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An Overview of BOC Facility Accreditation and Continuing Accreditation

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Helpful Hints

The Board of Certification/Accreditation (BOC) Facility Accreditation Standards, inclusive of the Centers for Medicare and Medicaid Services (CMS) Quality Standards and National Supplier Standards, were developed to assure the public of the availability of comprehensive orthotic/prosthetic and Durable Medical Equipment (DME) / Home Medical Equipment (HME) services, consistent with federal, state and local laws and regulations.

Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) facility accreditation is provided under the deemed authority granted to BOC as an accrediting organization awarded by CMS. Accredited facilities are required to reapply every three years.

BOC's policies and standards, as well as standards set forth by CMS, are updated periodically. BOC-accredited suppliers have an ongoing obligation to adhere to these policies and standards; noncompliance may result in revocation of accreditation.

Part 1. Business Administration

Section A. Corporate Structure and Governance

A.1.0. The supplier complies with all federal, state and local laws and is a legally constituted entity in the state in which it is located. When applicable, the organization must have a corporate charter and governing body that sets policy for the entity. (CMS Supplier Standard #1, #3)

A.1.1. The organization must have one or more individuals who perform leadership functions with the authority, responsibility and accountability to direct the organization and its key activities. The organization must identify those individuals who serve as its leadership and management. The leadership must ensure that the organization complies with these standards, as well as all other applicable laws and regulations, and that its programs and services meet patient needs. The supplier must post an organizational chart indicating the lines of authority and accountability.

A.1.2. Governance defines responsibilities in writing, provides for organizational management and planning, approves the written scope of services for the organization, selects the chief executive, provides for the resources necessary to maintain safe quality care, and works with other leaders to annually evaluate the organization's performance in relation to its mission, vision and goals.

A.1.3. The supplier agrees to notify BOC of any changes in ownership, corporate officers/structure or practitioners within 30 calendar days of hiring or termination. (CMS Supplier Standard # 2, #17)

A.1.4. The supplier must have a designated **Compliance Officer** to assure compliance with applicable laws and regulations. This person must be identifiable by employees and patients to enable contact if issues or concerns arise. The supplier must post the contact information in public view.

CMS: 1-800-Medicare
BOC: 1-877-776-2200

A.1.5. The supplier's policies and procedures must be designed to promote the provision of high-quality patient care in compliance with all applicable federal and state laws, regulations, professional certification guidelines, and the professional scope of practice. Professional certification guidelines include those outlined by the Food and Drug Administration (FDA), the Health Insurance Portability and Accountability Act (HIPAA), the Americans with Disabilities Act (ADA), and the Occupational Safety and Health Administration (OSHA).

Compliance Officer: An employee or contracted individual whose responsibilities include ensuring that the company follows external regulatory requirements and internal policies.

A.2.0. Physical Location

A.2.1. The supplier is prohibited from sharing a practice location with another Medicare supplier, including a physician, physician group or another DMEPOS supplier. (CMS Supplier Standard #29)

A.2.2. The supplier must maintain a physical facility on an appropriate site. The location must be at least 200 square feet and must contain space for storing business records, including the supplier's delivery, maintenance, financial and patient communication records.

A.2.3. All of the supplier's locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be accredited separately. In the case of a multi-site supplier, records may be maintained at a centralized location. (CMS Supplier Standard #24)

A post office box or commercial mailbox is **not** considered a physical facility.

A.2.4. The supplier must permit CMS or its agents to conduct on-site inspections to ensure the supplier's compliance. The supplier location must be accessible to patients during reasonable business hours with a visible sign and posted hours of operation. The facility may not be located in a gated community or in an area with restricted access.

A.2.5. The supplier must maintain a primary business telephone number listed under the name of the business in a local directory or a toll-free telephone number available through directory assistance. The exclusive use of a beeper, answering machine, answering service or cell phone during posted business hours is prohibited.

A.2.6. The supplier must inform BOC when a new location is opened, and the supplier must not convey or reassign a supplier number. (CMS Supplier Standard #23, #18)

Not applicable for Orthotics and Prosthetics (O&P) facilities.

A.2.7. The supplier must remain open to the public for a minimum of 30 hours per week, with the exception of physicians (as defined in Section 1848(j) (3) of the Social Security Act), physical and occupational therapists

or a DMEPOS supplier working with custom-made orthotics and prosthetics. (CMS Supplier Standard #30)

A.3.0. Scope of Service

A.3.1. The supplier receiving payment must be the entity furnishing and billing for the items and services.

A.3.2. Suppliers must have individuals on staff to support the specialties, products and services provided. Professional personnel (e.g., orthotists, prosthetists or respiratory therapists) who are required by National Provider East (Novitas Solutions) or National Provider West (Palmetto GBA) regulation to be licensed or certified must be employed by the supplier or may be contracted. A supplier may contract services for cleaning, delivery and repair.

A.3.3. The supplier must inform CMS and BOC when they have a change in their product line or services. The supplier may be subject to an additional site survey. (CMS Supplier Standard #22, #25)

A.3.4. The supplier must fill, fabricate or fit prescribed items from its own inventory or contract with other companies for the purchase of items necessary to fill the order. A supplier may not contract with any entity that is currently excluded from the Medicare program and **third-party payors**, from any state healthcare programs, or from any other federal procurement or non-procurement programs. (CMS Supplier Standard #4)

Third-Party Payor: An insurance carrier other than Medicare (e.g., Workman's Comp., Blue Cross Blue Shield, Aetna).

A.4.0 Standard Business Practices

A.4.1. The supplier must have a comprehensive liability insurance policy in the amount set by CMS. If a supplier manufactures its own items, the insurance must also cover product liability and complete operations. (CMS Supplier Standard #10)

A.4.2. Failure to maintain required insurance at all times will result in revocation of the supplier's billing privileges retroactive to the date the insurance lapsed. National Provider East (Novitas Solutions), National Provider West (Palmetto GBA) and BOC must be listed as certificate holders.

A.4.3. The supplier must meet the surety bond requirements in 42 Code of Federal Regulations (CFR) 424.57(d). (CMS Supplier Standard #26)

In order for a contract to be considered acceptable, it must:

- Be current
- Identify both parties with signatures
- Contain an established, reasonable credit limit (cash on delivery is not acceptable)
- Provide the credit terms with the net due amount stated
- Show both companies identified within the contract
- Contain the effective dates of the contract

A.5.0. Prevention of Fraud, Waste and Abuse

A.5.1. The organization must implement business practices to prevent and control fraud, waste and abuse by using procedures that articulate standards of conduct to ensure the organization's compliance with CMS quality and supplier standards, applicable laws and regulations.

A.5.2. The Compliance Officer must train and educate employees, contractors and agents on compliance policies, procedures, internal monitoring and reporting of deficiencies. Management must document and keep records regarding compliance efforts (e.g., training, non-compliant situations and actions taken).

A.6.0. Ethics

A.6.1. The supplier and practitioner must subscribe to a body of ethical statements respective to supplier or professional categories, credentials or licensure. The supplier must recognize its responsibility to patients.

Section B. Financial Management

B.1.0. The supplier must implement financial management practices that ensure accurate accounting and billing to CMS, patients and third-party payors.

B.1.1. Financial records must be accurate, complete and current. Records must reflect cash- or accrual-based accounting practices and maintain a mechanism to track actual revenues and expenses. The supplier must maintain accounts that link equipment and items to the patient and manage revenues and expenses on an ongoing basis related to patient services.

B.1.2. The supplier agrees to produce records as requested by the BOC site surveyor for the purpose of completing the site survey and as proof of compliance with BOC and CMS standards. (CMS Supplier Standard #21)

B.2.0. Annual Operating Budget

B.2.1. The supplier must have an annual operating budget, as appropriate to the business's size and scope of services, to meet the needs of patients and maintain business operations.

B.2.2. Management must periodically review the business's actual financial performance in relation to the operating budget, making adjustments as necessary utilizing year-end projections on services and appropriate infrastructure to determine budget variance.

B.3.0. Income Statements and Balance Sheets

B.3.1. The supplier must periodically produce financial statements that include a balance sheet denoting the company's assets and liabilities and an income statement reflecting the revenue earned over a specific time period. Guidelines for corporate balance sheets are provided by the **International Accounting Standards Committee (IASC)**.

IASC Website:
http://www.iasplus.com/standard/standard.htm

B.3.2. The supplier's financial statements should all be related so that changes in assets and liabilities on the balance sheet will also be reflected

in the revenues and expenses reported on the income statement, showing the company's gains or losses.

B.4.0. Service Contracts

B.4.1. The supplier must maintain **service contracts**, as needed. The supplier should ensure that contracts specify job requirements, including policies and related qualifications for contracted personnel to include necessary licensures and certifications. The contracts must be signed by both parties with the date of execution noted.

Service Contracts: Agreements between the supplier and outside entities to perform certain functions at an agreed price over a fixed period of time (e.g., delivery, repair and maintenance).

Section C. Human Resource Management

C.1.0. The supplier must document the individual skills, qualifications, health assurances, and number and types of personnel needed. These are defined by the mission, scope, complexity of services, equipment and products provided, and laws and regulations, as applicable. This applies to all employees and contractors. A supplier must maintain a personnel file on each employee.

C.1.1. All technical personnel must be competent to deliver and set up equipment and train patients or caregivers on the proper use and care of the equipment. The supplier must monitor performance in providing patient services. The supplier must document personnel issues and how they are addressed within individual employee records and implement procedures for similarly established compliance among contractors.

C.1.2. Where applicable, each supplier location must employ or have access to the employed services of at least one credentialed practitioner who is certified, licensed or registered to provide respective patient care. Each location must have at least one credentialed practitioner either on site or off site during regular business hours.

C.1.3. The supplier may employ credentialed or non-credentialed **privileged personnel** to provide orthotic or prosthetic patient care with either direct or indirect supervision. Direct supervision occurs on site and in person while indirect supervision means the supervising practitioner is readily available for consultation. A designated credentialed practitioner or supervisor is a certified, licensed or registered orthotist or prosthetist who directly or indirectly supervises credentialed or non-credentialed privileged personnel to provide patient care.

Privileged personnel: Individuals who provide patient care within the scope of practice for orthotics or prosthetics under the direct or indirect supervision of a designated credentialed practitioner. Privileged individuals' competency is determined by the supervising practitioner, who is responsible for clinical actions taken.

C.1.4. The designated supervisor is responsible for the specific training/education taken by privileged personnel. The designated supervisor must document the training/education in the form of **written objective criteria** in the privileged personnel's employee file. Documentation may be in the form of the following, each specific to the patient care service:

Written objective criteria: The means by which privileged personnel are assessed. This documentation must show the knowledge and skill required to provide a specific patient care service and must be related to the associated diagnosis.

- Proof of completion of continuing education courses
- Documented in-house/in-service training
- Documented work experience

C.1.5. The supplier must comply with all applicable federal and state licensure regulations. When off site, the credentialed practitioner or supervisor will be available for on-site patient care services within a reasonable travel time or will be accessible via **telemedicine** to respond to on-site consultative needs.

Telemedicine: The use of communications and information technologies for the delivery of clinical care; it may be as simple as professionals discussing a case together over the phone or as complex as using videoconferencing equipment to conduct real-time consultations.

C.2.0. Competency Assessments and Continuing Education

C.2.1. The supplier must develop, implement and maintain a written staff education for all employees, specific to the respective responsibilities and the individual tasks and services provided to patients.

C.2.2. The staff education plan informs employees of requirements for safe and competent patient services based on criteria derived from standards, clinical manuals, manufacturers' guidelines, etc. It should also include prevention and control of infection, patient rights and HIV/AIDS education.

C.3.0. Licenses, Registrations and Certifications

C.3.1. The supplier must display all federal, state or local licenses, registrations, or certifications in public view as required. For more information on licensure, visit Palmetto GBA **licensure page**.

Palmetto GBA

www.palmettogba.com

C.4.0. Employee Manual

C.4.1. A supplier must provide a manual to each employee that includes the following:

- Job descriptions for each position
- Policies and procedures
- Facility hours of business and closures
- Emergency contacts
- Employee benefits
- Health assurance

C.5.0. Background Checks

C.5.1. The supplier must conduct background checks and **Office of the Inspector General (OIG)** exclusion list reviews for all employees and contractors as required by law or regulation.

OIG Website:
http://exclusions.oig.hhs.gov

Section D. Consumer Services

D.1.0. The supplier must ensure that any healthcare professional staff member providing patient care services complete continuing education consistent with the **specialized equipment** and services provided.

D.1.1. The supplier must have policies and procedures, in compliance with the appropriate provisions and requirements of the CMS Quality Standards and Supplier Standards, in effect. The supplier must provide a copy of CMS Supplier Standards to each patient who receives a Medicare-covered item. (CMS Supplier Standard #16, #24)

D.1.2. The supplier must implement and maintain a management program for equipment and items that promotes safe use and minimizes infections and hazards for its staff and patients.

D.1.3. The supplier must advise each patient to follow up with his or her prescribing physician for additional instructions.

A supplier that provides equipment or services must provide the following to patients and caregivers:

- Instructions
- Information regarding expected delivery time
- Verification of receipt
- Documentation of make and model of equipment
- Option to rent or purchase equipment, when applicable
- Contact information for regular business hours and after hours
- (CMS Supplier Standard #5)

D.2.0. Patient Training and Education

D.2.1. The supplier must document that it or another qualified party has provided patients with necessary information and instructions on how to use prescribed devices safely and effectively. The supplier is responsible for the delivery and instruction of items and for maintaining the proper documentation. (CMS Supplier Standard #12)

D.3.0. Plan of Care

D.3.1. Depending on federal, state, and local laws and regulations, credentialed healthcare professionals should perform the initial setup via an assessment by instructing and monitoring the patient and caregiver. Patients are to be monitored according to physician orders and manufacturer's instructions after the initial evaluation to identify and resolve potential problems and assess the continued quality of patient care.

D.3.2. The supplier must consult with the prescribing physician before finalizing the service plan if it differs from the physician's order. Special attention should be given to the family support system, the patient's abilities and readiness to learn, the barriers and safety hazards in the home environment and any other relevant information that may affect the goal. When the supplier cannot or will not provide equipment or services that are prescribed for the patient, the supplier must notify the prescribing physician, practitioner or other healthcare team member promptly (i.e., within five business days).

D.3.3. The supplier must formulate a treatment plan that is consistent with the prescribing physician's dispensing order or the written plan of care, in accordance with Medicare rules, and must consult the physician when appropriate.

D.3.4. Training materials must be tailored to the needs, abilities and languages of the patients or caregivers and may include:

- Procedures to follow in case of emergency
- Infection prevention and control

- Habilitation and rehabilitation techniques
- Instructions for use of supplies needed to attach, maintain and clean devices
- Instructions for reporting changes in the patient's condition
- Established goals and outcomes for the patient

D.4.0. Coordination of Healthcare with the Physician

D.4.1. The communication between the supplier and the prescribing physician is extremely important. All communication is to be documented in the patient's file. At no time can a patient's prescription be altered by the supplier. If a change of prescription is agreed upon between the supplier and the physician due to the patient's needs or abilities, the physician must submit a replacement prescription to the patient or supplier prior to the patient receiving his or her device or equipment. A **Certificate of Medical Necessity (CMN)** must be kept in the patient's records along with the physician's prescription, maintained and updated by the physician as deemed necessary.

CMN: A document completed and signed by the prescribing physician that verifies the patient's need for durable medical equipment.

D.5.0. Verification of Delivery

D.5.1. The supplier is responsible for the delivery of and instruction for items and for maintaining the proper documentation in patient records. (CMS Supplier Standard #12)

D.5.2. The supplier must ensure that the item delivered is consistent with the prescribing physician's orders and identify the patient's needs, risks and limitations. The supplier must provide associated supplies (e.g., adhesives, solvents, lubricants) to attach, maintain and clean the items as necessary.

D.6.0. Preventative Maintenance

D.6.1. The supplier must provide instructions related to setup, features, routine use, troubleshooting, cleaning, infection control and maintenance of the equipment provided. The supplier must identify, monitor and report equipment and item failure, repair, and preventative maintenance for items provided to patients.

D.7.0. Emergency Management Plan

D.7.1. The supplier must have a written plan with procedures enabling it to maintain operations and provide continuing patient care and support in the event of a disaster or emergency. The plan may include arrangements with alternative suppliers in the event the supplier cannot service its patients. The initiation, development and maintenance of this plan should be in consultation with the state or county emergency management agency.

Section E. Performance Management

E.1.0. The supplier must implement a performance management plan that measures consumer services, billing practices and adverse events. Certain aspects of services that have an increased potential to cause harm or injury or that create a greater-than-expected number of adjustments, repairs or replacements must be documented and improved.

E.1.1. The supplier must measure patient satisfaction, problems and concerns. The frequency of billing and coding errors must be documented and corrected.

E.1.2. The supplier must seek input from staff, patients and outside sources when assessing the quality of its operations and services. Annually, the supplier must evaluate its performance with respect to its mission, goals and objectives.

E.2.0. Consumer Surveys

E.2.1. The supplier must generate data from patient satisfaction surveys and complaints about products and services. Data should be gathered regarding response times to patient questions, problems and concerns. Data should reflect the impact of supplier's business practices on the adequacy of patient access to DMEPOS items, services and information. (CMS Supplier Standard #13)

E.2.2. The supplier must agree not to contact a patient by telephone when supplying a Medicare-covered item unless one of the following applies: (CMS Supplier Standard #11)

- The individual has given written permission to the supplier to contact them concerning the furnishing of a Medicare-covered item
- The supplier is contacting the individual to coordinate the delivery of the item
- The contact concerns the furnishing of a Medicare-covered item other than those already furnished to the individual
- Suppliers using leads from a third party (e.g., website, television, advertisements) must include in the patient file evidence of the beneficiary's written consent to be contacted regarding the suppling of equipment. The beneficiary's consent must include:
    - The name of the specific DMEPOS supplier to which they are giving the consent
    - A clear statement that the beneficiary authorizes the named supplier to contact them regarding medical equipment

E.3.0. Adverse Events

E.3.1. The supplier must implement a policy and procedure for avoiding **adverse events** to patients due to inadequate or malfunctioning equipment, items or services. The supplier must keep records of all adverse

Adverse Events: Unfavorable occurrences in which a patient is injured, or a patient's condition is worsened due to faulty equipment or inappropriate fitting of an O&P device.

events that occur in the use of prescribed equipment, including date, nature of the event and resolution.

E.3.2. A physician may prescribe a particular brand and method of use for an item if the physician determines that this specification would avoid an adverse medical outcome. The specification reasoning must be documented in the patient's record. Any change in the prescription requires a revised written prescription by the physician.

E.4.0. Incident Report

E.4.1. The supplier must define and implement a process for identifying, analyzing, reporting, managing and preventing incidents. This includes a risk-reduction strategy and action plan that measures the effectiveness of process and system improvements.

E.4.2. Data collected will measure potentially high-risk processes (e.g., blood-borne pathogens). Analyzing the collected data will assist the supplier in determining whether there are unacceptable levels of performance.

E.4.3. The supplier must investigate any incident or injury in which the equipment provided may have been involved. The investigation must be initiated within 24 hours of the supplier's awareness of the incident, injury or infection resulting in the patient's hospitalization or death. Other incidents, injuries or infections must be investigated within 72 hours of supplier awareness.

E.5.0. Complaint Resolution

E.5.1. The supplier must respond to a complaint within five business days. **Complaint records** must be kept at the supplier's physical location and made available to CMS or BOC upon request.

Complaint records must contain the following:

- Patient's name, address, telephone number and insurance claim number
- Date received, name of the person receiving the complaint, as well as a summary of the complaint and resolution
- Supplier respondent's name
- Summary of investigation
- (CMS Supplier Standard #20)

E.5.2. The supplier must provide written notification to the patient regarding the results of its investigation within 14 calendar days if an investigation has occurred. (CMS Supplier Standard #19)

E.5.3. CMS Hotline: 1-800-Medicare / BOC: 1-877-776-2200. The complaint policies should include contact telephone numbers for BOC, CMS and the specific state consumer hotline.

E.6.0. Vehicle Maintenance, Use and Documentation

E.6.1. Delivery vehicles must be supplied with a first aid kit, eye wash, fire extinguisher, cleaning and disinfectant supplies, and exam gloves. The vehicle must be clean and maintained in a safe condition.

E.6.2. Clean and contaminated equipment must be separated during transportation and placed on flooring material that is easily disinfected. No carpeting can be used in the equipment storage areas. Contaminated

equipment should be covered in plastic to avoid contact with non-contaminated items.

Section F. Product Safety

F.1.0. The supplier must implement an equipment management program that promotes the safe use of equipment for staff and patients. The supplier must document and log equipment failure. The supplier must provide education and training that details all the risks and manufacturer recommendations for DMEPOS items.

F.2.0. Maintenance Plan

F.2.1. The supplier must perform preventative and routine maintenance according to the manufacturer's guidelines. All medical equipment should be inspected for safety between patient uses. The inspection should be documented for ongoing maintenance and testing procedures.

F.2.2. When storing equipment, separate items according to the following designations: patient-ready and dirty equipment, cleaning and disinfecting equipment, damaged equipment, and obsolete inventory.

F.2.3. Considerations must be made for temperature requirements, expiration dates and maintenance of battery charges. Equipment must be checked in intervals based on manufacturers' recommendations, risk levels and amount of use.

F.2.4. All medical equipment provided to patients must be documented and tracked upon delivery and pick up. In the case of recall, equipment is to be tracked by make, model and serial number. Staff, patients, caregivers and prescribing physicians are to be notified by the Compliance Officer in the case of equipment hazard notices and recalls.

For information on the Safe Medical Devices Act of 1990, visit:
http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm

F.2.5. Monitoring and reporting incidents in which a medical device is connected to serious illness, injury or death should meet the requirements of the **Safe Medical Devices Act of 1990**.

F.2.6. The supplier must conduct a home assessment to determine adequacy of home care by evaluating the following:

- Electrical compatibility
- Exposure to liquids
- Specific electrical and power requirements for equipment such as ventilators, oxygen concentrators and infusion pumps
- Battery condition and charge

F.3.0. Safety of the Workplace

F.3.1. The supplier must provide a place of employment that is free from hazards and complies with standards, rules and regulations issued under the OSHA Act.

The supplier must conduct a workplace hazard assessment to ensure compliance with OSHA.

F.4.0. Retired and Expired Items

F.4.1. The supplier must use the information from the item management plan to identify and implement changes that will improve care, treatment and service. The supplier must have a plan to remove, quarantine and destroy expired or retired items from its inventory.

F.5.0. Exposure Control Plan

F.5.1. The supplier must be committed to providing a safe and healthy work environment for the entire staff. In pursuit of this goal, the supplier must create an **Exposure Control Plan (ECP)** to eliminate or minimize occupational exposure to blood-borne pathogens in accordance with OSHA Standard 29 CFR 1910.1030.

ECP Website: http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=10051

F.5.2. The supplier must have a copy of the ECP accessible to employees in compliance with appropriate OSHA standards.

F.5.3. Universal precautions must be observed to prevent contact with blood or other potentially infectious materials. The ECP must be reviewed and updated annually to reflect new or modified tasks and procedures that affect occupational exposure.

F.5.4. The supplier must provide hand-washing stations and personal protective equipment, such as gloves, gowns, lab coats, face masks and eye protection, according to the care provided.

The facility must be clean and sanitary. Newly received equipment for patient use must be kept in a clean area, separated from dirty or used equipment. Clean equipment must be kept covered until it is used.

F.6.0. Hazard Communication

F.6.1. The supplier must maintain a written hazard communication plan that describes how the OSHA Hazard Communication Standard (HCS) will be implemented. Suppliers are responsible for informing and training employees on potential hazards associated with the chemicals currently in their facility.

SDS: Detailed information bulletins prepared by the manufacturer of a chemical describing the physical and chemical properties, physical and health hazards, routes of exposure, precautions for safe handling and use, emergency and first-aid procedures, and control measures.

F.6.2. A manual of hazardous materials must be clearly posted and available to employees; warning signs should be posted in appropriate areas. The inventory must include **Material Safety Data Sheets (MSDS) or Safety Data Sheets (SDS)**.

F.6.3. Each hazardous material must be labeled, tagged or marked with the identity of the material and appropriate hazard warning. If the material is transferred by the supplier from the original container to another container, all information must be clearly marked on the new container. Injuries or chemical exposures must be documented on an Incident Report Form.

F.6.4. A **Hazardous Communication Manual (HCM)** describes how the requirements for warnings, MSDS, employee information and training will be met.

The HCM must include:
- The person responsible for ensuring labeling of containers
- The location of hazardous materials
- A description of the labeling system
- The procedure for reviewing and updating label information
- Safety rules and procedures, including the clean up and disposal of hazardous materials
- The procedure for reporting noncompliance
- The appropriate steps to limit exposure to employees
- The location of protective equipment
- A plan for emergency evacuation
- A list of emergency telephone numbers

F.7.0. Employee Information and Training

F.7.1. All employees with occupational exposure must participate in training programs provided at no cost to the employee and during working hours by the supplier. Employees who may be exposed to hazardous chemicals when working must be provided information and training prior to the initial assignment to work with a hazardous chemical, as well as when hazards change.

Section G. Information Management

G.1.0. Patient's Bill of Rights and Responsibilities

G.1.1. The supplier must develop a Patient's Bill of Rights and Responsibilities to be given to each patient served that includes information on individual dignity, financial information and disclosure, access to healthcare, and experimental research. The supplier must have the patient sign for the receipt and understanding of the Patient's Bill of Rights and Responsibilities; verification must be kept in the patient's file.

G.2.0. Business Associate Agreement

G.2.1. The supplier must obtain satisfactory assurances from its business associates that they will safeguard the protected health information received or created on behalf of the covered supplier. Satisfactory assurances must be in writing in the form of a contract or other agreement between the supplier and the business associate.

HIPAA Website: https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html

G.3.0. HIPAA

G.3.1. For information on HIPAA standards, refer to the **HIPAA website**.

G.4.0. Confidentiality Responsibilities

G.4.1. The supplier must have appropriate administrative, technical and physical safeguards in place that protect against uses and disclosures not permitted by HIPAA. Supplier safeguards are not expected to guarantee the privacy of protected health information from any and all potential risks.

G.4.2. Reasonable safeguards vary from supplier to supplier, depending on factors (e.g., size of facility or nature of business). In implementing

reasonable safeguards, the supplier must analyze its own needs and circumstances, including the nature of the protected health information it holds, and assess the potential risks to patients' privacy.

G.5.0. Internet and Email Policies

G.5.1. CMS has delegated authority to enforce the HIPAA Security Standards for safeguarding the confidentiality, integrity and availability of Electronic Protected Health Information (EPHI). The supplier that conducts business activities by portable media and devices, laptops, personal digital assistants, home computers or other non-corporate equipment must follow HIPAA standards and train its employees accordingly.

HIPAA security and privacy rules: http://www.hhs.gov/ocr/privacy/hipaa/understanding/srsummary.html

G.5.2. Training must cover policies prohibiting use over open networks (e.g., internet and email) and downloading to public or remote computers. Refer to **HIPAA Security Rule 164.308(a)(4) and HIPAA Privacy Rule 164.508** in regard to implementation of policies and procedures for authorizing EPHI access, including information on safeguards to be implemented.

G.5.3. Other devices that may be causes of concern due to vulnerability include: smart phones, flash drives, memory cards, CDs, DVDs, back-up media, email accounts and other remote access devices. Hotel, library or other public workstations are also included.

G.6.0. Records Storage and Shredding

G.6.1. The supplier must maintain accurate, confidential and secure records in accordance with HIPAA and other applicable state standards. The supplier must take reasonable measures to store records in a location and manner that minimizes damage from fire, water or natural disaster. Personal information that is not stored in a patient's record and is discarded must be shredded.

Part 2. Service Requirements

Section A. Supplier and Physician Collaboration

A.1.0. The supplier, in collaboration with the prescribing physician, must review the patient's record and incorporate any necessary revisions related to the patient's condition that affect the equipment or services provided. (CMS Supplier Standard #28)

A.1.1. The supplier must review the patient's record and incorporate any necessary information related to the patient's condition that affects the provision of the DMEPOS and related services, or to the actual items or services provided.

A.2.0. CMN

A.2.1. The supplier must complete the appropriate sections based on CMN instructions and submit them to the referring physician for review, completion (as needed) and the physician's signature. The supplier must have a photocopy, facsimile or original signed order in the patient's record. The supplier must meet Chapter 5 of Medicare's **Program Integrity Manual**. (CMS Supplier Standard #28)

Program Integrity Manual Website: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019033.html

A.3.0. Confirmation of Physician's Orders

A.3.1. The supplier must communicate with the prescribing physician before finalizing a treatment plan. Any changes or suggestions should be discussed and approved by the physician in writing. Documentation must be noted in the patient's file.

A.3.2. The supplier must refer the patient to the prescribing physician for intervention or treatment beyond the supplier's scope of practice.

A.4.0. Coordination

A.4.1. The supplier must incorporate information from other healthcare team members in the delivery of the device or equipment. The supplier must solicit feedback from the physician to determine the effectiveness of the device provided to the patient.

Section B. Product Information, Delivery and Documentation

B.1.0. Order Intake Form

B.1.1. The supplier may develop and use an **order intake form** during the initial evaluation of the patient.

Order Intake Forms may include:

- Type of equipment and service prescribed
- Pertinent diagnoses, including mental status
- Frequency of visits
- Prognoses
- Potential for rehabilitation
- Functional limitations
- Permitted activities
- Safety measures to protect against injury
- Instructions

B.2.0. Patient Instructions for Equipment Use

B.2.1. The supplier must provide or coordinate the provision of appropriate information related to the setup, features, routine use, troubleshooting, cleaning and maintenance of items provided. The supplier must advise the patient or caregiver of any safety considerations and provide relevant information and instructions on infection control. A notation of instructions given to the patient or caregiver should be documented in the patient's file.

B.3.0. Release of Information

B.3.1. The HIPAA Privacy Rule allows a supplier to obtain patient consent for uses and disclosures of protected health information for treatment, payment or healthcare operations. Suppliers that do so have complete discretion to design a process that best suits their needs.

B.3.2. By contrast, an **authorization** is required by the HIPAA Privacy Rule for uses and disclosures of protected health information not otherwise

Authorization: A detailed document that gives suppliers permission to use protected health information for specified purposes, which are generally those other than treatment, payment or healthcare operations, or to disclose protected health information to a third party specified by the patient.

allowed by the HIPAA Privacy Rule. An authorization must include: a description of the protected health information to be used and disclosed, the person authorized to make the use or disclosure, the person to whom the supplier may make the disclosure, an expiration date and, in some cases, the purpose for which the information may be used or disclosed.

B.4.0. Patient Record

B.4.1. The supplier must develop patient records that are kept in a locked file cabinet or locked room. The patient record should have an information form, physicians' prescriptions, a CMN, a detailed written order, practitioner notes, delivery tickets, measurements, pretreatment photographs when appropriate, medical history, a signed HIPAA form, instructions for use and care of equipment and billing information.

B.5.0. Warranty, Repair and Return Policies

B.5.1. The supplier must honor all warranties expressed and implied under applicable federal, state or local laws and regulations. A supplier must not charge the patient, the Medicare program or third-party payors for the repair or replacement of Medicare-covered items or for services covered under warranty. The supplier must provide upon request documentation that it has provided patients with information about items covered under warranty, in the form of copies of letters, logs or signed notices. (CMS Supplier Standard #6, #14)

B.5.2. The item must function as required and intended after being repaired or replaced. This standard applies to all purchased and rented items. The supplier must provide or arrange for loaned equipment that is equal to the originally prescribed items, with the exception of orthotics and prosthetics. The supplier may contract with a qualified entity to repair or service equipment. The supplier must accept returns for items of substandard quality from patients. (CMS Supplier Standard #14, #15)

B.6.0. Mail Orders

B.6.1. For initial equipment or items provided by mail order delivery, the supplier must verify and document in the patient's chart that the patient and caregiver have received all instructions.

B.6.2. The supplier must ensure the patient and caregiver are able to use all prescribed items safely and effectively.

Section C. Follow Up

C.1.0. The supplier must provide appropriate patient follow-up care consistent with the services rendered. The supplier must inform the patient or caregiver of the procedures for repairing, replacing and adjusting the device or equipment, as well as the possible risks.

C.1.1. The supplier must give instructions on reporting any problem to the supplier or referring physician. (CMS Supplier Standard #28)

C.2.0. Training to Patient or Caregiver

C.2.1. Patient and caregiver training should be performed by a credentialed practitioner as required. The credentialed practitioner is to monitor the patient and recommend changes as needed.

C.2.2. Training should be done as often as requested by the patient, caregiver or physician until objectives of the training are reached. Detailed clinical notes of all training and outcomes should be kept in the patient's file.

C.3.0. After-Hours Emergency Care

C.3.1. The supplier must provide patients with a telephone number to be used in the case of an emergency after facility business hours. This number should be an **answering service** able to contact the supplier at all times by beeper, home phone or cell phone.

The answering service should always be kept informed of the on-call schedule.

C.3.2. The emergency number is to be provided to the patient in written form upon delivery of an item and should be clearly noted on the facility's exterior entrance.

C.3.3. All emergency situations are to be addressed immediately and documented by the supplier in an emergency log and in the patient's record. Documentation should indicate the reason for the emergency, the action taken and the follow up with the patient.

Part 3. Product-Specific Service Requirements

Section A. Respiratory Services

The supplier must follow CMS quality standards as written in Section A.

A.1.0. Respiratory Services encompasses the provision of HME and supplies that require technical and professional services. The supplier must provide respiratory services 24 hours a day, seven days a week as needed by the patient or caregiver.

A.2.0. Oxygen Therapy in the Home

A.2.1. HME and supplies covered in this section include:

- Oxygen concentrators, reservoirs, high-pressure cylinders, oxygen accessories and supplies, and oxygen conserving devices

- Home Invasive Mechanical Ventilators
- Continuous Positive Airway Pressure (CPAP) Devices
- Respiratory Assist Devices (RADs)
- Intermittent Positive Pressure Breathing (IPPB) Devices
- Nebulizers

A.3.0. Instruction and Delivery

A.3.1. The supplier must provide training to the patient or caregiver in compliance with the most current *American Association for Respiratory Care Practice Guidelines*. This includes guidelines for long-term invasive mechanical ventilation in the home, oxygen therapy in the home or extended-care facility, IPPB devices, providing patient and caregiver training, and suctioning of the patient in the home as required by state. (CMS Supplier Standard #27)

A.3.2. The supplier must employ a credentialed professional (e.g., respiratory therapist, respiratory therapy technician or respiratory care practitioner) or other state-required personnel. The use of contracted professionals in states where certification or license is required is allowed unless prohibited by state regulation.

A.3.3. For oxygen delivery, the supplier must meet Department of Transportation Pipeline and Hazardous Materials Safety Administration **Standard 49 CFR 195**.

Standard 49 CFR 195 Website: https://www.phmsa.dot.gov/pipeline/annotated-regulations/49-cfr-195

A.4.0. Emergency Maintenance and Back-Up Systems

A.4.1. The supplier must ensure that patients receiving oxygen have ample back-up parts or supplies to meet their needs, in case of equipment failure, emergency or disaster, relative to the supplier's maximum anticipated response time.

A.4.2. For oxygen patients, the supplier must provide emergency maintenance, replacement equipment or a back-up system in a timely manner to prevent an interruption in prescription requirements. Calibration of all respiratory equipment must be performed by a credentialed practitioner or respiratory therapist.

A.4.3. The supplier must develop and maintain a plan for maintaining respiratory equipment that includes the daily inspection of equipment, the service of equipment according to manufacturers' instructions, a back-up system and an emergency plan. Refer to the **American Association of Respiratory Therapist Guidelines**.

American Association of Respiratory Therapist Guidelines Website: http://www.aarc.org/

A.5.0. Oxygen Safety and Hazard Information

A.5.1. The supplier must warn patients and caregivers of hazards associated with the use of oxygen and respiratory equipment. "No smoking"

signs must be posted in surrounding areas. Equipment must be checked according to the equipment manufacturer's recommendations or annually, at a minimum.

A.6.0. Record Keeping

A.6.1. The supplier must show the disbursement of equipment and oxygen in a log and track it in case of recall by the manufacturer. Maintenance, repair and calibration must be recorded in both the patient's record and on the equipment inventory log. The calibration of oxygen is to be checked according to established manufacturer guidelines.

Section B. Complex Rehabilitation-Assistive Technology, Manual Wheelchairs and Power Mobility Devices

The supplier must follow CMS Quality Standards as written in Section B.

B.1.0. Intake and Assessment

B.1.1. The supplier must verify that seating, positioning and specialty assistive technology have been evaluated and documented in the patient's record.

B.2.0. Personnel and Assessment Requirements

B.2.1. The supplier providing complex rehabilitative wheelchairs and assistive technology must employ (W2 employees) at least one qualified individual as a Certified **Rehabilitative Technology Supplier (CRTS)** per location.

Qualified RTS: An individual that is a CRTS or an Assistive Technology Professional.

B.2.2. The CRTS must have at least one trained technician available to service each location appropriately depending on the size and scope of the business. A trained technician is identified by the following:

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

B.2.3. The CRTS must coordinate services with the prescribing physician to conduct face-to-face evaluations of the patient in an appropriate setting and include input from other members of the healthcare team (e.g., physical therapist or occupational therapist) to provide the patient with appropriate

equipment for trial and simulation. The CRTS must maintain all of the information obtained during the assessment in the patient's record.

B.2.4. The CRTS must implement procedures for assembly and setup of equipment and a process to verify that the final product meets the specifications of the original product recommendation approved by the prescribing physician.

B.2.5. If a patient is evaluated in the supplier's facility, the supplier must provide private, clean and safe rooms appropriate for fittings and evaluations. The CRTS must maintain a repair shop located in the facility or easily accessible from another location of the supplier, as well as an area appropriate for assembly and modification of products.

B.3.0. Delivery and Set Up

B.3.1. For suppliers of complex rehabilitation and assistive technology, the supplier must include information from other healthcare team members (e.g., physical therapists or occupational therapists) and the prescribing physician upon the delivery of the device or equipment.

Section C. Custom-Fabricated and Custom-Fitted Orthotic and Prosthetic Devices, External Breast Prostheses, and Therapeutic Shoes and Inserts; Custom-Made Somatic, Ocular and Facial Prostheses

The supplier must follow CMS Quality Standards as written in Section C.

C.1.0. Personnel Requirements

C.1.1. The supplier must be trained in a broad range of treatment options to ensure that the items prescribed are optimal for the patient's condition. The provision of custom-fabricated or custom-fitted devices (i.e., those other than off-the-shelf items) requires access to a facility with the equipment necessary to fulfill the supplier's responsibility to provide follow-up treatment. This includes modification, adjustment, maintenance and repair of the items. Credentialed individuals supplying these items must possess specialized education, training and experience in fitting.

C.2.0. Intake and Assessment

C.2.1 The supplier must assess the patient's need for and use of the orthoses and prostheses, including comprehensive history and pertinent medical history, such as allergies, skin conditions, diagnoses, results of diagnostic evaluations, patient expectations and pre-treatment photographic documentation when appropriate.

C.2.2. The supplier must determine the appropriate orthoses or prostheses and specifications based on the patient's need for use to ensure optimum therapeutic benefits and appropriate strength, durability and function as

required. The supplier must also formulate a treatment plan that is consistent with the prescribing physician's dispensing order or the written plan of care, in accordance with Medicare rules, and consult the physician when appropriate.

C.2.3. The supplier must perform an in-person diagnostic examination related to the patient's use and need of the orthoses or prostheses, including sensory function, range of motion, joint stability, skin condition, presence of edema or wounds, vascularity, pain, manual muscle testing, and cognitive ability.

C.2.4. The supplier must establish goals and expected outcomes for the patient's use of the orthoses or prostheses, including pain reduction and comfort, enhancement of function, joint stability, prevention of deformity, and cosmetic issues. The supplier must seek feedback from the patient or prescribing physician as necessary to determine the appropriateness of the orthoses or prostheses.

C.2.5. The supplier must communicate the recommended treatment plan, including disclosure of potential risk, benefits and precautions, as well as procedures for repairing, replacing or adjusting items and the estimated time involved in the process to the patient, caregiver and prescribing physician. The supplier must ensure the treatment plan is consistent with the prescribing physician's dispensing order.

C.2.6. The supplier must assess the orthoses or prostheses for structural safety and ensure that manufacturer guidelines are followed (e.g., proper closure function and patient weight limits) prior to the face-to-face fitting and delivery.

C.3.0. Training and Instruction

C.3.1. The supplier must provide instructions to the patient or caregiver for the specific orthoses, prostheses or therapeutic shoe inserts as follows:

- Using, maintaining and cleaning the orthoses or prostheses
- Putting on, adjusting and taking off orthoses and prostheses
- Inspecting the skin for pressure areas, redness, irritation, pain or edema
- Using an appropriate interface (e.g., socks, gloves or shoes)
- Reporting problems related to the orthoses or prostheses
- Scheduling follow-up appointments as necessary
- Establishing an appropriate "wear schedule"

C.3.2. The supplier must provide the necessary supplies to attach, maintain and clean the items, as applicable, and provide information about how to subsequently obtain the necessary supplies. The supplier must refer the

patient to the prescribing physician as necessary for intervention beyond the supplier's scope of practice.

C.4.0. Follow Up

C.4.1. The supplier must have access to a facility with the equipment necessary to provide follow-up treatment and fabrication or modification of the specific orthoses and prostheses.

C.4.2. The supplier must follow these steps:

Step 1: Review recommended maintenance with the patient or caregiver.

Step 2: Solicit feedback from the patient, caregiver or prescribing physician as necessary to determine the effectiveness of the orthoses or prostheses.

Step 3: Review and change the treatment plan based on the patient's condition.

Step 4: Continue to assist the patient until the orthoses or prostheses reach the optimal level of fit and function.

Step 5: Provide appropriate patient follow-up treatment.

Part 4. State of Florida – Specific Service Requirements

Section A. Business Administration (Florida Specific)

A.1.0. Change of Ownership

A.1.1. The provider shall notify the Agency for Health Care Administration (AHCA) (or "Agency") in writing at least 60 calendar days before the anticipated date of the change of ownership. BOC must immediately notify the Agency of a provider's unreported change of ownership as defined by Florida Statutes.

A.2.0. Change of Address

A.2.1. Until HME rules are revised, change of address requests must be received no less than 24 hours in advance (not 21–120 calendar days as currently stated); failure to report in a timely manner will result in a $500 fine. Failure to amend a license prior to changing the address of record constitutes unlicensed activity.

A.3.0. Reporting Changes

A.3.1. Changes must be reported 21 calendar days after the report period or the effective date of information, whichever is earlier. These changes

include but are not limited to any change of information contained in most recent application for licensure or required insurance. The provider must inform the Agency no less than 30 calendar days prior to discontinuance of operation and inform clients of such discontinuance.

Section B. Standard Business Practices (Florida Specific)

B.1.0. Standard Business Practices

B.1.1. HME locations that require a license are any locations in-state or out-of-state that rent, sell, distribute, or offer to rent or sell to or for a consumer durable HME that requires services. The provider must have at least one category of equipment that is provided directly, filling orders from its own inventory. A separate license is required for all HME providers operating on separate premises.

B.1.2. The AHCA licensee must notify the Agency within 45 calendar days of a change of the general manager.

B.1.3. Commercial and professional liability insurance must be maintained at all times in an amount equal or greater than $250,000 per claim. Insurance must be in the name of the provider/licensee and at the address to be licensed.

B.1.4. Maintain a listing of those whom the applicant contracts. This includes both the providers who provide equipment or services and the providers for whom the applicant provides services or equipment. The contractor must have liability insurance not less than $250,000 per claim. The contract must be a written agreement describing equipment or services to be provided by the contractor. This includes the designation of monitoring and charging/billing responsibilities, management of records, the contract period, procedures for reporting service and maintenance, and notes, dates and signatures of all parties. Retain contracts for a minimum of five years.

B.1.5. All providers must have available at the time of survey at least one category of equipment that is provided directly, filling orders from its own inventory. Failure to comply will result in provider's application being denied or revocation of its license.

Section C. General Manager Requirements

C.1.0. Qualifications

C.1.1. A minimum of two years' experience in business management or a college degree in business or a healthcare-related field can substitute for the required experience year for year.

C.2.0. Duties

C.2.1. The general manager is responsible for the following areas either directly or by clear delegation in writing:

- Assuring the maintenance of consumer records including equipment repair and maintenance records as referenced in Florida Statute Section 400.94.
- Maintaining job descriptions of staff; assuring trained and qualified staff essential to the services provided as referenced in Florida Statute Sections 400.934(4), (5), (15).
- Keeping program personnel up to date with healthcare information and practices
- Directing staff in performance of their duties
- Assuring that staff can accommodate all consumers' languages
- Assuring an adequate inventory of equipment and supplies to provide consumers currently being served
- Assuring that policies are developed and implemented as required in state law and rule
- Maintaining and updating procedural manuals related to business functions
- Maintaining customer service complaint records containing the specifics related to the complaint and how the complaint was resolved.

C.3.0. Responsibilities

C.3.1. The general manager is responsible for the general administering to personnel directly or by clear delegation in written form.

Section D. Reporting Unlicensed Providers (Florida Specific)

D.1.0. Any person aware of the operation of an unlicensed provider must report that provider to the Agency. Providers must report unlicensed HME providers to the AHCA Consumer Complaint, Publication and Information Call Center at the toll-free number of 1(888) 419-3456 or the local number of (850) 487-3183.

D.1.1. The right of inspection extends to any business that the Agency has reason to believe is being operated as a provider without a license, but the inspection of any business suspected of operating without the appropriate license may not be made without the permission of the owner or person in charge unless a warrant is fist obtained from a circuit court. All inspections shall be unannounced except as specified in Florida Statute Section 408.806. Inspections for re-licensure are conducted biannually.

D.1.2. The licensee must also inform the clients of discontinuance of operations by notice published at least once a week for four consecutive weeks in the newspaper of greatest general circulation in the county in which the provider was located. Alternatively, the licensee or, in the event of death or dissolution of a licensee, the estate or agent of the licensee shall make arrangements to forward records for each client based on client's choice. The licensee shall be responsible for retaining and appropriately distributing all records within the timeframes prescribed in authorizing statutes and applicable rules.

D.1.3. BOC must immediately report any evidence of unlicensed activity to include unreported changes of ownership. Specify the grounds for denial and/or revocation.

Section E. Moratorium or Emergency Suspension (Florida Specific)

E.1.0. The Agency may impose an immediate moratorium or emergency suspension as defined in Florida Statue Section 120.60 on any provider if the Agency determines that any condition related to the provider or licensee presents a threat to the health, safety or welfare of a client.

E.1.1. A provider or licensee, the license of which is denied or revoked, may be subject to immediate imposition of a moratorium or emergency suspension to run concurrently with licensure denial, revocation or injunction.

E.1.2. A moratorium or emergency suspension remains in effect after a change of ownership, unless the Agency has determined that the conditions that created the moratorium, emergency suspension or denial of licensure have been corrected.

E.1.3. When a moratorium or emergency suspension is placed on a provider or licensee, notice of the action shall be posted and visible to the public at the location of the provider until the action is lifted.

Section F. Financial Management

F.1.0. The controlling interest may not withhold evidence of financial instability from the Agency. If the provider has shown financial stability, the provider must submit proof of financial ability to operate including financial schedules and correction of financial instability.

F.1.1. Delivery personnel must have a valid driver’s license as required by law for the vehicle being driven and physical ability to work without continuous direct supervision. Delivery and equipment staff shall have successfully completed a document training program covering all components of their assigned jobs including training for each type of equipment delivered. Duties include safe and clean transport of equipment

and supplies to and from consumer homes, safe set up of equipment and record keeping of deliveries.

Section G. Human Resource Management

G.1.0. Personnel files must also include verification of previous five years employment history, if possible. If the licensed location is a distribution center, it will be allowed 48 hours to obtain patient or personnel records from their licensed central service center and submit records to the area office when related to a complaint investigation.

G.2.0. Licenses, Registrations and Certifications

G.2.1. A license must be displayed and readily visible to clients who enter the HME address that appears on the license and is only valid for the licensee to whom the license is issued with valid effective and expiration dates. BOC must immediately report any evidence of unlicensed activity to include unreported changes of ownership.

Section H. Consumer Services (Florida Specific)

H.1.0. Emergency Management Plan

H.1.1. In the event the HME provider cannot ensure provision of equipment and services, they must coordinate with another HME provider.

H.1.2. A licensee required by authorizing statutes to have an emergency plan must designate a safety liaison to serve as the primary contact for emergency operations. An entity subject to this part may temporarily exceed its licensed capacity to act as a receiving provider in accordance with an approved emergency operation plan for up to 15 calendar days. While in an overactive status, each provider must furnish or arrange for appropriate care and services to all clients. In addition, the Agency may approve requests for overcapacity in excess of 15 calendar days; approvals may be based upon satisfactory justification and need as provided by the receiving and sending providers. An inactive license may be issued to a licensee subject to this section when the provider is located in a geographic location under a state of emergency, as declared by the Governor.

Section I. Performance Management

I.1.0. The provider must establish a system for resolution of complaints and service problems.

I.1.1. On or before the first day that services are provided to the client, the licensee must inform the client and his or her immediate family or representative, if appropriate, of the right to report complaints and/or abusive, neglectful or exploitative practices. The licensee must provide toll-free numbers to clients in a manner that is clearly legible. The complaint form must include the following statement “To report a complaint regarding the services you received, please call toll free [Phone Number].” The

current phone number for the AHCA Complaint Administration Unit is 1-888-419-3456. To report abuse, neglect or exploitation, please call the Florida Abuse Hotline at 1-800-962-2873. The provider shall establish appropriate policies and procedures and provide such notice to clients. Providers must report other unlicensed HME providers to the Florida AHCA Consumer Complaint Administration Unit.

I.1.2. Each license shall maintain as public information, available upon request, records of all inspection reports pertaining to that provider that have been filed by the Agency, unless those reports are exempt from or contain information that is exempt or otherwise made confidential by law. Copies of such reports shall be retained for at least three years following the date the reports are filed/issued, regardless of change of ownership. A licensee shall, upon request of any person who has completed a written application with the intent to be admitted by such provider or of any person who is a client of such provider or relative, spouse or guardian of such person, furnish to the requestor a copy of the last inspection report pertaining to the licensed provider that was issued by the Agency or by an accredited organization if such a report is in lieu of a licensure inspection.

Section J. Special Needs Registry

J.1.0. In case of emergency, the HME provider must document in the special needs registry of the consumer's file if the consumer plans to evacuate or to remain in home with a caregiver or family member who can take responsibility for equipment services normally provided by HME staff or independent contractors referred by the HME provider. If the consumer does not have a caregiver or family member present, the HME provider needs to make referrals in order for equipment services to continue. If the consumer is receiving services through other licensed healthcare providers or federal or state–funded program, the HME provider will check with the other service provider or program case manager to verify whether the consumer has already been registered. If so, a note will be made in the consumer's file that special needs registration has been reviewed and handled by the other provider or program. HME providers are not required to assist consumers in skilled nursing facilities, assisted living facilities or adult family care homes with special needs registration, as those licensed facilities are responsible for evacuation and alternative sheltering of their clients.

J.1.1. The HME provider must assist in registering all of its special needs clients and all persons with special needs who receive services with the local emergency management agency. The collected registration information must be furnished to the local county emergency management agency by the HME provider. The registry shall identify those persons in need of assistance (i.e., those with physical, mental or cognitive impairment or sensory disabilities) and plan for resource allocation to meet the identified needs of such persons during evacuations and sheltering.

Section K. Comprehensive Emergency Management Plan

K.1.0. The HME provider must prepare and maintain a Comprehensive Emergency Management Plan (CEMP) that meets minimum criteria established by the Agency. The plan shall provide for continuing HME services for life-supporting and life-sustaining equipment during an emergency that interrupts HME in the patient's home. The CEMP shall include the means by which the HME provider will contact and prioritize patients in need of continued services, continue to provide equipment and perform the same type and quality of services the consumer received prior to evacuation. The CEMP shall identify the resources necessary to continue essential care or services or shall include a referral to other organizations for such care and services, subject to written agreement and communication between staff members, county health departments and local emergency management agencies. Also, the CEMP shall include the maintenance of consumer's equipment and supply lists that can accompany any consumer who is transported from their home.

K.1.1. The HME provider must submit the CEMP to county health department for their review and approval for each county that the HME provider serves. The county health department has 90 calendar days from receipt of the plan to complete its review to ensure the plan is in accordance with Agency criteria. If a HME provider fails to submit a plan or fails to submit the requested information or revisions within 30 calendar days after written notification from the county health department, the county health department shall notify the Agency. The Agency shall notify the HME provider that such failure constitutes a deficiency, subject to a fine of $5,000 per occurrence.

K.1.2. In addition to the annual review of the CEMP, any substantive changes (i.e., change of address, changes to administrative staff who are responsible for coordinating HME's emergency responses or their telephone numbers, or changes to the type of equipment or equipment services provided) must be reported to the county emergency management office and to the county health department for each county that the HME provider serves. HME staff must be informed of those changes. The contact information must include telephone numbers at which coordinating staff can be contacted outside of the HME provider's regular office hours. All HME providers must report these changes, regardless of whether their plan has been previously reviewed.

K.1.3. When a HME provider goes through a change of ownership, the new owner must review the CEMP and report any substantive changes (i.e., change of address, changes to administrative staff who are responsible for coordinating HME's emergency responses or their telephone numbers, or changes to the type of equipment or equipment services provided) to the county emergency management office and to the county health department for each county that the HME provider serves. HME staff must be informed of those changes.

K.1.4. The prioritized list shall be current and include how services will be continued, whether the patient is to be transported to a special needs shelter and whether the patient has life-supporting or life-sustaining equipment, including a specific type of equipment and related supplies. Upon request, the prioritized list shall be furnished to the county health department and emergency management office.

K.1.5. The HME provider must provide the same type and quality of equipment services to its consumers, which must include those being served in assisted living facilities and adult family care homes who evacuate to special needs shelters, unless the emergency situation makes it impossible to provide services due to impassable roads, or when the consumer does not go to the location specified in their consumer record or is forced to relocate outside of the geographic service area of the HME provider.

Section L. Financial Management

L.1.0. If an applicant/licensee shows financial instability at any time, the Agency may require applicant/licensee to provide proof of financial ability to operate by submission of AHCA Form 3100-0009, Proof of Financial Stability, which includes a balance sheet and income and expense statement for the next two years of operation.

L.1.1. A level 2 background screening must be conducted every five years on the following:

Licensee is an individual, a general manager or similarly titled person who is responsible for the day-to-day operations, a financial officer or similarly titled individual who is responsible for the financial operation of the licensee or provider, any person with a controlling interest who the Agency has reason to believe has committed an offense prohibited by Florida Statute, or any person seeking employment who provides personal care or services and has access to client funds, personal property and living areas.

L.1.2. A controlling interest may not withhold from the Agency any evidence of financial liability. Any person who violates this subsection commits a misdemeanor of the second degree. Each day of continuing violation is a separate offense.

Section M. Service Requirements

M.1.0. Repairs and Warranty Disclosures

M.1.1. Maintenance personnel must be able to maintain and coordinate the repair of all equipment as required by manufacturing standards, work without continuous direct supervision and complete maintenance logs to include personnel signature. They must also attend any equipment maintenance training required by the manufacturer.

M.1.2. The HME provider must disclose consumer information to each consumer who purchases items, including all applicable warranty information. This information consists of the provider standards to which the item must conform.

M.2.0 Consumer Record

M.2.1. A record must be kept for each consumer. These consumer records must be made available to AHCA representatives when an inspection or a complaint investigation is conducted.

Section N. Patient Information

N.1.0. Confidentiality Responsibilities

N.1.1. Upon request by the consumer or as otherwise required by state law and rules or federal law and regulations, the HME provider must assist customers with meeting the necessary filing requirements to obtain third-party payment to which a consumer may be entitled.

N. 1.2. A person or entity may not offer or advertise services that require licensure as defined by Florida law or rule to the public without obtaining a valid license from the Agency. If after receiving notification from the Agency, such person or entity fails to cease operation and apply for a license, the person or entity shall be subject to penalties as prescribed by authorizing statutes and applicable rules. A license holder may not advertise to the public that the provider holds a license for services not included in that provider's license. All patient information that is received by any HME employee, HME contractor or AHCA employee is confidential patient information and may not be disclosed from patient's file without written consent of the patient, the patient's guardian or the patient's power of attorney.