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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 Accreditation Standards and ensure that your facility is ready for accreditation. ABC’s Patient Care Accreditation program recognizes those 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 Facility 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, affordability and consultative approach 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 Patient Care Accreditation Standards.
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 need to have in place before you apply. The remaining eligibility requirements are identified throughout the Standards and are relevant to specific products and services your organization may provide.

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 DMEPOS services for which you are applying.

• Licensed according to applicable state and federal laws and regulations and maintains all current legal authorization to operate.

• Operational and have a minimum of 10* complete patient charts available at the time of the onsite survey.

• Applying for ABC Accreditation for all of the services it provides, regardless of whether Medicare is billed for these services. This requirement extends only to those services for which ABC offers accreditation.

• Applying for ABC Accreditation for all patient care locations and each location must be in an appropriate clinical setting. The decision of what is an appropriate clinical setting is solely within ABC’s discretion.

• 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 and conditions in the application materials.

• Not falsify or misrepresent your accreditation status.

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

*If the facility is newly established and has a limited patient care history, ABC may determine that a smaller number of complete patient charts is acceptable.
Application Information

Once your facility has met the eligibility criteria and is compliant with the Standards, you are ready to submit your application along with the required documents. You must apply for all products and services your facility currently provides. We recommend that you do not submit your application until you are ready and available for an onsite survey. Please be sure that your application is complete before submitting it—all fields are required. The non-negotiable and non-refundable accreditation fee must be included with your application paperwork. An incomplete application or missing documentation will delay your accreditation process.

The following items are required with your completed application:

- Accreditation fee (non-negotiable and non-refundable)
- A copy of all professional staff licenses and non-ABC certifications – it is NOT necessary to submit copies of certifications for ABC credentialed individuals
- Legal documentation of ownership (e.g. Articles of Incorporation)
- Narrative of your criminal history (if applicable)
- If necessary, we may require additional information. All information and application materials are solely used by ABC and its survey contractors or as required by law. All submissions are handled in accordance with HIPAA regulations.

You will receive an email confirmation once your application has been received, as well as an email and written confirmation once we establish that your application is complete.

Incomplete Applications

If your application is incomplete, we will send a request for additional materials via certified mail to the primary contact listed on your application. We must receive all requested materials by the deadline indicated in the letter. If your application is still incomplete by the deadline, your application will be denied. If your application is denied, you must resubmit a new application and fees. Incomplete applications will be processed after all required documents and/or fees are received. Any delay in completing your application could result in a delay in your accreditation.

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 ABC Professional Discipline Committee
- Pursue legal action against your facility
Office Hours

Your onsite survey will occur during the days and hours of operation listed on your application. If your facility is by appointment only, you must note this on your application including the days and hours 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, that schedule must also be indicated on your application. It is very important that you inform us of all schedule changes as all surveys are unannounced.

Requesting Blackout Dates

Your survey could occur at any time once your application has been processed. If your facility will be closed or any key personnel will be out of the office for a period of time, blackout dates may be requested. You may request up to 14 blackout dates; these dates may be consecutive.

All requests for blackout dates must be submitted, in writing, at least 30 days in advance. Any request for blackout dates not received at least 30 days in advance will not be accepted. These requests must be on company letterhead and signed and dated by the accreditation contact, CEO or owner of the company. We will notify the surveyor of all blackout requests and will attempt to honor such requests. We recommend that you submit any blackout requests with your application.

Application Hold Request Policy

If your facility is not ready for the survey or will be unavailable for more than 14 consecutive days, we recommend that you request to put your application on hold. This will remove your application from the survey queue. Your application will remain on hold until you notify us 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 be denied. These requests must be on company letterhead, signed and dated by the accreditation contact, CEO or owner of the company. 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 utilize 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 radius 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 when affiliates are added in the middle of an accreditation cycle. 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.

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.
Administrative Offices and Warehouse Locations

You must list all related administrative locations and product warehouses on your application and include a detailed letter describing what activities or items are at those facilities. These locations are not patient care facilities.

Warehouse and administrative offices require an onsite survey and will be assessed the base affiliate fee if within a 100-mile radius. 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. Annual fees do not apply to these types of locations.

Essentially Women (EW) Application Discount Policy

Mastectomy-only facilities that are active members of the Essentially Women buying group are eligible for a discount on their accreditation fee. These facilities must provide their EW membership number in the designated area of the payment page. Requests for discount reimbursement or refunds after the application has been submitted will not be accepted. EW members that are providing services in addition to mastectomy, such as Orthotics and Prosthetics, are not eligible for the discount.

Third Party Consultant Materials Policy

We recognize that there are several organizations and consultants that provide a variety of accreditation services. Third party materials and services are not reviewed or endorsed by ABC, nor can we recommend any company providing these services. You may utilize a third party’s materials and services at your discretion; however, you are not required to use a third party to assist with the accreditation process. We advise all facilities to conduct thorough research of any consulting company you wish to use.
Accreditation Programs

ABC offers different accreditation programs tailored to the type of patient care services provided at each of your patient care locations. As noted on the application, you can apply for a main service and add additional services. 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 for those services.

**Orthotics & Prosthetics**
These services must be provided by a certified or licensed orthotist and prosthetist. Orthotics & Prosthetics 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 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. Off-the-shelf orthotics is included in this program. This program is designed for facilities that only provide prefabricated custom fit and off-the-shelf orthotic services and devices. **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 by the patient and does not include therapeutic and diabetic footwear. A list of OTS codes is available on the [ABC website](http://www.abcwebsite.com).

**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, including pneumatic compression devices (lymphedema pumps).

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

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

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**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.

Please refer to the following chart for guidance on what products are covered by each of the programs.
<table>
<thead>
<tr>
<th><strong>Durable Medical Equipment</strong></th>
<th><strong>Ancillary Assistive Devices</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>All Ancillary Assistive Devices</td>
<td>Automatic External Defibrillators (AEDs)</td>
</tr>
<tr>
<td>Continuous Passive Motion (CPM)</td>
<td>Blood Glucose Monitors and Supplies (mail order)</td>
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<tr>
<td>Continuous Positive Air Pressure (CPAP)</td>
<td>Blood Glucose Monitor and Supplies (non-mail order)</td>
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<td>Contracture Treatment Devices: Dynamic Splint</td>
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<td>Enteral Equipment and Supplies</td>
<td>Enteral Nutrients</td>
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<tr>
<td>External Infusion Pumps and Supplies</td>
<td>Heat and Cold Applications</td>
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<tr>
<td>Gastric Suction Pumps</td>
<td>Neuromuscular Electrical Stimulators (NMES)</td>
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<tr>
<td>Hemodialysis Equipment and Supplies</td>
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</tr>
<tr>
<td>High Frequency Chest Wall Oscillation (HFCWO) Devices</td>
<td>Ostomy Supplies</td>
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<td>Home Dialysis Equipment and Supplies</td>
<td>Patient Lifts</td>
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<tr>
<td>Hospital Beds – Electric</td>
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</tr>
<tr>
<td>Hospital Beds – Manual</td>
<td>Perenteral Nutrients</td>
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<tr>
<td>Implanted Infusion Pumps and Supplies</td>
<td>Pneumatic Compression Devices (lymphedema pumps)</td>
</tr>
<tr>
<td>Infrared Heating Pad Systems</td>
<td>Power Operated Vehicles (scooters)</td>
</tr>
<tr>
<td>Insulin Infusion Pumps and Supplies</td>
<td>Seat Lift Mechanisms</td>
</tr>
<tr>
<td>Intermittent Positive Pressure Breathing (IPPB)</td>
<td>Speech Generating Devices</td>
</tr>
<tr>
<td>Invasive Mechanical Ventilation Devices</td>
<td>Support Surfaces: Pressure Reducing Beds/Mattresses/Pads</td>
</tr>
<tr>
<td>Mechanical In-Exsufflation Devices</td>
<td>Surgical Dressings</td>
</tr>
<tr>
<td>Nebulizer Equipment and Supplies</td>
<td>Tracheostomy Supplies</td>
</tr>
<tr>
<td>Negative Pressure Wound Therapy Pumps and Supplies</td>
<td>Traction Equipment</td>
</tr>
<tr>
<td>Neurostimulators and Supplies</td>
<td>Transcutaneous Electrical Nerve Stimulators (TENS)</td>
</tr>
<tr>
<td>Oxygen Equipment and Supplies</td>
<td>Ultraviolet Light Devices</td>
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<tr>
<td>Parenteral Equipment and Supplies</td>
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<tr>
<td>Rentals (Products in AAD and/or DME category)</td>
<td>Walkers</td>
</tr>
<tr>
<td>Respiratory Assist Devices</td>
<td>Wheelchair Seating/Cushions</td>
</tr>
<tr>
<td>Ventilators Accessories/Supplies</td>
<td>Wheelchairs – Standard Manual Accessories</td>
</tr>
<tr>
<td>Wheelchairs-Complex Rehab. Power Chair</td>
<td></td>
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<tr>
<td>Wheelchairs-Complex Rehab. Power Chair Accessories</td>
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</tbody>
</table>

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
Your compliance with the ABC Accreditation Standards is determined by a review of your application materials along with a consultative onsite survey. 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 will need to reapply with a new application and submit 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)
All applicants must meet the basic eligibility criteria listed in this Guide. If you are considering accreditation for your facility, we encourage you to complete the Pre-Application Checklist 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 completed application and fees.

Reaccreditation Survey
Most accreditations are valid for up to three years. Your facility’s primary contact will receive regular mail and email notifications about renewing your accreditation beginning approximately seven months prior to your expiration date. However, it is your responsibility to submit your reaccreditation application on time. Reaccreditation applications are due no later than six 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 a new 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 completed. For an explanation of the CAP process, please refer to the Accreditation Decision section. 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 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. 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. You should also notify us of a potential conflict of interest by submitting a written statement either with their application or via email. Surveyors/apprentices with a confirmed conflict are not assigned that survey.

ABC staff is available to you before and after your survey for any questions you might have. Simply call or email us. Your surveyor is not available to you after your onsite survey and we cannot provide you a surveyor’s personal contact information.

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).

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 being used and what constitutes deviation from or noncompliance with those standards. It is imperative that surveyors be totally familiar with the content of your application and all related materials provided to them prior to the site visit.

Approach
ABC surveyors appreciate the confidential nature of the task at hand and understand the need for professionalism, flexibility and a cooperative attitude. ABC surveyors also understand that the survey process should not only be a measure of your compliance with the Standards, but an opportunity for learning and improvement. That is why our surveyors take a consultative approach when surveying each facility. If your facility has any areas of deficiency, your surveyor will explain why your are deficient and provide you with suggestions on how you can improve. We want you to be successful and our surveyors are here to help you make that happen.
Accreditation Survey Process

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

Preparing for your Survey
Before applying, you should make sure your facility is compliant with the Accreditation 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. Additional preparation resources can be found in the Resources section of this Guide or on our website.

Survey Structure

Initial Interview
Your surveyor(s) will conduct an initial meeting with your facility’s accreditation 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) 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. 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 data 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 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 an initial report to ABC. They cannot give you the survey score, as all results must first be validated and finalized. Finalized results will be mailed to your primary contact within four to six weeks of your survey date. Results for reaccreditation surveys are not sent if there are any outstanding invoices, such as annual fees. Any questions regarding accreditation status should be directed to the ABC Facility Accreditation staff.

Summary of Findings
Once your survey results have been validated, you will receive a written Summary of Findings along with your survey report and decision letter. 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). If your facility passes the survey, we will issue an accreditation certificate for each location. Certificates remain the property of ABC and must be returned if requested.
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 a letter and certificate with a three-year accreditation.

Corrective Action Plan (CAP) Decisions
If your surveyor found deficiencies and/or 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 your accreditation (if your facility was already accredited prior to your survey).

There are no fees associated with CAP submission and they may be mailed, emailed or faxed to the Accreditation Department’s direct fax, 703-842-8027. It is recommended that you make copies of your CAP documents, as any items submitted to ABC will not be returned.

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.

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. You may be granted accreditation based upon your CAP.

Corrective Action Plan Timeline
CAPs are due within 60 days of the decision letter date. We will mail and email you notification of the CAP requirement along with a certified mail reminder. Failure to submit a CAP by the deadline will result in denial or revocation of accreditation. Due to the intense 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 the missed standard(s), we will inform you in writing. If additional information is necessary in order for us to make an accreditation decision, we will make one additional written 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 documentation that shows how changes have been made to address each missed standard. This can include completed forms, logs, training notes, annual reports, patient notes (with patient identifying information removed) and meeting minutes. **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. Please use the format specified in your CAP request letter.

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:

**New Facilities**

- First day following your survey, if your facility passes the initial survey

**Renewing Facilities**

- Date reaccreditation application was received by ABC, if your facility is accredited and passes the reaccreditation survey

**Both**

- Date that your CAP was received, if your 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 or verified with other third parties and are not considered in good standing.

Accreditation Decision Review

All onsite survey reports 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 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 Summary of Findings 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:

ABC
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.

Accreditation applications can be accessed on the ABC website, abcop.org, and must be submitted with the accreditation fees for the primary and, if applicable, affiliate and/or warehouse/administrative locations. Additional fees are required for any accreditation program that is added to your main accreditation. 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.

Annual Fees
Annual renewal notices are emailed in September and mailed in October of each year. Your annual fees are due on December 1st. Annual renewal fees are required for all accredited facilities and 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:

a) Removal from ABC’s weekly Medicare report
b) Removal from ABC’s Directory
c) Inability to verify your facility’s accreditation with all third party payers
d) Revocation of facility accreditation

Certificate Reprint Fees
If you wish to obtain an additional accreditation certificate, a $25 fee is required per certificate.
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:

**Adding a Location**

You are required to apply for accreditation for all patient care sites and related administrative and warehouse locations. Administrative, warehouse and patient care sites that are within a 100-mile radius of your primary location and under the same Tax ID may apply as affiliate locations (not to exceed four affiliates per 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 should wait until you are actively providing that service at your facility. 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 covered in your facility’s current accreditation and does not require an additional survey, you can submit a detailed statement on your company letterhead that specifies what items 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.

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 send ABC the original active accreditation certificate. If you reopen your facility at a later date, you must submit a new application and all fees.

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. On your application, please make sure you mark the box for Ownership Change. If you are adding owners to your facilities, you can maintain your accreditation 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 owner must submit a new application with a detailed letter, legal documentation of the sale and all fees. Facilities that are ABC accredited and in good standing under the previous owner will receive a 90-day accreditation during the survey process. 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 with 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 legal documentation (i.e. Sale 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 in writing of employment status changes for all certified and licensed personnel within 30 days of the change. In the event that a personnel change leaves your facility without a qualifying professional, you have 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 period.
Complaint Process

ABC’s Professional Discipline Committee will investigate all complaints involving an ABC accredited facility or any accreditation applicant that appears to be out of compliance with the Accreditation Standards. 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 against your facility 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 published 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.

During the six-month grace period, you should not accept new patients in the discipline in which you have no qualifying professional. Failure to notify ABC of a personnel change may result in the loss of your accreditation.
Announcing and Promoting Your Accreditation

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

**Logos**

Once you are accredited, we encourage you to use the ABC logo on your facility’s 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 lo-res version of the ABC Accreditation logo.

**Press Releases**

We encourage you to publicize your accreditation status and as such we will provide you with a sample press release in your accreditation notification packet. You can also download a copy of the sample press release by logging into your facility’s MY ABC account.

**Customizable Brochures**

To extend your marketing reach, ABC has created customizable brochures exclusively for our accredited facilities. These brochures help explain the importance of ABC accreditation, the hard work it takes to obtain it and how being ABC accredited helps you provide better patient care. Give them to your patients, referral sources and insurance contractors. The best part is—we’ve done all the work for you! Simply log into your facility’s MY ABC account and click the link to customize and order as many as you’d like.

You must abide by the ABC Logo Guidelines when using the logo to advertise your accreditation status to the general public. False or misleading advertising signifies noncompliance and will result in penalties up to and including revocation of your accreditation. The Logo Guidelines are 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.

**Public Information Requests**

Upon request, ABC will release your accreditation status to the public. This information is released without written authorization or notification. Accredited facility information is also available online through the ABC Directory.
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. ABC’s assessment of your compliance will take into account your facility’s size and services provided. However, all facilities are evaluated on the same set of Standards.

We are committed to providing you with useful resources to guide you through the accreditation process. The following Standards and Compliance Tips are a valuable resource if you are planning to apply for accreditation or looking toward reaccreditation. For many of the Standards we have included 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, you are required to have written policies and procedures that address the clinical and business aspects of your business.

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 licenses, certificates and operation permits in a location accessible to the public.

TIP

Documents must be 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.

All operating documents must be current:

• Licenses
• Certificates
• Permits
AD.1.2.2
You must display all licenses and certificates held by patient care providers in a location accessible to the public.

TIP
Licenses and/or certificates for all patient care providers must be 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.

AD.2
Your business has designated at least one person who has the authority, responsibility and accountability to direct the business 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
You must disclose all ownership interests in your business totaling 5% or more.

TIP
To be in compliance, you must identify all of your business owners. You can do this with corporate records, organizational charts and/or your 855S Form. This is a Medicare requirement. See the full Medicare requirements at 42 CFR §420.201 through §420.206 of the Code of Federal Regulations. [www.ecfr.gov](http://www.ecfr.gov)

AD.4
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.4.1
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 performed. 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.4.2
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 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 [www.cms.gov](http://www.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.

AD.5.1
Your business must have written policies and procedures, which require you to verify 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) requires health care entities to routinely 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. 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. Although the OIG does not define routinely, ABC encourages facilities to check this list on an annual basis.
AD.5.2
You must routinely verify and document that current employees and contractors are not on the Office of Inspector General (OIG) List of Excluded Individuals and Entities (LEIE). You must also verify and document that prospective new hires are not on the LEIE as part of the hiring process.

TIP
You must verify that current individuals or entities, including but not limited to employees (W-2) and contractors (1099), are not on the List of Excluded Individuals and Entities (LEIE). 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 frequency of these checks should be in compliance with your written policies and procedures. Although the OIG does not define routinely, ABC encourages you to check this list on an annual basis at a minimum.

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
AD.7
Your business must make reasonable physical accommodations for your employees and your patients.

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**TIP**
Your business must comply with applicable requirements of the Americans with Disabilities Act (ADA). [www.ada.gov](http://www.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

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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

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

You must show your surveyor 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 apply 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 will provide only staff that is qualified in relation to 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 document that you have verified current licenses, registrations and certifications held by all staff members who provide patient services.

TIP
All of the licenses, registrations and certifications held by all patient care providers should 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.
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 that is 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 to patients 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 either be kept in staff continuing education records or each individual staff member’s personnel file.

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 the licensure scope of practice. (See exception to this standard permitted in HR.6. and 6.1.)

TIP
You must be able to provide a current copy of any required state licenses. Your patient care records must indicate by notes and signatures that care is being provided by licensed staff. If you allow privileging of non-licensed staff as permitted in HR.6 and HR.6.1, you must have appropriate documentation of your privileging process.
HR.4.2
In the absence of state licensure requirements, staff providing custom fit-high or custom fabricated orthotic, prosthetic and/or pedorthic services shall be certified as appropriate as an Orthotist, Prosthetist or Pedorthist and function within the ABC Scope of Practice. Otherwise, personnel providing patient care services must be certified and function within the ABC Scope of Practice. (See exceptions to this standard permitted in HR 6.1)

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. If you allow privileging of staff as permitted in HR.6.1, you must have appropriate documentation of your privileging process.

HR.5
You must meet all CMS (Medicare) requirements for the items provided and for the employment of specialty personnel.

TIP
The business must meet all requirements described on the CMS 8555 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 non-credentialed or non-licensed staff to provide patient care under the supervision of a credentialed 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 credentialed or licensed individual practicing within their scope of practice.

You may privilege credentialed staff to provide patient care beyond their ABC defined scope of practice.

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

TIP
Non-credentialed or non-licensed staff can be privileged to provide equipment, items or services. However, you must document that you have established Written Objective Criteria to assess the competency of each person. This requirement also includes credentialed staff privileged to provide items and services beyond their scope of practice. This documentation may take different forms, including but not limited to, proof of completion of continuing education courses related to particular equipment, 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. The supervisor’s co-signature must appear in all patient charts.
HR.6.1
If you have privileged a non-credentialed or non-licensed patient care provider (see HR 6), the initial patient evaluation, final fitting and delivery of custom-fit high or custom fabricated orthoses, prostheses and pedorthic devices must be done under Direct Supervision*.

*See definition of Direct Supervision in the ABC Scope of Practice.

TIP
If you privilege non-credentialed or non-licensed staff to provide orthotic, prosthetic and/or pedorthic items and services, you must document that you have established Written Objective Criteria to assess the competency of each individual. The level of supervision is dependent on the complexity of the items being provided. For custom fabricated and custom fit-high items, the supervising credentialed patient care provider is responsible for the initial evaluation, final fitting and delivery.

This documentation may take different forms, including but not limited to, proof that the individual has completed continuing education courses related to a particular diagnosis or device, documentation of in-house training or in-service programs that are specific to the patient care service that the individual is being privileged to provide and/or documentation of an individual’s specific work experience in providing patient care. You will need written documentation for each privileged patient care provider describing what criteria they met and how it was met. The supervisor’s co-signature must appear in all patient charts along with the privileged care provider.

HR.7
You must provide performance reviews of your staff at least annually. These appraisals must provide your staff with feedback on competency and opportunities to improve performance.

TIP
During those reviews you will need to provide the individual with feedback on their competency and areas for improvement, if needed. These appraisals are to be documented in their personnel file or another file specifically maintained for that purpose.

HR.7.1
You must annually assess and document the continuing competence of staff related to the equipment, items and services they provide.

TIP
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 should document the ways in which each staff member maintains their competency through proof of completion of continuing education courses, documented in-house training, in-services and/or documented specific work experience. Place this documentation in their personnel file or another file specifically maintained for this purpose.
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.

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 previous tip. 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 ([www.rcjournal.com/cpgs](http://www.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 and effective patient care, in accordance with the ABC *Code of Professional Responsibility*.

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**TIP**

These policies and procedures should contain information on topics such as:

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

Additional resources: [Code of Professional Responsibility](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.1.2.1
You must have documentation that you have implemented practices to prevent and control fraud, waste and abuse.

**TIP**
Examples of this could include patient chart audits (to assure that the item billed for was provided) and annual audits performed by an external accounting firm.

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 sent 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 a fitting stock to effectively provide therapeutic footwear patients with the proper fit and function of footwear. ABC requires the following minimum levels of fitting stock, if you provide:

1. Greater than 250 patients requiring therapeutic shoes per year, at least 40 pairs
2. Greater than 500 patients requiring therapeutic shoes per year, at least 60 pairs
3. Greater than 750 patients requiring therapeutic shoes per year, at least 80 pairs
4. Greater than 1,000 patients requiring therapeutic shoes per year, at least 100 pairs

**TIP**
If you provide therapeutic footwear, 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
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.2.3
If you provide custom fabricated or custom fitted orthoses, prostheses or pedorthic devices you must have access to the 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 basic 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 item(s) or service(s) 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. Patient non-compliance must be documented and evaluated. You must attempt to correct non-compliance through performance management activities, patient education and communication with the referral source. These actions must be documented in the patient’s record.

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.3.3
You must provide follow-up care consistent with the diagnosis and complexity of service(s) provided. This follow-up care, along with any non-compliance with follow-up care, must be documented in the patient’s record.

**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.

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.

**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.3.4.1
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 and expected outcomes related to the use of the item or services provided.

**TIP**

Patient records must include documentation that specific patient goals and expected outcomes have been established. This documentation is usually recorded in the clinical notes section of the record.

**PC.4.1**

The patient care provider must document the patient’s progress toward meeting their goals and expected outcomes related to the use of the item or services provided.

**TIP**

Surveys, interviews, evaluations, outcome measurements and other methods may be used to measure the patient’s progress.

**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**

You must have policies and procedures that inform patients of their rights. 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 rights.
PC.6
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. The proper care, cleaning and use of the item
3. Disclosure of the potential risks, benefits and precautions
4. How to report any failures or malfunctions
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.6.1
Your policies and procedures must describe how you provide information related to the setup (including preparation of enteral/parenteral nutrients), features, routine use, troubleshooting, cleaning, infection control practices and maintenance of all equipment and item(s) provided.

**TIP**
Patient records must include evidence that the patient has been provided all of this information.

PC.6.2
You must give the patient and/or caregiver relevant information about infection control issues related to the use of the items provided. This patient education must be documented in the patient’s record.

**TIP**
Patient records must indicate that the patient has been educated on how to control infections that could arise from using the equipment. You may do this through care and use information sheets and/or verbal instructions.

PC.6.3
You must provide the patient and/or caregiver with instructions on how to inspect the 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 has been educated on how to inspect their skin. Care and use information sheets or verbal instructions may be used.
PC.6.4
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.6.5
For initial equipment and/or item(s) 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 equipment and item(s).

PC.6.6
You must make sure that the patient and/or caregiver can use all provided equipment and item(s) safely and effectively in the settings the item(s) 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.6.7
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, language 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.6.8
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(s) 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.6.9
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 [www.rcjournal.com](http://www.rcjournal.com).

PC.6.9.1
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 also have an on-call policy 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 patients 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 a listing of community resources available to your staff in the event that authorities need to be contacted. 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.

**TIP**
Provide training on your emergency plan to your staff and document this training with sign in sheets and an agenda for the session.
PC.8.1
You must annually assess your risk from emergencies and disasters and ensure that a contingency plan addresses the identified risks. Common disasters include, but are not limited to: power outages and severe weather such as hurricanes, tornadoes, floods, fires, ice, earthquakes, wildfires and mud slides.

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. You must provide training on any changes to the emergency plan to your staff and document this training with sign in sheets and an agenda for the training.

PC.9
You 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.

PC.9.1
You must have a written contingency plan that describes your response to after-hours and emergency maintenance, backup or replacement of equipment, devices and/or items. This plan should be based in part on the criticality of services you provide to assure the continuation of critical care throughout an emergency.

TIP
Staff should be trained on the contingency plan and this training should be documented.

PC.9.2
You must 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.

www.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 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.

PS.2.2
Before you distribute, dispense or deliver items to a patient, you must verify and document that the items are not misbranded and are appropriately labeled for their intended use and distribution.

**TIP**
Look for evidence of repackaging, relabeling and/or prior use.

PS.2.3
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, equipment and/or service.

**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.
PS.4
You must have a written plan for identifying and monitoring equipment and item failures, repairs and recalls and communicating these to your staff.

TIP
Documentation of the plan 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 investigate a patient’s complaint in which the item you provided may have contributed to an incident, injury or infection. If the incident, injury or infection results in the patient’s hospitalization or death, the investigation should be started within 24 hours of becoming aware of the situation. For other occurrences, you must investigate within 72 hours of becoming aware of the situation.

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.

You must provide the patient with written notification within 14 days of the results of the investigation and response.

TIP
You must have a policy in place for the investigation and documentation of incidents, injuries and/or infections. You must also have a documented process for responding to these incidents which includes notifying the patient.

PS.6
You must implement a plan to make sure that the patient and/or caregiver can use all of the equipment and item(s) 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’s 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 record 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 item(s).

**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.

PS.8
You must store the items and supplies for patient use in accordance with appropriate infection control procedures and to 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 an accredited business.

**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 and serial 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.

PS.11
Your policies and procedures must establish a mechanism to minimize cross-contamination and infection control 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 maintain a plan 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.

PS.12.1
You must document the repair and preventive maintenance of equipment and supplies prior to placement into patient-ready status.

**TIP**
You need a plan to track and document that this maintenance has taken place by maintaining equipment maintenance logs, tags or other documentation.

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. Backup 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 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 to quickly access 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 and any other required documentation.

PR.3
Your patient records must be reasonably protected from all 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 patient’s clinical, technical, social and/or financial information must be treated in a confidential manner.

**TIP**
You must establish a confidentiality policy and 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 or pictorial and 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, item(s) and services were received
3. The make and model number of any non-custom equipment and/or item(s) 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 of the patient care provider, their findings, recommendations, treatment plan and follow-up schedule

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 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 expectations

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:

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 expectations

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.6.2

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. Pursues 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 critical issues 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 seek input at least annually from employees, patients and referral sources when assessing the quality of your operations and services.

**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, many national associations and other groups have them as free resources or for purchase and can be adapted for use in your facility. It is recommended that your patient satisfaction survey be conducted within two months following the provision of 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.

PM.2.1
The results of the patient satisfaction survey must be documented and evaluated.

**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 and/or complaints about the products 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.

**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 practices 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.

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 shall 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:

1. Provide a physical environment free of hazards
2. Manage staff activities to reduce the risk of injuries

Your written safety management program must include:

1. Information concerning specific procedures to be followed by staff
2. Provisions for the management of patients
3. Annual safety inspections of your facility and operations
4. 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 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 building(s) 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:

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 area(s) that are properly equipped for patient evaluation and care.

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

FS.2.2
If you provide items that require modification, maintenance and/or repair, you must have a specific, dedicated laboratory area or a laboratory area in close and easily accessible proximity, for servicing, maintaining, adjusting, repairing, modifying and/or fabricating those items.

FS.3
You must conduct and document safety management orientations for all staff that address:

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 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 (for example, 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. You must provide appropriate education and training to all staff on this plan. 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. You must document that staff has been trained on the emergency evacuation plan with sign in sheets, program agendas or course certificates.

FS.3.2.1
You must conduct an annual emergency evacuation drill in accordance with the evacuation plan. The drill(s) must be done at least annually 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.
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 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 might 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:

1. Occupational Safety and Health Administration (OSHA) blood borne pathogen regulations
2. Centers for Disease Control (CDC)
3. 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. 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 (oig.hhs.gov).

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 who would 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.

**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.

CB.4
You must establish file auditing and monitoring 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 have ongoing file auditing and monitoring procedures of the claims and billing compliance program. You must write an evaluation of the results of the 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.

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
Resources

As part of our commitment to value, we offer 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](http://abcop.org).

**Relevant Standards Tool**—This quick and easy online tool helps you determine exactly which standards apply to the devices and services you provide your patients. Simply choose the specific product categories you provide and the Relevant Standards Tool 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.

**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 or Aon Affinity.
- 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. Just look for the Additional Resources section of the Patient Care Accreditation Getting Started page.

**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](http://www.sam.gov).
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 back up 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

☐ Is able to 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 smaller number of complete patient charts are 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
- For corporations, you need proof that you hold an annual meeting as required by your state’s regulations.–AD.1.1
- 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.–AD1.1

☐ 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.4

☐ Verify that your staff members, including contractors, current employees and new hires are not 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.1, PC.1.1, PC.1.2
- 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 4.1, 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

☐ 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.6.3

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.6.8

☐ 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.9.2

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.2.2, PS.2.3

☐ 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.

☐ 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

☐ Have identified areas that can be improved and that you have developed a plan on how to improve those areas. Make sure you document your plan and outcome.–PM 1.1

☐ 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.

This list is not inclusive and not intended to replace a thorough knowledge and understanding of the Standards.
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.