



American Board for Certification
in Orthotics, Prosthetics & Pedorthics, Inc.



Mastectomy Facility Accreditation Guide

- Getting Started
- Standards
- Resources and Tools

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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 Patient Care Facility Accreditation Standards and ensure that your facility is ready for accreditation. ABC's Patient Care Accreditation program recognizes patient care facilities that promote the best business and patient care practices in the O&P profession. Are you the best at what you do? Prove it with ABC Accreditation!

Who We Are

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

ABC is governed by a voluntary board of directors composed of orthotic, prosthetic and pedorthic health care professionals and consumers. In coordination with the board, ABC accreditation policy is administered by the Facility Accreditation Committee. ABC's

mission is to establish and promote the highest standards of organizational and clinical performance in the delivery of orthotic, prosthetic and pedorthic services. Our high standards, 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 policies and standards outlined in the Mastectomy Facility Accreditation Guide.

Mastectomy Accreditation

ABC offers different accreditation programs tailored to the type of patient care services provided at each of your patient care locations. This program is only for facilities who provide Mastectomy only services (post-mastectomy prostheses and accessories) and these services must be provided by a certified or licensed mastectomy fitter. This program does not include pneumatic compression devices (lymphedema pumps).

If your facility is providing services or items not included with the Mastectomy program, please review our ABC Facility Accreditation Patient Care Guide, which is available on our website at ABCop.org.

Remember that you must apply for ABC Accreditation in all of the services provided regardless of whether you are billing CMS or another payer for those services.

Eligibility Criteria

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

Your organization must be:

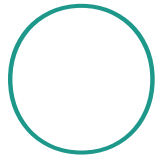
- Located within the United States, one of its territories or possessions or be a Department

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

of Defense medical treatment facility or program.

- A formally organized and legally established business that is currently providing the Durable Medical Equipment, Prosthetics, Orthotic, and Supplies (DMEPOS) services for which you are applying.
- Licensed according to applicable state and federal laws and regulations and maintains all current legal authorizations to operate.
- Operational and have a minimum of 10* complete patient charts per patient care provider available at the time of the onsite survey.
- Applying for ABC Accreditation for all of the services provided, regardless of whether Medicare or another payer is billed for these services. This requirement extends only to those services for which ABC offers accreditation.
- Applying for ABC Accreditation for all patient care locations. Each location must be in an appropriate clinical setting. The decision of what is an appropriate clinical setting is solely within ABC's discretion.
- Compliant with state licensure requirements.
 - In addition, you must:
 - Clearly define the items and services you provide to patients, insurance companies, referral sources and regulatory bodies, including Medicare.
 - Comply with the ABC *Code of Professional Responsibility*.
 - Agree to the Terms of Agreement in the application and policies listed in this Guide.
 - Not falsify or misrepresent your accreditation status.

Application Information



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

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

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

The following items are required with your completed application:

- Application fee (non-negotiable and non-refundable)
- Good standing of annual fees for existing accredited facilities (any outstanding annual fees must be paid before application can be submitted)
- Valid email address to receive communication from ABC
- Proof of certification and /or state licenses of staff providing patient care services.

It is NOT necessary to submit copies of certifications for ABC credentialed individuals

- Legal documentation of ownership (e.g. Articles of Incorporation, Transfer of Shares Certificate)
- Narrative of your criminal history (if applicable)

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

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

Incomplete Applications

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

Falsification of your Application

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

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

Office Hours

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

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

Requesting Blackout Dates

New Applicants

New facilities, including affiliate add-ons, are not eligible to submit any blackout dates as limited availability can add delay to your onsite survey.

Renewal Applicants

Existing ABC accredited facilities that are submitting renewal applications are eligible to submit blackout dates. 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 so that the surveyor does not show up on those dates. This includes doctor appointments, religious holidays and vacation trips. Surveys are not conducted on major federal holidays or their observances. You may request up to 14 blackout dates during a six-month period; these dates may be consecutive.

All requests for blackout dates must be provided by submitting the online Blackout Date Request Form available online at ABCop.org by the deadline provided in your facility's application receipt email. Any request for blackout dates after we received your form will be denied. Be sure to add any holidays or vacation days that will be within your survey timeframe.

Application Hold Request Policy

If your facility is not ready for the survey, is undergoing a major change (such as an ownership change, location move, opening another facility within the next 90 days) or

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

Affiliate Locations

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

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

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

Administrative Offices and Warehouse Locations

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

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

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.

Essentially Women's (EW) Discount

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 in the online application. 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 a discount.

Accreditation Survey

The Basics

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

Types of Surveys

Initial Survey (First-time Applicants)

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

Reaccreditation Survey

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

Resurvey

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

Verification Survey

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

Quality Control Survey

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

Surveyors

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

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

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

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

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

About Our Surveyors:

Background

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

Site Surveyor Training

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

Approach

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

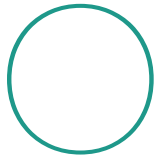
Knowledge

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

Skills

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

Accreditation Survey Process



Our goal is to make the accreditation process as effective and uncomplicated as possible. The following information will

help you understand what you can expect from the process.

Preparing for your Survey

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

Survey Structure

Initial Interview

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

- Briefly introduce him/herself, along with other members of the survey team (if applicable)
- Discuss the survey objectives and the day's schedule
- Answer any questions you may have regarding the survey

- Ask for the general layout of your facility and a description of any other details about your facility and your staff that should be noted

Information Gathering

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

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

By applying for accreditation, you authorize ABC and our surveyor's access to all records (including patient, personnel, financial management, risk management, operational review, quality assurance and quality improvement) and physical areas necessary to determine your facility's compliance with the ABC Standards. Your surveyor will also conduct staff and patient interviews and may look at other areas as they relate to the Standards. All Protected Health Information (PHI) is treated in accordance with Health Insurance Portability and Accountability Act (HIPAA) regulations. Per CMS, surveyors are required to call a sampling of your facility's Medicare patients and ask the patient or caregiver a few questions about the device, education, and follow-up they received. We recommend that a staff member be present while your surveyor makes these calls.

Closing Interview

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

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

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

After the Survey - Results

Scoring Process

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

Accreditation Decision

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

Accreditation Decisions

Full Approval

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

Corrective Action Plan (CAP) Decisions

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

Pass with a Corrective Action Plan requirement

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

Fail with a Corrective Action Plan requirement

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

Corrective Action Plan Timeline

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

Incomplete Corrective Action Plans

If your initial CAP does not adequately demonstrate compliance with missed standard(s), we will inform you via email and/or letter. If additional information is necessary in order for us to make an accreditation decision, we will make one additional request

for follow-up materials within a specified timeframe. All materials are due by the deadline stated in the correspondence.

Supporting Corrective Action Documentation and Format

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

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

Denial

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

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

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

Accreditation Effective Dates

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

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

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

Reporting to Medicare and Other Third Parties

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

Accreditation Decision Review

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

Appeals Process

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

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

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

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

Accreditation Fees

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

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

Application Fees

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

Annual Fees

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

- 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. Your facility's fees and accreditation must be current in order to process your reprint request.

Maintaining Your Accreditation

Accreditation requires that you continue to comply with the ABC Standards, abide by all policies and procedures and submit your annual fees on time. Failure to fulfill any of these requirements may result in the revocation of your facility's accreditation.

Facilities must notify ABC of any and all changes within 30 days of the effective date of change.

Such changes include:

Moving a Location

You are required to reapply for your facility should you change addresses as ABC is required to visit your new address. ABC cannot update our facility records without the completion of the accreditation application and associated fees with the updated address. You will then be scheduled for an onsite survey at your new location.

Adding a Location

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

Any affiliate or related office that opens after the primary location has been granted accreditation cannot advertise or otherwise consider itself an accredited patient care

center until you have applied for and been granted accreditation status by ABC. You must submit a new application, including all appropriate fees, upon the opening / acquisition/merger of an affiliate location. Once your application has been approved, ABC will determine if the location is eligible for a 90-day accreditation, with full accreditation contingent on passing your onsite survey with no significant compliance issues. If approved for full accreditation, this accreditation will be valid for the length of your primary location's current accreditation.

Changing Corporate Structure

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

Discontinuing a Service

You must notify ABC in writing if you discontinue providing mastectomy patient care services. If you add the service at a later date, you must reapply with all applicable fees.

Closing or Selling Your Facility

You must notify ABC in writing if you close or sell your facility; notification must be sent within 30 days of the sale or closure. You must also mail ABC the original active accreditation certificate. If you reopen your facility at a later date, you must submit a new online

application and all related fees. If your facility is sold, your accreditation is not transferrable to another owner, and the new owner of your facility will need to reapply (see Ownership changes).

Lawsuits and Disciplinary Actions

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

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

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

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

Ownership Changes

Adding Owners to Existing Ownership

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

Complete Change of Ownership

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

Removing an Owner from Existing Ownership

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

Personnel Changes

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

Complaint Process

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

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

- Possible abuse, neglect or exploitation
 - Professional misconduct
 - Noncompliance with state or federal laws
- You will be informed of all allegations and provided with copies of all complaint-related materials.

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

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

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

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

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

Announcing and Promoting Your Accreditation

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

Logo/Advertising Language

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

Press Releases

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

Public Information Requests

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

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

Accreditation Standards and Compliance Tips



BC Accreditation Standards represent baseline expectations of your business' physical location and the delivery of patient care.

We are committed to providing you with helpful resources to guide you through the accreditation process. The following Standards and Compliance Tips are a valuable resource as you plan to submit your accreditation application for the first time or for your reaccreditation. Many of the Standards have an accompanying tip that gives you 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 see fit.

Administrative Standards (AD)

The Administrative Standards address the legal status and legitimacy of the business, your compliance with Medicare and HIPAA requirements and the establishment of the internal policies and procedures of your business. The Standards require that your business be legally established, 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 you must have complete financial records.

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 of your staff
- A way for your staff to communicate with management
- Patient care and management, including patient and family education and patient rights
- Staff response to evidence of patients who may at risk from real or perceived abuse, neglect or exploitation
- Communication with healthcare prescriber if you can't fulfill the prescription
- A claims and billing compliance program

that describes your compliance with federal and state policies

- Verification that no employees, contractors and new hires are listed on the Office of Inspector General (OIG) List of Excluded Individuals and Entities (LEIE).

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 show your surveyor your legal documentation of proof of ownership of your business as well your 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.

You will need to provide proof of the following to your surveyor:

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

Use the Annual Facility Review Checklist available in the online Resource Pack to help you keep organized on these requirements as well as other annual reviews. Log in to your MY ABC account to access the Resource Pack.

AD.1.1

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

TIP

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

AD.1.2

Your business has a physical location accessible to the public.

TIP

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

AD.1.2.1

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

TIP

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

- Business license from your city or county
- Zoning or occupancy permit

- Fictitious business name permit (also called dba or doing business as permit)
- Sales tax license
- Fire department permit
- Special state-issued occupational or professional licenses

AD.2

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

TIP

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

AD.3

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

TIP

Your mission statement should be short and express your business's purpose in a way that sets the tone of how you treat your staff and your patients. It should also tell your patients at a glance the principals of the care and services they can expect. You may want to make your patients aware of your mission statement by displaying it in your patient waiting area, including it in your marketing/promotional materials or posting it on your company website.

AD.3.1

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

TIP

Your policies and procedures need to describe how your Mastectomy business and fittings are performed. Inform your staff about the policies as well as any changes you make in the future and make sure that you document any changes. You can document your changes by adding a page to your policy manual stating the effective date of the change. To show your onsite surveyor that your staff has been informed, you can provide your meeting agenda with attending staff member signatures or you can have those signatures in the employee's file.

AD.4

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

TIP

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

AD.5

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

TIP

You are responsible for being knowledgeable about all of the current CMS (Medicare) Supplier Standards, regulations and policies. You can read about them on the CMS website ([cms.gov](https://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. You must have proof of your liability insurance and surety bond, if applicable. The Medicare Supplier Standards and a Patient Acknowledgement form are available in the online Resource Kit.

AD.5.1

Your business must have written policies and procedures, which require you to annually verify and document that no employees, contractors and new hires are on the Office of Inspector General (OIG) List of Excluded Individuals and Entities (LEIE).

TIP

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

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

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

AD.6

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

TIP

HIPAA has many sections and requirements. You should be knowledgeable about the Act and how it impacts your business. Be sure that 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 (this could be you)
- Your 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 safeguards and passwords are in place
- Documentation of staff education

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

AD.8

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

You must maintain financial information or accounts that:

- 1-Manage revenues and expenses on an on-going basis**
- 2-Link items and supplies to the patient**
- 3-Reconcile charges to the patient for services, items and supplies with invoices, receipts and deposits**
- 4-Have a mechanism to track actual expenses and revenues**

TIP

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

Your surveyor must see evidence that:

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

Human Resources (HR)

The Human Resource Standards apply to all staff at the business' physical location, whether directly employed, contracted or 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 all of your care providers and support staff. The business ownership/leadership is responsible for hiring and privileging its staff and ensuring that your staff has the necessary skills to perform their job.

HR.2

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

TIP

You must verify the certifications and licenses (if applicable) of all of your fitters annually. You can contact your credentialing agency (licensure or certification board) and request verification that the individual's credentials are still valid via phone, email or check the agency's website directory. Once you have verified the credential/license, document the date and the method that you used in the employee's personnel file or another file that you have specifically for this purpose. Use the Annual Employee Verification form in the online Resource Pack to accomplish this verification.

HR.4.2

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

TIP

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

HR.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.

TIP

Non-credentialed or non-licensed employees can be privileged to provide devices, 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. Your documentation could be one of many different forms, including but not limited to, proof of completion of continuing education courses related to particular items, 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. Use the Instructions for Using Privileging Criteria and the Individual Privileging Criteria form in the online Resource Pack to help you with the documentation.

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

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

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.

- **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.
- **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.
- **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.
- **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.1.3

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

TIP

If you verbally communicate the delivery timeframe, make a note of what you told the customer in the patient record. You could also provide them 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

If a patient is referred to you by a healthcare prescriber for a device or item that you do not provide you must notify that the prescriber within five calendar days.

PC.2.1

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

TIP

Your fitting stock must be available for the surveyor to observe.

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

Make sure that you have all referrals, consultations and other communications from the prescriber in the patient's record. They cannot be altered in any way and must include the prescription, the patient's diagnosis and clinical notes. Use the Patient

Care Communication Log available in the online Resource Pack to document these interactions in the patient's chart.

PC.3.1

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

TIP

Document in the patient's record that the care you delivered was 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).

PC.3.3

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

TIP

Make follow up appointments as necessary for your patient's overall care. Write detailed notes including if the patient has or hasn't followed proper wearing and other instructions. Also document if they miss appointments or do not return calls.

PC.3.4

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

PC.4

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

TIP

In the patient notes, document the reason for the visit, what they would like you to do for them and what you plan on doing for the patient.

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 to inform patients of their rights. In addition, you must document in the patient records and/or have the patient sign that this information was given to them. Examples include a HIPAA acknowledgment form, after hours contact information and Medicare Supplier Standards form.

PC.6.1

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

- 1. The purpose and function of the item**
- 2. Infection control, including the proper care, cleaning and use of the item**
- 3. Disclosure of the potential risks, benefits and precautions**
- 4. How to report any failure or malfunction**
- 5. When and to whom to report changes in physical condition when it relates to the device**

TIP

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

PC.6.2

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

TIP

Make sure to discuss or provide a brochure to the patient or their caregiver on how to look at the patient's skin to make sure there isn't redness, irritation, skin breakdown, pain, edema or sensitive skin areas. Document how you provided this information to the patient or caregiver.

PC.7

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

TIP

Provide staff instructions on the steps to take if it appears a patient may be in danger of physical or emotional harm. Your policy should include how to contact the appropriate local government agencies and how to document the situation in the patient's file. You may wish to seek legal counsel to develop this written policy.

Product Safety (PS):

The Product Safety Standards require that you affirm the safety and appropriateness of the items and services that you provide to patients.

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.

Patient Records (PR)

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

1) Secure and Confidential Patient Records:

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

2) Back-up Patient Records:

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

3) Uniform Documentation:

Each patient record should consistently include a patient evaluation/assessment, the diagnosis being treated and appropriate comorbidities, patient education, the referring physician or appropriately licensed healthcare prescriber's order and the patient's goal.

PR.2

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

TIP

You must have a paper or electronic system in place that allows you quick access to patient information. Security could include locks on file cabinets or passwords on computers.

PR.2.1

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

TIP

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

PR.6.1.1

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

- 1. Pertinent medical history**
- 2. Allergies to materials**
- 3. Skin condition**
- 4. Diagnosis**
- 5. Previous use of orthoses, prostheses and/or pedorthic devices**
- 6. Results of diagnostic evaluations**
- 7. Patient goals and expectations**

TIP

All patient records must be consistent. As applicable, each patient record must include: The records should include:

- The patient's skin condition, such as healed, rash, edema
- The diagnosis from the prescribing healthcare provider
- Range of motion, for example, frozen shoulder which could require a front closure bra
- Any history of previous use of bras and prosthesis
- Results of your diagnostic evaluations, such as measurements, weight changes or new surgeries
- The patient's expectations, for example:
 - Personal activity goals (swimming and wants swim form), self-esteem, balance or to relieve back or neck pain

Performance Management and Improvement (PM)

The Performance Management Standard allow you to track and identify the strengths and weaknesses of your business and patient care procedures. You must have a program in place to monitor, evaluate and improve the quality of your patient care.

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 business. It is recommended that your patient satisfaction survey be conducted within two months following the provision of a new or replacement bra or prosthesis. Your survey should be designed to gather many types of information, including:

- Satisfaction with the product and your services
- Your timeliness in responding to questions, problems and concerns
- The convenience of your business hours and ability to schedule an appointment

Use the *How to Write and Analyze Patient Satisfaction Surveys* in the online Resource Pack to help you create your satisfaction survey.

Facility Safety and Management (FS)

ABC's Facility Safety and Management Standards are designed to ensure that your business location and premises are appropriate for providing patient care. These Standards address two critical categories: facility safety and safety management.

FS.2.1

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

TIP

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

FS.3.2.1

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

TIP

To practice these plans, your annual evacuation drill needs to include all staff and needs to be documented as to date and time. Use the Fire/Emergency Drill Documentation form available in the online Resource Pack to document your drill.

Claims and Billing Compliance (CB)

The Claims and Billing Compliance Standards are designed to support your business' compliance with billing guidelines set by the Centers for Medicare and Medicaid Services and the Office of the Inspector General. You are 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:

- You establish a claims and billing compliance program based upon formal policies and procedures that prevent inappropriate billing.
- A qualified and trained individual is responsible for maintaining the compliance program and oversees that the program is administered consistently.
- Appropriate staff is properly trained and educated on claims development and billing procedures in order to effectively manage the claims process and minimize the submission of improper claims.
- Auditing and monitoring mechanisms are implemented to ensure consistent compliance and identify areas of improvement.
- Written employment criteria and disciplinary guidelines are implemented for all billing and claims staff.

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

Your compliance program must include written policies and procedures that address:

- Appointing a compliance officer
- Billing monitoring and auditing procedures
- Chart audits—including the frequency and number of audits you'll do
- The procedures you follow if errors are found and what corrective actions you have taken
- Education of your billing staff
- Identifying and dealing with fraud and abuse

CB.2

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

TIP

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

CB.3

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

TIP

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

CB.4

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

CB.4.1

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

TIP

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

Your auditing policy should specifically indicate the number or percentage of charts you will audit. Outline how often you will conduct an audit (we recommend at least annually).

Minimally, your chart audit should consist of the following:

- Documentation of the current prescription
- That the quantities dispensed match the prescription
- A signed and dated delivery receipt.

Delivery receipt date is the actual date the items were received by the patient or the mail/ship date.

CB.4.2

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

TIP

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

This plan should include:

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

Resources

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

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

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.

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

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

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

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

- 15% discount on property and liability insurance premiums through Cailor Fleming.
- Discount on certificate framing.

Medicare Resources

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

Additional Information

HITECH

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

GSA Excluded Parties Systems

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

Patient Care Accreditation Pre-Application Checklist

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

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

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

Eligibility Criteria

Before you apply, make sure your business:

- Is located within the United States, one of its territories or possessions or is a Department of Defense medical treatment facility or program
- Is a formally organized and legally established business that provides the services and items for which you are applying
- Is licensed according to applicable state and federal laws and regulations and maintains all current legal authorization, permits and zoning requirements to operate
- Is operational and has a physical location
- Applies for ABC accreditation for all patient care locations and all services being provided, regardless of whether Medicare or another third party is billed for these services. (This requirement only extends to those services for which ABC offers accreditation.)
- Employs the appropriately credentialed staff for all scopes of service being provided
- Has met the Patient Care Facility Accreditation Standards
- Has a minimum of 10* complete patient charts
- Has designated at least one individual to be in charge of accreditation and compliance and that you also have assigned a backup contact
- Meets all Medicare DMEPOS Quality and Supplier Standards (if applicable) and is compliant with the Americans with Disabilities Act (ADA) and Occupational Safety and Health Administration (OSHA) regulations
- Must be 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 minimum of five complete patient charts per patient care provider is acceptable.*

Meeting the Standards

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

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

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

Administrative (AD)

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

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

Make sure you also:

- Post any business licenses, certificates and operating permits in your reception area or another area that is accessible to the public.-AD.1.2.1**
- Designate specific individual(s) who are authorized to perform in a leadership capacity and who are responsible and accountable to oversee the activities and operations of your business.-AD.2**
- Adopt a mission statement.-AD.3**
- Verify that 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:

- Maintain complete and current employee personnel records, including items such as verification of credentials and continuing education.-HR.2**
- Have privileging documents for each non-credentialed or licensed individual (these should be maintained in each employee's personnel file.)-HR.6.**

Patient Care (PC)

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

- Have posted Patient Rights and Responsibilities information in your reception or patient waiting area.-PC.5.1**
 - Provide all patients with a time frame for services and delivery of items.-PC.1.3**
 - Collect and keep signed and detailed orders from the physician in each patient's record-PC.3**
 - Provide specific and detailed follow-up schedules and instructions to the patient. Be sure to note if the patient has not fully complied.-PC.3.3**
 - 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**
 - 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.6.1**
 - Provide and document education and instructions to each patient and/or caregiver on how to identify and deal with pressure areas, skin breakdown, redness, edema, etc. as well as infection control.-PC.6.2**
- Your surveyor will also be checking to make sure you have:
- Created and implemented detailed policies and procedures as it pertains to providing the necessary instruction and information for the patient and/or caregiver to maintain and safely use the specific item(s).-PC.6.1**
 - 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**

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:

- 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**

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**
- 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.6.1.1**

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:

- Collect and analyze patient satisfaction surveys-PM.2**

Facility Safety (FS)

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

- 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**
- 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.3.2.1**

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**

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.



330 John Carlyle St, Suite 210 • Alexandria, VA 22314
Tel: (703) 836-7114 • Fax: (703) 836-0838

ABCop.org