



Mastectomy-Only Facility Accreditation Standards

The following mastectomy-only facility standards are effective March 1, 2016.

For more information on the accreditation process, please refer to the Mastectomy-only Facility Accreditation Guide.

ADMINISTRATIVE

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.

AD.1.1

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

AD.1.2

Your business has a physical location accessible to the public.

AD.1.2.1

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

AD.1.2.2

You must display all licenses and certificates held by patient care providers in a location accessible to the public.

AD.2

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

AD.3

You must disclose all ownership interests in your business totaling 5% or more.

AD.4

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

AD.4.1

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

AD.4.2

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

AD.5

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

AD.5.1

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

AD.5.2

You must routinely verify and document that current employees and contractors are not on the Office of Inspector General (OIG) List of Excluded Individuals and Entities (LEIE). You must also verify and document that prospective new hires are not on the LEIE as part of the hiring process.

AD.6

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

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

HUMAN RESOURCES

HR.2

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

HR.6

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

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

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

PATIENT CARE AND MANAGEMENT

PC.1.3

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

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.

PC.2.2

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

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.

PC.3.1

You must provide patient care in accordance with the most recent prescription for the item(s) or service(s) provided. All patient care must be in accordance with the payer requirements.

PC.3.3

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

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

PC.4.1

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

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

PC.6

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

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

PC.6.3

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

PC.7

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

PRODUCT SAFETY

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

PATIENT RECORDS

PR.2

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

PR.2.1

Your patient records must include federal, state, local and applicable third party payer 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:

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

PERFORMANCE MANAGEMENT AND IMPROVEMENT

PM.2

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

FACILITY SAFETY AND MANAGEMENT

FS.2.1

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

FS.3.2.1

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

CLAIMS AND BILLING COMPLIANCE

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.

CB.2

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

CB.3

You must provide claims development and billing education for all staff involved with or responsible for, claims and billing.

CB.4

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

CB.4.1

You must have ongoing file auditing and monitoring procedures of the claims and billing compliance program. You must write an evaluation of the results of the compliance program and act on any necessary changes.

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.

**If you have any questions or need assistance with the accreditation standards or process,
please contact us at 703-836-7114 ext. 253.**