and supplies. Training must be provided to all staff and documented with meeting minutes or other records.

PS.8.1

A consistent system must be established and maintained to assure the proper handling of equipment, both new and used, regardless of how or where those items come into your possession. You must document how you segregate clean and dirty equipment. You must also document each item's progress through your system of dispensing and recovery of items.

TIP

You must document your clean and dirty equipment segregation process. This includes the proper handling of equipment that addresses cross-contamination and infection control procedures. Training must be provided to all staff and documented with meeting minutes or other records.

PS.8.2

All of the equipment and supplies you provide to patients must be maintained in a state of patient-readiness in accordance with manufacturer's guidelines.

TIP

Consult manufacturer's guidelines to ensure accuracy for maintenance and patient-readiness.

PS.9

You must deliver and setup all equipment and supplies in a timely manner. The timeframe should be agreed upon by the patient/caregiver, the healthcare prescriber and you. You may coordinate the setup of the equipment and supplies by another entity; however, they must be a DMEPOS accredited supplier.

TIP

You must establish policies for a home delivery and setup process that ensures that patients receive equipment and supplies in a timely manner. If you use outside services, you must have contracts, proof of sub-contractor accreditation and appropriate Business Associate Agreements. Additionally, policy training must be provided to all staff and documented with meeting minutes or other records.

PS.9.1

You must have policies and procedures to document the requirements for setup, delivery and pickup of equipment.

TIP

Training must be provided to all staff and documented with meeting minutes or other records. If you use outside services, you must have contracts, proof of sub-contractor accreditation and appropriate Business Associate Agreements.

PS.9.2

Prior to final delivery of the item, you must:

1. Document that the item meets the specifications of the current prescription

2. Check the item for structural safety

3. Ensure that manufacturer guidelines have been followed

TIP

This can be documented in patient records, delivery receipts, warranties, tracking and equipment logs/tagging systems and/or other documentation.

PS.9.3

If you provide complex rehabilitative wheelchairs and assistive technology, you must implement procedures for assembly and setup of equipment as well as have a process to verify that the final device meets the specifications of the original device recommendation approved by the healthcare prescriber.

PS.9.4

If patients are evaluated in your facility, you must have an appropriate designated area and equipment for assembly, modification, adjustment and repair of provided equipment and/or items in your facility or in a facility in close and easily accessible proximity.

PS.9.5

If you provide complex rehabilitative wheelchairs and assistive technology, you must provide the patient with equipment for trial and simulation, when applicable.

TIP

The patient record and/or delivery logs must reflect that trial equipment was provided.

PS.10

You must track and document on a report the status of all equipment and supplies provided to patients. You must know at all times the condition and location of all equipment in the event that a recall or other similar events were to occur.

The status report must accurately reflect critical information including:

1. Contact and emergency contact information for all persons to whom equipment or items have been sold or rented

2. The manufacturer's model, serial number and/or lot number for each piece of equipment

TIP

You should maintain a database or log that contains contact information for all persons to whom equipment or items have been sold or rented and the manufacturer's model and serial number for each piece of equipment. Use the Equipment Maintenance Log in the online Resource Kit to document this information.

PS.11

Your policies and procedures must establish a mechanism to minimize cross-contamination and infection during the setup, delivery and pickup process.

PS.11.1

You must have written policies and procedures for cleaning, sanitizing, function testing, maintaining and preparing items or equipment for reuse. The area in which the equipment is stored in a patient-ready status must be clearly identified as clean.

TIP

You must have policies and procedures in place to ensure that any equipment you intend to make available for patients to reuse is cleaned, functioning properly, clearly labeled and stored in a clearly identified clean area. Policies should include universal precautions and cross-contamination procedures.

PS.11.2

You must have written policies and procedures that provide for the cleaning, disinfection and/or proper disposal of returned items or equipment.

TIP

You must have policies and procedures in place to ensure that returned items and equipment are cleaned, disinfected and clearly labeled. Policies should include universal precautions and cross-contamination procedures.

PS.12

You must implement and document a policy for identifying, monitoring and reporting repair and preventive maintenance for equipment and supplies provided to patients in accordance with manufacturer's specifications.

TIP

This might include an equipment maintenance log that tracks preventive maintenance and repairs and an inventory of manufacturer instruction manuals/specifications. Use the Equipment Maintenance Log in the online Resource Kit.

PS.13

You must provide or arrange for loaner equipment similar to the original equipment during any repair period.

TIP

You must have the inventory on hand or be able to obtain the equipment from another source. Your procedures should include a list of other equipment sources in the event that you do not have the inventory available.

PS.13.1

You must provide all supplies that are necessary to operate the equipment and perform any necessary adjustments

Patient Records (PR)

The Patient Records Standards contain specific requirements on the centralization, accessibility and protection of patient records, as well as keeping Protected Health Information (PHI) secure and confidential. Federal HIPAA regulations apply to all facilities providing DMEPOS services. Your business should establish documented policies and procedures that address the creation and maintenance of patient records. An effective patient record program must adhere to three principles:

1. Secure and Confidential Patient Records

Your business must maintain a secure patient record system that allows prompt retrieval. Except as required by law, patient records must be treated in a strictly confidential manner.

2. Back-up Patient Records

Your business is required to take appropriate measures to backup electronic patient data.

3. Uniform Documentation

Each patient record should consistently include a patient evaluation/assessment, the diagnosis being treated and appropriate comorbidities, pretreatment photographic documentation (if applicable), patient education, the referring physician or appropriately licensed healthcare prescriber's order and the treatment plan.

PR.1

You must have written policies and procedures that address the creation, confidentiality, security and maintenance of patient records.

PR.2

You must have a secure patient record system that allows prompt retrieval of information.

TIP

You must have a system in place that allows you quick access to patient information. This system may be paper or electronic and it must be secure.

PR.2.1

Your patient records must include federal, state, local and applicable third party payer required documentation.

TIP

Patient records should include, but are not limited to, certificates of medical necessity (CMNs), prescriptions, written orders, delivery receipts, payment authorizations, physician communications, progress notes and any other required documentation.

PR.3

Your patient records must be protected from risks. You must take appropriate measures to maintain backups of patient data.

TIP

You must have policies protecting your patient records from all risks such as theft, fire and/or natural disasters. Your procedures must include how you successfully and efficiently back up your patient records and how you would recover those records in the event of a disaster or theft.

PR.4

Except as required by law, any records that contain a patient's clinical, technical, personal and/or financial information must be treated in a confidential manner.

TIP

You must implement procedures to ensure that all patient information is protected.

PR.5

Non-clinical patient information, such as third party payer and financial information, must be maintained according to generally accepted business and accounting principles.

TIP

You must follow generally accepted business practices and accounting principles in regard to maintaining patient financial information; this includes patient records, accounts receivable (EOB, statements, cash postings, adjustments, billing records), accounts payable and other financial records. You must be knowledgeable of the generally accepted business practices and accounting principles that apply to your business.

PR.6

You must have a written policy that your patient records include the following:

1. Written, pictorial or documented oral instructions related to the use, maintenance, cleaning, infection control practices for and potential hazards of equipment and/or items

2. Verification that the equipment, items and services were received

3. The make and model number of any non-custom equipment and/or items provided

TIP

At a minimum, patient records must include documentation that the patient received:

- The equipment, item(s) and/or service(s)
- The appropriate instructions on the use of equipment
- Information about the manufacturer's guidelines or any other appropriate information for the maintenance of the item
- Education on how to properly clean the item
- Information on infection control issues and potential hazards

You must also document the make and model number of any non-custom items and equipment provided to the patient in your equipment log or similar tracking system.

PR.6.1

Your patient records must include:

1. Patient evaluation/assessment that contains diagnosis, prescription or valid order, relevant patient history and medical necessity

2. Pre-treatment photographic documentation as appropriate for the item

3. Patient education

4. The name and title of the patient care provider, their findings, recommendations, treatment plan and follow-up schedule

TIP

All patient records must be consistent. If you use photographic documentation, you will have a policy that describes how, when and under what circumstances photographic documentation is used.

PR.6.1.1

Your patient records must document the patient's need for and use of the orthosis, prosthesis and/or pedorthic device, including, but not limited to:

1. Pertinent medical history

2. Allergies to materials

3. Skin condition

4. Diagnosis

5. Previous use of orthoses, prostheses and/or pedorthic devices

6. Results of diagnostic evaluations

7. Patient goals and expectations

TIP

All patient records must be consistent. As applicable, each patient record must include the reason the patient needs an orthosis, prosthesis or pedorthic device and how it will be used.

The records should include:

- The patient's skin condition
- The diagnosis from the prescribing healthcare provider
- Any history of previous use of an orthosis, prosthesis or pedorthic device
- Results of your diagnostic evaluations
- The patient's goals and expectations

PR.6.2

If you are providing complex rehabilitative and assistive technology, all of the information obtained during the assessment must be maintained in the patient's record.

PR.7

You must have technical records that include a detailed description relevant to any orthosis, prosthesis and/or pedorthic device provided.

TIP

Documentation of this standard may include a detailed description of the device, materials, components, measurement forms, order forms, packing slips and delivery receipts.

PR.7.1

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

Performance Management and Improvement (PM):

The Performance Management Standards allow an organization to track and trend the strengths and weaknesses of your business and patient care operations. Business' providing patient care must have a program in place to monitor, evaluate and improve the quality of patient care. Effective performance management programs require the following:

1. Organizational Support

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

2. Data Collection

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

3. Data Analysis

After collecting information, the next step involves making sense of the raw data. Since you used guidelines and goals to decide what to monitor in your data collection, you should use those same guidelines and goals to compare where you are now to where you want to be in the future. When you look at data collected over a period of time—monthly, quarterly or annually, depending on your facility's size—you are better able to analyze trends and identify organizational changes that need to be made. A performance management system will help you focus on long-term vision instead of a short-term crisis.

PM.1

You must have a written performance management program that does the following:

1. Monitors and evaluates the quality and appropriateness of patient care

2. Seeks opportunities to improve services

3. Resolves identified problems

The governing body of your business must support the performance management program by documenting, requiring and participating in the program.

TIP

Your performance management program must define these elements and include the appropriate response times for corrective action. The effectiveness of the action you take must be assessed, reported and communicated through the proper channels in your business

PM.1.1

You must document how you seek input from employees, patients and referral sources when assessing the quality of your operations and services. This should be an on-going activity but must be done at least annually.

TIP

You may do this through staff meetings, staff interviews, patient surveys or interviews, meetings with your referral sources or other means. Any method you use to seek input must be documented in a file for this purpose.

PM.2

Your performance management program must include the use of a patient satisfaction survey.

TIP

If you do not have a patient satisfaction survey of your own, one is available in the Resource Kit on the ABC website. It is recommended that your patient satisfaction survey be conducted within two months after providing a new or replacement device. Your survey should be designed to gather many types of information, which are detailed in Standards PM.3, PM.4 and PM.5 and included in the Resource Kit sample.

PM.2.1

The results of the patient satisfaction survey must be documented and evaluated, at least annually.

TIP

You must use the results of the patient satisfaction surveys to improve your business performance and the quality of care and services that you provide. Your performance management program must document that you use surveys and include how you evaluate and incorporate the survey results.

PM.3

You must collect, monitor and measure patient satisfaction with the items and services provided.

TIP

You must solicit feedback from your patients on their satisfaction with the items and services you provide. Once you have collected this data, you need to measure the results in order to identify those areas that may need improvement.

PM.4

You must collect, monitor and measure the timeliness of response to patient questions, problems and concerns. For any formal complaints, you must provide the patient or caregiver with written notification within 14 days of the results of the investigation of their complaint.

TIP

This could be documented in your patient complaint log and/or patient satisfaction survey.

PM.5

You must collect, monitor and measure the impact of your business operations on the adequacy of patient access to equipment, items, services and information.

TIP

This measurement of your business practices can be accomplished through patient surveys.

PM.6

You must collect and measure data to evaluate the frequency of billing and coding errors.

TIP

You must have a policy that measures the frequency of billing and coding errors. You could use documents such as patient records, billing logs and/or rejected claims reports to collect this data. Use the Billing and Coding Error Report in the online Resource Kit to record your findings.

PM.7

You must collect and measure data to monitor any adverse events to patients due to inadequate or malfunctioning equipment, items or services once you become aware of such adverse events.

TIP

Once you are aware of deficient or broken equipment, you must provide documentation (patient records, patient incident reporting policy and procedures) that you are identifying and monitoring the impact to your patients. Examples of adverse events are injuries, accidents, signs and symptoms of infection or hospitalizations.

PM.8

You must collect and evaluate data that allows you to identify and monitor adverse or beneficial trends associated with the quality of care for your patients.

TIP

Your performance management plan must include measures of the outcomes of consumer services, billing practices and adverse events. This information can be gathered through follow-ups, patient record reviews, outcome studies and/or patient satisfaction surveys.

PM.9

Action must be taken when you identify an opportunity to improve the quality of care. The effectiveness of the action taken must be evaluated through continued monitoring. Your recommendations, actions and conclusions must be documented.

TIP

Potential improvements could be identified through patient satisfaction survey assessments, staff meetings, interviews with patients, referral sources or other means. You must document both the action taken and the monitoring of its effectiveness.

PM.10

You must perform a written review of your performance management program at least annually. You must document any changes to your performance management processes.

TIP

Document your review with notes, a report or meeting minutes. If your review identifies needed changes, you must also update the appropriate performance management program manuals or files.

Facility Safety and Management (FS)

ABC's Facility Safety and Management Standards are designed to ensure the location and environment of patient care is appropriate for the items and services provided. These Standards address three critical categories: facility safety, safety management and environmental safety.

1. Facility Safety

The Standards require your facility to appropriately accommodate patients and provide an office space to adequately fulfill your patient care and business activities. Further, the Standards require that your facility comply with all appropriate health, fire and occupancy codes, including appropriate requirements of the Americans with Disabilities Act (ADA).

2. Safety Management

Safety management requires that accredited facilities implement processes designed to maintain and improve the quality of the patient care environment. You are expected to establish a safety management program commensurate with the scope and complexity of the items and services provided in order to assure a continued safe physical location and environment. The Standards also require that a Safety Officer be appointed to oversee the program, carry out inspections and perform an evaluation of those inspections. In addition, you must develop specific plans to respond to potential emergency situations, including fires and disasters common to your geographical location. Personnel must be trained to carry out duties and responsibilities specified in the contingency plans. Finally, you must have a plan to facilitate the continuation of patient care services in the event of a

disaster (including power outages and technical malfunctions) affecting the facility, the region or a larger area.

3. Environmental Safety

Facilities should implement policies and procedures that minimize patient and staff exposure to health and environmental risks.

The Standards require adoption of appropriate infection control procedures, including the use of universal precautions and other aspects of OSHA's blood borne pathogens regulations.

In addition, you are required to administer an equipment management program that is designed to assure proper performance of your equipment and is supported by appropriate preventive maintenance programs.

FS.1

You must have a written safety management program designed to:

- **Provide a physical environment free of hazards**
- **Manage staff activities to reduce the risk of injuries**

Your written safety management program must include, but is not limited to:

- **Information concerning specific procedures to be followed by staff**
- **Provisions for the management of patients**
- **Provisions for compliance with relevant OSHA standards**
- **Access to Safety Data Sheets (SDS) for any on-site chemicals**
- **Evaluation of the results of the safety inspection**

TIP

You must have written policies and procedures that reduce the risk of injury to employees and patients. The policies must include specific procedures to be followed by staff and specific requirements for the management of patients. You may find the OSHA website (link) helpful in developing your safety management program.

FS.1.1

Your safety management program must describe and document annual safety inspections of your facility and operations.

TIP

You must prove that you conduct annual safety inspections of the facility and document any corrective actions taken as a result of the inspection.

FS.2

The interior and exterior of your buildings and grounds must be appropriate to the nature of the services provided and to the patient population served. In compliance with applicable laws, your facility must be designed to accommodate the needs of the physically challenged, including but not limited to:

1. Appropriate exterior handicap access; including the path from the parking lot to the facility

2. Ramps and/or elevators that comply with federal, state and local requirements for handicap access

3. Interior areas for patient use including restrooms that are wheelchair accessible as well as designed and equipped to meet the needs of disabled persons

4. A patient waiting/reception area, as applicable

5. Compliance with state and local health codes and occupancy classifications for your location

6. Ensuring there is adequate space to manage the business

FS.2.1

Each of your patient care locations must provide specific dedicated private treatment areas that are properly equipped for patient evaluation and care.

TIP

A private treatment area is one that provides visual and auditory privacy.

FS.3

You must annually conduct and document a safety management orientation for all staff that addresses:

1. General safety management issues

2. Safety plans

3. Emergency preparedness

4. Emergency plans

5. Special hazards related to assigned duties

6. Safety practices

7. Changes in your safety management program

TIP

The annual training should include any changes in the safety management program since the last training. You should have training guides or employee handbooks to use in conducting safety management orientations for employees. You must document this staff training with sign in sheets, program agendas or course certificates.

FS.3.1

If you utilize specialized emergency equipment such as an Automatic External Defibrillator (AED), your staff must be trained in the proper use of that equipment. You must document this training.

TIP

You must document this staff training with sign in sheets, program agendas or course certificates.

FS.3.2

You must have a written emergency evacuation plan that addresses appropriate staff response to fires or other emergencies. Based upon occupancy classification, the program includes provisions for appropriate fire alarm and fire suppression systems.

TIP

Your emergency evacuation plan should include an evacuation route as well as the duties of specific staff in the event of an emergency. These duties might cover who is responsible for calling fire and other emergency personnel and who is responsible for checking that all patients have safely evacuated the premises. Your drill also needs to include testing of the fire suppression and/or alarm systems, if applicable.

FS.3.2.1

You must conduct an annual emergency evacuation drill in accordance with the evacuation plan. The drill(s) must be done for all staff on all shifts.

FS.3.2.2

You must write an evaluation of the effectiveness of the emergency evacuation plan and annual drill. Results of the evaluation must be included in your performance management plan.

TIP

Your evaluation might include items such as timeliness of the evacuation, confirmation that all staff and patients exited the premises, all staff gathered at the predetermined meeting location and that the all clear procedures for returning to the facility were followed. The written evaluation should be kept in your emergency preparedness files. Use the Fire Emergency Drill Documentation form in the online Resource Kit to document your drill.

FS.3.3

You must have a written disaster preparedness program designed to manage the consequences of natural disasters or other events that threaten your business's structural integrity, infrastructure, including electronic records and/or ability to serve your patients.

TIP

Fires are not the only emergency for which you must be prepared. Other events such as natural disasters (e.g., flood, tornado, hurricane, ice or windstorms) or widespread and lengthy power outages could also disrupt your ability to serve your patients. You must provide documentation that you have a plan to manage the consequences of a disaster or interruption. This should include a process for data backup and/or restoration in order to continue operations in the event of a disaster or contracts and/or agreements with other companies to assist with patients

FS.4

You must have policies and procedures that prohibit the use of smoking materials within your facility.

TIP

This policy should be included in staff orientation and training as well as posted in a location visible to all staff and patients.

FS.5

You must have policies and procedures for the use of universal precautions to minimize the risk of transmission of infection when caring for patients. As appropriate, these policies include procedures to comply with:

- **Occupational Safety and Health Administration (OSHA) blood borne pathogen regulations**
- **Centers for Disease Control (CDC) guidelines**
- **World Health Organization (WHO) hand hygiene protocols**

TIP

A copy of this policy should be placed in your policy manual and be available to all staff. You must document that staff has been trained on these policies and procedures with sign in sheets, program agendas or course certificates.

FS.5.1

You must maintain suitable cleanliness of your facility and equipment used in patient care. You must have appropriate hazardous waste disposal procedures in accordance with the services you offer.

TIP

Staff training should include what is appropriate cleaning of the facility and equipment, even if you use an outside cleaning service, and a process to respond to pest infestation. You must have a process to ensure that your staff is trained and consistently follows appropriate hazardous waste disposal procedures. Hazardous waste disposal monitoring should be part of your performance management plan.

Claims and Billing Compliance (CB)

The Claims and Billing Compliance Standards are designed to support your organization's compliance with billing guidelines set by the Centers for Medicare and Medicaid Services and the Office of the Inspector General (OIG). Depending upon the size of your business and scope of services provided, your business is expected to develop a compliance program that encompasses the spirit of the OIG's Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry.

The Standards parallel the five critical elements presented in the OIG's Guidance:

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

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

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

You must assure that a designated person oversees a consistently administered program.

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

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

4. Auditing and monitoring mechanisms are implemented to ensure consistent compliance.
An ongoing monitoring mechanism not only ensures that the compliance program is followed; it will also help identify those elements of the program that may need improvement.
5. Written employment criteria and disciplinary guidelines are implemented.
You must demonstrate that you carefully screen potential employees that will be responsible for billing practices and that you administer reasonable disciplinary measures for inappropriate billing activities. These Standards are designed to reflect the elements of the OIG's compliance guidance and require facilities to establish procedures to minimize the occurrence of fraud and abuse and to protect the business from its effects.
In addition to claims development and billing compliance, your business must also prevent identity theft by having systems to verify patient identity, report suspicious activity and mitigate the effect of a breach.

CB.1

You must administer a claims and billing compliance program with written policies, procedures and standards that describe your compliance with federal and state policies.

TIP

Many national associations and agencies provide education programs in claims and billing compliance.

CB.2

You must designate a qualified and trained individual to be responsible for maintaining the claims and billing compliance program.

TIP

You must indicate in your policy which specific staff member is responsible for claims and billing and document their qualifications and training with a job description, meeting minutes, attendance logs, course certificates or in-service agendas.

CB.3

You must provide claims development and billing education for all staff involved with or responsible for, claims and billing. You must have documentation that you have implemented practices to prevent and control fraud, waste and abuse.

TIP

Your designated staff members must be educated and trained in claims development and billing particular to job duties and responsibilities related to the compliance program. You must document this education with meeting minutes, attendance logs, course certificates or in-service agendas. Use the Billing Education Documentation form in the online Resource Kit to document this information.

CB.4

You must establish ongoing file auditing and monitoring policies and procedures for clinical and financial records to ensure consistent compliance with all applicable federal, state and private payer healthcare plans.

CB.4.1

You must annually write an evaluation of the results of the file auditing and monitoring compliance program and act on any necessary changes.

TIP

You must have meeting minutes, patient records and/or other documentation to reflect ongoing monitoring and auditing of the claims and billing compliance program. You must have documentation of audit reports and if necessary, the corrective actions you have taken. Use the Billing and Coding Error Report in the online Resource Kit to record your findings.

CB.4.2

You must have written policies and procedures that ensure investigations of suspected or actual noncompliance are handled appropriately and any necessary corrective action is taken.

TIP

You must have a plan that addresses how you conduct internal investigations of suspected noncompliance.

This plan should include:

- A time limit for closing an investigation of suspected claims and billing noncompliance
- Options for corrective action after determining that an act of noncompliance has occurred, including disciplinary action, a review of existing policies and procedures and employee training
- An indication of when it would be necessary to conduct a noncompliance investigation by an outside, independent investigator
- An indication of how and when to refer an act of noncompliance to CMS or law enforcement authorities
- An indication of when to report the suspected noncompliance to ABC as required by the Code of Professional Responsibility

RESOURCES

As part of our commitment to value, we offer you the following tools to help you comply with both ABC and Medicare Standards. These easy-to-use resources will help guide you through the accreditation process. All of these resources are available on the ABC website, ABCop.org.

Relevant Standards Tool—This quick and easy online tool helps you determine exactly which Standards apply to the devices and items you provide your patients. Simply choose the specific product categories you provide and the program generates a custom list of the Standards that apply to those product categories. This list can then be used to help you focus on these areas for compliance as you prepare for your onsite survey.

Compliance Kit—The Compliance Kit is available exclusively to accredited facilities as well facilities that have submitted applications to ABC. The Compliance Kit comprises of a Compliance Calendar, monthly compliance emails, as well as our online Resource Pack, which is full of templates and guidance to help you meet compliance. To access the online portion of the Kit, sign into your facility's MY ABC account.

Annual Accreditation Task Planner—This checklist provides an overview of all of the standards that require annual or routine tasks required to maintain your accreditation. This can help your facility organize and manage your compliance activities year-round!

Webinar Library—These online seminars were created with facilities in mind and are designed to provide more details on a variety topics from preparing for your accreditation to patient care documentation.

Top 10 Overlooked Items & What to Expect during Your ABC Onsite Survey—An informative review of the top 10 items often overlooked by business owners as they prepare for their survey. ABC surveyors find that missing these key elements of the survey could mean the difference between passing and failing. Also included is information on everything you can expect during the survey, from when your surveyor arrives at your facility to what they'll be asking to see while there and when you'll receive your results.

Online FAQs—Detailed information on the most common questions applicants ask regarding every aspect of the accreditation process.

Additional Resources—Other value added resources to help you with your business include:

- 15% discount on property and liability insurance premiums through Cailor Fleming
- Customizable brochure for marketing your accreditation value to patients, referral sources and insurers.
- Discount on certificate framing.

Medicare Resources

To assist you with your Medicare related questions, we have compiled the most commonly referenced information about Medicare as it pertains to your facility's accreditation. You will find the direct links to these resources on the ABC website on the Patient Care Accreditation Getting Started page under the Additional Resources section.

Additional Information

HITECH

HITECH is the law passed to encourage the adoption of electronic health records (EHR) by 2016, which includes financial incentives. After 2016, penalties may be levied against suppliers who do not use EHRs. HITECH did have an effect on HIPAA by adjusting how facilities must notify patients if it is suspected that their protected health information is compromised, along with a few other subtle changes.

GSA EXCLUDED PARTIES SYSTEMS

The capabilities of searching within CCR/FedReg, ORCA and EPLS have been consolidated to Systems for Award Management (SAM) www.sam.gov.

PATIENT CARE ACCREDITATION PRE-APPLICATION CHECKLIST

Thank you for choosing ABC for your facility accreditation. To help ensure that you are ready for the accreditation process, we have created the following checklist. Please review the following items *before* you submit your application in order to be prepared for the accreditation and onsite survey process.

Don't forget—it's a Medicare requirement that all onsite surveys are unannounced and unscheduled.

This checklist does not replace the need for you to have a thorough understanding of the Patient Care Facility Accreditation Standards.

Eligibility Criteria

Before you apply, make sure your business:

Is located within the United States, one of its territories or possessions or is a Department of Defense medical treatment facility or program

Is a formally organized and legally established business that provides the services and items for which you are applying

- ☐ Is licensed according to applicable state and federal laws and regulations and maintains all current legal authorization, permits and zoning requirements to operate
- ☐ Is operational and has a physical location
- ☐ Applies for ABC accreditation for all patient care locations and all services being provided, regardless of whether Medicare or another third party is billed for these services. (This requirement only extends to those services for which ABC offers accreditation.)
- ☐ Employs the appropriately credentialed staff for all scopes of service being provided
- ☐ Has met the Patient Care Facility Accreditation Standards
- ☐ Has a minimum of 10* complete patient charts
- ☐ Has designated at least one individual to be in charge of accreditation and compliance and that you also have assigned a backup contact
- ☐ Meets all Medicare DMEPOS Quality and Supplier Standards (if applicable) and is compliant with the Americans with Disabilities Act (ADA) and Occupational Safety and Health Administration (OSHA) regulations
- ☐ Must disclose the full listing of ownership (any individuals or parties holding more than 5% of controlling interest) or provide the list of your facility's board of directors or trustees

**If your facility is newly established and has a limited patient care history, we may determine that a minimum of five complete patient charts per patient care provider is acceptable.*

Meeting the Standards

Once you are confident that you have met the eligibility criteria, it's time to prepare your facility for the onsite survey.

This list is organized by standard to help you reference items in the *Patient Care Facility Accreditation Standards* but is ***not*** a complete listing.

Now would be a good time to re-read the Standards and make sure that you are in compliance with all that apply to your practice. This list is intended to highlight some of the areas that tend to be overlooked during preparation for the accreditation process.

Administrative (AD)

The Administrative Standards address the legal status and legitimacy of your business as well as compliance with federal, state and local requirements for operation. The following documents are required for your practice, business or corporation. Your surveyor will physically check that you have each of the following documents. You should have them organized and available for the surveyor to review.

- ☐ Articles of Incorporation or other documents establishing legal formation of the company.–AD.1
- ☐ Current bylaws, if your organization is incorporated.–AD.1
- ☐ Your Financial Policy (operating budgets, revenue, expense tracking and other documents that show how you manage the financial aspects of your business.)–AD.8

Make sure you also:

- ☐ Post any business licenses, certificates and operating permits in your reception area or another area that is accessible to the public.–AD1.2.1
- ☐ Designate specific individual(s) who are authorized to perform in a leadership capacity and who are responsible and accountable to oversee the activities and operations of your business.–AD.2
- ☐ Adopt a mission statement.–AD.3
- ☐ Verify that no staff members, including contractors, current employees or new hires are on the OIG List of Excluded Individuals and Entities (LEIE). We recommend that this be done on an annual basis.–AD.5.1

Human Resources (HR)

The Human Resource Standards address your employees, including patient care providers and support staff. For each of your staff members, your surveyor will need to verify that you:

- ☐ Established a written Policies and Procedures Manual that includes detailed job descriptions.–HR.1
- ☐ Maintain complete and current employee personnel records, including items such as verification of credentials and continuing education.–HR.2, HR.4
- ☐ Conduct and document a periodic review of all staff at least annually.–HR.7
- ☐ Have privileging documents for each non-credentialed or licensed individual (these should be maintained in each employee's personnel file.)–HR.6., HR.6.1

Make sure each of your staff members:

- ☐ Have received documented orientation and training so that they are familiar with your policies and procedures.–HR.3
- ☐ Can access your facility's Policies and Procedures Manual and any other educational, training and reference materials.–HR.3

Patient Care (PC)

The Patient Care Standards address patient interaction, education and follow-up care. They are designed to ensure that the patient receives appropriate and effective care and that the patient's needs have been met. Your surveyor will be looking at your facility and patient charts to make sure you:

- ☐ Have posted Patient Rights and Responsibilities information in your reception or patient waiting area.–PC.5.1
- ☐ Provide all patients with a time frame for services and delivery of items.–PC.1.3
- ☐ Collect and keep signed and detailed orders from the physician in each patient's record–PC.3
- ☐ Provide specific and detailed follow-up schedules and instructions to the patient. Be sure to note if the patient has not fully complied.–PC.3.3
- ☐ Formulate and document a specific treatment plan per the physician's orders for each patient. If your assessment requires additional consultation with the physician, make sure you document the reason and communication with the physician.–PC.3.4.2
- ☐ Allow each patient to be involved with the establishment of goals and expected outcomes for the items they receive and document these goals and outcomes in the patient's chart.–PC.4, PC.5
- ☐ Inform patients of the availability of after-hours services.–PC.5.1
- ☐ Provide written information to each patient and/or caregiver(s) about the function, care, use, maintenance and precautions of the device, how to report failures and the importance of reporting any changes in their physical condition or the operation of the device(s). Make sure you have documented that you have provided this information in each of your patient's charts.–PC.6, PC.6.1
- ☐ Provide and document education and instructions to each patient and/or caregiver on how to identify and deal with pressure areas, skin breakdown, redness, edema, etc. as well as infection control.–PC.6.2

Your surveyor will also be checking to make sure you have:

- ☐ Created and implemented detailed policies and procedures as it pertains to providing the necessary instruction and information for the patient and/or caregiver to maintain and safely use the specific item(s).–PC.6.1, PC.6.6, PC.6.7

☐ Addressed in your policies and procedures how staff will handle situations and contact proper authorities where there is a patient who may be at risk from real or perceived abuse, neglect or exploitation. Make sure you also provide staff with the proper resources and contacts.–PC.7

☐ Had your staff take part in scheduled emergency drill(s) at least annually (e.g. fire, tornado) and that you have documented how effective the drill(s) were.–PC.9.1

Product Safety (PS)

The Product Safety (PS) Standards address how you ensure the safe use of equipment and minimize the safety risks, infections and hazards for your staff and patients. The surveyor will be checking your facility and patient charts to see if you:

Verify and maintain evidence that the product being delivered is genuine and not counterfeit. Evidence includes original packing slips, warranties, manufacturer copies of features and instructions, etc.–PS.2, PS.2.1, PS.2.2

☐ Educate your staff on how to keep your facility safe for staff members as well as patients. Education should include the safe and proper use of the equipment and items including identifying and minimizing safety concerns like infections and hazards. Make sure you document any safety management meetings so that you have written evidence of the ongoing implementation of your safety programs.–PS.3

☐ Conduct and document thorough checks of the final product before delivery. Ask yourself, "Does the product meet the specifications in the prescription? Does it meet the manufacturer guidelines and description? Is the item structurally sound?"–PS.9.2

☐ Have a mechanism in place that ensures that the facility's equipment is maintained and that any issues are addressed appropriately.–PS.12

Patient Records (PR)

The Patient Records (PR) Standards address the maintenance of patient record information in a secure and organized manner. The surveyor will be checking to ensure that you:

☐ Maintain your patient records in a central and secure area. Ensure that only the proper personnel have access to the file areas or systems (e.g. locking filing cabinet, password protected computer file system).–PR.2

☐ Securely maintain backups of patient records to be used in case of emergency. –PR.3

☐ Document how your staff backs up this information, how you keep it secure and what the protocol is in the event that you need to access the backup.–PR.3

☐ Keep consistent and uniform records in accordance to your facility's policies and procedures regarding the content of your patient records. All patient records should require the same information (e.g. patient history, evaluation and assessment, documentation of patient education, practitioner name and treatment plan, etc.).–PR.6, PR.6.1, PR.6.1.1

Performance Management (PM)

Every business must have an effective performance management plan. An effective plan can help take your facility to the next level. Your surveyor will make sure that you:

- ☐ Have a detailed and documented Performance Management Plan—this plan describes the organization of, scope of and mechanisms for overseeing the monitoring, evaluating and problem solving activities related to your business's operations and clinical care.–PM.1
- ☐ Collect and analyze patient satisfaction surveys–PM.2.1, PM.3
- ☐ Monitor your business for any adverse events, such as accident, infection and injury. If an adverse event occurs, document, research and take any immediate steps to establish a change in your policy and/or procedures.–PM.7
- ☐ Conduct a review, at least annually, of your performance management plan. Ask yourself, "Has this worked for us? Are we improving?" If not, make recommendations and take action to make your program better. Be sure to document your review and actions.–PM.9, PM.10

Facility Safety (FS)

The Facility Safety (FS) Standards address your organization's overall safety compliance–facility safety, safety management and environmental safety. You should:

- ☐ Have a formally documented Facility Safety Program (report of annual safety inspection, corrective actions.)–FS.1
- ☐ Provide patient care in a dedicated treatment area that supports both visual and audible privacy for the patient. While seeing the patient, other patients and staff should not be able to see into the treatment area nor should they be able to hear dialogue between the patient and practitioner.–FS.2.1
- ☐ Conduct periodic safety orientations for all staff. Make sure to write down what topics were covered at each session and include a list of attendees.–FS.3
- ☐ Educate staff on their roles during emergency evacuation procedures (in response to fire or other emergencies) and conduct, at least annually, an evacuation drill. Make sure you document the details of your drill, such as the date, time, attendees, scenario and time it took to meet at the designated meeting space. When reviewing the drill, be sure to think about ways to make the process more effective. If you have changes, make sure you document them.–FS.3.2, FS.3.2.1, FS.3.2.2

- ☐ Have a written contingency plan in the event of any natural disasters or other events that may affect your business. This plan should include a protocol for everything from fires, hurricanes and tornadoes to theft and power outages.–FS.3.3
- ☐ Train employees on taking precautions to minimize the risk of infection.–FS.5
- ☐ Adequately clean facility areas and equipment and properly dispose of any hazardous waste materials.–FS.5.1

Claims and Billing Compliance (CB)

Claims and Billing Compliance Standards address your facility's billing guidelines set forth by CMS and the Office of the Inspector General (OIG). The surveyor will be checking to see that you:

- ☐ Created and implement a compliance program that addresses the critical elements of appropriate reimbursement practices.–CB.1
- ☐ Designate a staff member to be responsible for the program. This person should be able to show that they have received claims and billing specific training.
- ☐ Training verification includes course certificates or an agenda from an in-house program.–CB.2, CB.3
- ☐ Conduct regular audits of your patient charts to ensure that clinical and financial records are complete. If there is any information missing, take corrective action and document when action was taken. If policy changes are made to your compliance program, make sure to document those too. Make sure you can show, in writing, detailed evidence of the review and corrective action.–CB.4, CB.4.1

Other Reminders

Compliance with the Standards is also about your physical location and your access to care. Your surveyor will also be evaluating you on the following areas related to your physical location.

Outside Your Facility

Take a close look at your building entrance—look for the following:

- ☐ Handicapped spaces in your parking lot are clearly indicated.
- ☐ Ramps into your facility are compliant with the Americans with Disabilities Act
- ☐ (ADA) regulations and are in good condition.
- ☐ Days and Hours of Operation are posted and visible from the exterior of the building.

Reception and Patient Waiting Area

In your reception area, make sure that the following documents are posted and can be easily seen by your patients:

- ☐ Medicare Supplier Standards (there are currently 30 Medicare Supplier Standards)
- ☐ HIPAA Policy (and contact information regarding questions/and or complaints)
- ☐ Your Business License
- ☐ Your Sales and Use Tax Permit (when required)
- ☐ Each patient care provider's certification and license (if applicable)
- ☐ Emergency contact numbers
- ☐ First Aid, CPR and other Medical Emergency Instructions
- ☐ Fire Evacuation Maps

Exam Rooms

In each of your exam rooms, your surveyor will inspect the following:

- ☐ Proof that all conversations between you and your patient are private.
- ☐ Exam room windows are covered in order to maintain patient privacy.
- ☐ Other patient charts or x-rays are not left in the exam room.
- ☐ Fire exit instructions are clear, concise and visible in each room.
- ☐ Walkers, rails, parallel bars, etc. are available (also known as supported ambulation devices).
- ☐ Rooms, tables and sinks are clean, neat and cleaned between each patient.
- ☐ There is at least one biohazard disposal bag/bin for potentially contaminated waste.
- ☐ Wall outlets have safety caps in rooms that are used by children.

Thank you for choosing ABC. If you have any questions about this checklist or the Standards, please contact us at 703.836.7114 or accreditation@ABCop.org.

ADDITIONAL RESOURCES JUST FOR YOU

The online Resource Pack is your go to source for sample forms, templates, checklists and articles available for you to review, use and modify to fit your practice's needs. You can access the Resource Pack from your facility's MY ABC account.

Resource Pack Includes

ADMINISTRATIVE

- Annual Facility Review Checklist *UPDATED
- OIG Exclusion Checklist (AD.5.1)
- Patient Acknowledgement Form

HUMAN RESOURCES

- Employee Verification (HR.2, 4.1 and 4.2)
- Instructions for Establishing Privileging Criteria (HR.6 and 6.1) *UPDATED
- Individual Privileging Record Template (HR.6 and 6.1)
- Employee Performance Evaluation Form (HR.7)
- Assessment of Employee Continued Competency (HR.7)

PRODUCT SAFETY

- Equipment Maintenance Log (PS.3.1 and PS.12) *UPDATED

PERFORMANCE MANAGEMENT

- Free Sample Patient Satisfaction Survey (PM.2)
- How to Write and Analyze Customer Satisfaction Surveys (PM.2.1)
- Guide to Patient Satisfaction Trends
- Billing and Coding Error Report (PM.6)

FACILITY SAFETY

- Safety Management Checklist (FS.1.1) *NEW for 2019
- Fire Emergency Drill Documentation (FS.3.2.1 and 3.2.2)
- Disaster Preparedness Resources (FS.3.3) *NEW for 2019

CLAIMS AND BILLING

- Billing Education Documentation (CB.3)
- Patient Chart Audit Form (CB.4 and 4.1)

PATIENT CARE

Patient Care Communication Log

MISCELLANEOUS

Medicare Patient Phone Surveys

Medicare Complaint Form

CAP FAQ Flyer

Sample Referral Thank You Card *NEW for 2019

Sample Accreditation Press Release

NOTES

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