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A. Facility and Equipment

Standard

A-1 – Address (MANDATORY)

American Academy of Sleep Medicine (AASM) accredited Durable Medical Equipment (DME) suppliers must have a permanent, physical address recognized by the United States Postal Service. The DME supplier address may include a P.O. Box for mailing purposes only. The DME supplier must display all valid licenses, certificates of occupancy and permits to operate in an area accessible to visitors.

A-2 – DME Supplier Availability

The DME supplier must:

- a. Maintain a publicly listed telephone number. Exclusive use of a pager, mobile phone, or answering machine will not serve to meet this standard.
- b. Maintain a designated contact person accessible to the patient and/or caregiver(s) via telephone. For suppliers providing life-sustaining equipment (e.g. oxygen concentrators, reservoirs, high-pressure cylinders, oxygen accessories and supplies, oxygen conserving devices, and invasive home ventilators), the contact person must be available twenty-four hours a day, seven days a week.
- c. Maintain posted hours of operation.

If the DME supplier chooses to distribute patient education materials and advertising, this information must display the DME supplier contact information.

A-3 – Appropriate Equipment (MANDATORY)

The DME supplier must provide appropriate quality equipment to patients. For this accreditation, such equipment may include any of the items listed below:

- a. Continuous Positive Airway Pressure (CPAP) and Auto Adjusting Continuous Positive Airway Pressure devices.
- b. Oxygen concentrators, reservoirs, high-pressure cylinders, liquid oxygen, oxygen accessories and supplies and oxygen conserving devices.
- c. Home Invasive Mechanical Ventilators.
- d. Respiratory Assist Devices (RAD), including but not limited to: Bi-level, Bi-level Spontaneous, Bi-level Spontaneous/Timed, Auto Adjusting Bi-level Positive Airway Pressure devices, and Servo Ventilation devices.
- e. Nebulizers.
- f. Suction Equipment.
- g. Insufflators and Exsufflators.
- h. Portable Oximeters.

A current and valid prescription must be maintained on file from the ordering healthcare professional and must contain a diagnosis code appropriate for the equipment and/or item(s) prescribed.

Technical staff involved in the distribution and set-up of equipment must possess appropriate licensure and certification necessary to distribute DME equipment based on their individual state requirements.

A-4 – Materials for DME Equipment

The DME supplier must have the available manufacturer features, warranties and instructions for each DME equipment and/or item(s) that it provides. For equipment and/or item(s) dispensed which have unique serial numbers, there must be a written or electronic database maintained indicating the equipment and/or item(s). The patient name and/or medical record number must correspond to the equipment and/or item(s) dispensed.

B. Financial Management

Standard

B-1 – Financial Management Policies

The DME supplier must implement financial management practices that ensure accurate accounting and billing to insurance companies and patients. Financial records must be accurate, complete, current and reflect cash or accrual base accounting practices. Internal controls must be implemented and documented with policies addressing, at a minimum, each of the following:

- a. Balance sheets
- b. Income statements
- c. Cash controls including:
 - i. Bank reconciliations
 - ii. Statements of cash flow
- d. Payable controls including:
 - i. Authorization of payment
 - ii. Monthly reconciliation for cash or accrual base accounting
- e. Invoicing controls using currently published CPT and ICD-9 codes

B-2 – Patient Accounts

The DME supplier must maintain accounts that link equipment and/or item(s) to the patient and manage revenues and expenses on an ongoing basis, as they relate to patient services, including the following:

- a. Billing reconciliation of equipment, item(s) and/or service(s) using invoices, receipts and deposits maintained through an equipment/patient database.

C. Claims Submission Audit

Standard

C-1 – Patient Records Audit

A minimum of five patient DME records must be audited at least annually by the DME supplier. The audit must demonstrate:

- a. Accurately coded bills for equipment, item(s) and/or service(s) documented in the patient DME chart.
- b. Reasonable and medically necessary equipment, item(s) and/or service(s) have been provided to the patient.

C-2 – Billing Discrepancies Procedure

The DME supplier must have a procedure for identifying and correcting billing discrepancies. This procedure must include:

1. Designation of staff member(s) or billing company responsible.
2. The use of audits and/or other risk evaluation techniques to monitor billing activities.
3. Procedures to resolve and prevent recurrence of identified discrepancies.

D. Practice Standards and Procedures

Standard

D-1 – Policy and Procedures Manual

The DME supplier must implement and maintain a policy and procedures manual that is easily accessible to all applicable staff members, in written or electronic format. The manual must:

1. Contain all policies, procedures and protocols specific to the DME supplier.
2. Include names and job descriptions for all DME supplier personnel.
3. Delineate education, training, responsibilities, certifications and licensures.
4. Document continuing education requirements related to the specialized equipment, item(s) and/or service(s) it provides to patients.
5. Include evidence of annual review, with periodic updates by the manager, director or owner, as warranted.

6. Support compliance with all State and Federal regulations, as it pertains to the business, including but not limited to, Stark Laws and the Health Insurance Portability and Accountability Act (HIPAA).
7. Maintain a charity policy for patients unable to afford equipment, item(s) and/or service(s). The DME supplier must provide evidence of adherence to and use of this policy.

D-2 – CPT/ICD-9 Codes Update

The DME supplier must have guidelines in place to ensure that the most current CPT/ICD-9 codes are utilized.

E. Human Resources Management

Standard

E-1 – Personnel Responsibilities

Technical staff (such as registered or certified polysomnographic technologists, registered or certified respiratory therapists and technicians who have completed an A-STEP accredited program or a CAAHEP accredited sleep technology training program, electroneurodiagnostic (END) program, or respiratory therapy add-on track for sleep technology) must be trained to deliver and set-up equipment, item(s) and/or service(s) and to train patients and/or caregiver(s).

- a. Where required by state law, these individuals must be licensed by their appropriate state or national governing board specific to their professional designation.
- b. All technical staff must participate in and document an average of 10 hours per year of continuing education credit (CEC) educational activities on sleep, respiratory therapy or other related topics over a three year period.
- c. The DME supplier must verify and maintain copies of current licenses, registrations and certifications for personnel who provide patient services. These documents must be verified upon employment and at least annually.

E-2 – Personnel Training

Training must be provided annually for each staff person who performs coding and billing of services provided by the DME supplier. Some suggested areas of training include:

- a. Coding requirements related to the services coded and billed.
- b. Claim development and submission processes.
- c. Documentation of services rendered.
- d. Billing standards and procedures, including review of rejected claims.

- e. Reason(s) for claim rejection.
- f. Legal sanctions for submitting deliberately false or reckless billings.

Documentation of training must be maintained by the DME supplier and be available upon request to accreditation organizations and government officials or their authorized agents. Training materials, attendance sheets and course outlines must be maintained in a file, written log or electronic database and must be available for review.

F. Consumer Services

Standard

F-1 – Receipt of Delivered Equipment

The DME supplier must:

- a. Provide information to the patient regarding expected delivery time for receipt of equipment, item(s) and/or service(s).
- b. Verify and document in the patient's DME chart the patient's receipt of all equipment, item(s) and/or service(s).
- c. Provide their telephone number to each patient at the time of delivery of the prescribed equipment and/or item(s).

F-2 – Options for Renting/Buying Equipment

The DME supplier must provide options for patients and/or caregiver(s) to rent or purchase equipment and/or item(s), when applicable.

F-3– Patient Complaints

- a. Within five calendar days of receiving a patient's complaint, the DME supplier must notify the patient that it has received the complaint and has initiated an investigation of the incident.
- b. Within fourteen calendar days, the DME supplier must provide written notification to the patient of the result of the investigation and maintain such notification in the patient's DME chart.
- c. The DME supplier must maintain documentation of all complaints received, findings from prior and current investigations and complaint resolutions.
- d. Based upon the results of each investigation, procedures must be developed to correct the problem identified in order to prevent future occurrences.

G. Training/Instruction to Patient and/or Caregiver(s)

Standard

G-1 – Verification of Training

The DME supplier must, as applicable:

- a. Provide, or coordinate the provision of, appropriate information related to the set-up, features, routine use, troubleshooting and maintenance of all equipment and/or item(s) provided to the patient and/or caregiver(s).
- b. Coordinate, either in person or via remote electronic video communication system, the initial equipment set-up and provide adequate training and instructions for the use of equipment and/or item(s). Verification of set-up location (at the DME supplier location, in the patient's home or via a video communication system) must be documented in the patient's DME chart.
- c. Supply to the patient and/or caregiver(s) clear, written or pictorial, oral or electronic instructions related to the use, maintenance, infection control practices for, and potential hazards of, equipment and/or item(s) as appropriate. It is expected that translations of all these materials will be available, and interpreter services provided for non-English speaking patients, when applicable.

H. Performance Management

Standard

H-1 – Quality Assurance Program

The DME supplier must implement a quality assurance program that measures outcomes of consumer services, positive airway pressure (PAP) compliance, billing practices and adverse events.

The DME supplier must track all adverse events that are secondary to providing the patient with inadequate services or malfunctioning equipment (e.g. injuries, accidents, signs and symptoms of infection, hospitalization). The number of adverse events, event outcomes and resolutions must be maintained in a written log or electronic database.

The DME supplier must measure each of the following quality assurance parameters:

- a. Patient satisfaction and complaints about product(s) and/or service(s) rendered.
- b. Timeliness of response to patient's question(s), problem(s) and/or concern(s).
- c. Patient access times to receive ordered equipment, item(s) and/or service(s).
- d. Positive airway pressure (PAP) compliance expressed as a percentage and objectively measured for all patients who acquire a PAP device from the DME supplier.

- e. Frequency of billing and coding errors (e.g. number of insurance claims denied, errors resulting in claims denial).

These quality assurance indicators must be reported and reviewed at least once per quarter. For each quality assurance indicator, the DME supplier must specify:

- a. A goal percentage.
- b. An action plan if the goal percentage is reached in four consecutive quarters (i.e. raise the goal percentage or create a different quality assurance indicator to measure the parameter).
- c. An action plan if the goal percentage is not consistently reached in four consecutive quarters.

The DME supplier's manager, director or owner must sign and date the report. A copy of each signed report must be kept on file for the duration of the accreditation period.

I. Product Safety

Standard

I-1 – Equipment Safety Program

The DME supplier must have a policy, in written or electronic format, which promotes the safe use of equipment and/or item(s) and minimizes safety risks, infections and hazards both for its staff dispensing equipment and/or item(s) and for its patients receiving the equipment and/or item(s) for use.

I-2 – Equipment Failure, Repair and Maintenance Plan

The DME supplier must have, in written or electronic format, a policy for identifying, monitoring and reporting (where indicated) failure, repair and preventive maintenance of equipment and/or item(s) provided to the patient.

I-3 – Equipment Incident Investigation

The DME supplier must investigate any incident, injury or infection in which the DME supplier may have contributed to the event.

- a. The investigation must be initiated as soon as possible and within twenty-four hours after the DME supplier becomes aware of any incident, injury or infection.
- b. The investigation must include documentation of all necessary information, pertinent conclusions, and whether changes in the system(s) or processes are needed.
- c. The DME supplier must provide subsequent follow-up to the incident to prevent future occurrences.

I-4 – Emergency Plan

The DME supplier must have an emergency plan, in written or electronic format, which enables the DME supplier to respond to emergencies and disasters. The DME supplier must establish an arrangement with alternative DME supplier(s) in the event that the DME supplier cannot service its own customers as a result of an emergency or disaster. The emergency plan must delineate the following:

- a. Mechanisms and specific details for contacting emergency personnel.
- b. DME supplier personnel to be contacted in an emergency and their specific responsibilities.

I-5 – Product Verification (MANDATORY)

The DME supplier must verify, authenticate and document the following in the patient's DME chart prior to distributing, dispensing or delivering equipment, item(s) and/or service(s) to the patient:

- a. The products are not adulterated, counterfeit, suspected of being counterfeit and have not been obtained by fraud or deceit; and
- b. The products are not misbranded and are appropriately labeled for the intended distribution channels.

J. Information Management

Standard

J- 1 – Maintain Patient Records

The DME supplier must maintain accurate, pertinent, accessible, confidential and secure patient records, in written or electronic format, in accordance with privacy and security standards of the Health Insurance Portability and Accountability Act (HIPAA) and other applicable state standards. These records must provide documentation of all patient interactions in the patient's DME chart.

J-2 – Fraud, Waste and Abuse Policies (MANDATORY)

The DME supplier must implement policies to prevent and control fraud, waste and abuse by using standards of conduct which ensure the organization's compliance with applicable Federal, State, local laws and regulations. These standards must be available for review in either written or electronic format.

K. Intake & Assessment

Standard

K-1 – Consultation with Ordering Healthcare Professional

The DME supplier must contact the ordering healthcare professional as needed to confirm an order and to recommend any necessary changes, refinements and/or additional evaluations to the prescribed equipment, item(s) and/or service(s). These interactions must be documented in the patient's DME chart. Any changes in the patient's medical equipment necessitate an updated prescription, which must be kept unaltered in the patient's DME chart. Any certificates of medical necessity must also be maintained in the patient's DME chart.

K-2 – Review Patient Records

The DME supplier must review the patient's DME medical record, as warranted, and incorporate and maintain any pertinent information related to the patient's condition(s) which may affect the provision of the DME equipment, item(s) and/or service(s).

L. Equipment Delivery & Set-Up

Standard

L-1 – Delivery and Set-up in a Timely Manner

The DME supplier must provide the patient with all accredited respiratory and sleep-related equipment, item(s) and/or service(s) prescribed by an ordering healthcare professional in a timely manner.

- a. The DME supplier must verify that all equipment, item(s) and/or service(s) delivered to the patient are consistent with the ordering healthcare professional's request.
- b. The DME supplier must notify the ordering healthcare professional when the patient has been set-up with the ordered equipment, item(s) and/or service(s). This must be documented in the patient's DME chart.
- c. The DME supplier must notify the ordering healthcare professional when it will take longer than ten business days to provide the patient with equipment, item(s) and/or service(s).
- d. If the DME supplier cannot or will not provide the equipment, item(s) and/or service(s) prescribed for the patient, the DME supplier must notify the ordering healthcare professional within five business days of the original order.

L-2 - Loaner Equipment

The DME supplier must provide, or arrange for, loaner equipment and/or item(s) comparable to the original equipment and/or item(s) during any repair period. For each piece of equipment and/or item(s), the DME supplier must document in a written log book or electronic database:

- a. The serial number of the equipment and/or item(s).
- b. The date that the equipment and or item(s) were lent out.
- c. To whom the equipment and/or item(s) were lent.
- d. The date the equipment and/or item(s) were returned.

M. Follow-up

Standard

M-1 – Continued Equipment Management

The DME supplier must provide appropriate follow-up services to the patient and/or caregiver(s) consistent with the type(s) of equipment, item(s) and/or service(s) provided. Follow-up services must comply with the recommendations from the ordering healthcare professional.

M-2 – Equipment Recalls

The DME supplier must notify the patient of any manufacturer DME equipment and/or item(s) recalls within ninety days of manufacturer recall notification. The DME supplier must remove the recalled equipment and/or item(s), and replace it with comparable approved loaner equipment and/or item(s).

M-3 – Compliance with Positive Airway Pressure (PAP) Therapy

The DME supplier must offer follow-up to patients who are prescribed positive airway pressure (PAP) therapy to ensure compliance within twelve weeks of initiating therapy. .

Adequate compliance with therapy is defined as positive airway pressure (PAP) usage four hours or more per night on at least 70% of nights during a consecutive thirty-day period. Compliance must be measured objectively.

The DME supplier must create, maintain and archive a quarterly report which objectively measures positive airway pressure (PAP) percent compliance for all patients who acquire a PAP device from the DME supplier. This compliance report must serve as one of the measured parameters in the DME supplier's quality assurance program.

Positive airway pressure (PAP) therapy compliance assessment must measure treatment use and clinical response. This must be documented by any of the following modalities:

- a. Direct patient inquiry.
- b. Face-to-face clinical re-evaluation by the ordering healthcare professional.
- c. Questionnaires.
- d. Telephone inquiry to the ordering healthcare professional or the patient.
- e. An informatics system capable of obtaining positive airway pressure use.
- f. A metric of clinical response.

The patient's DME chart must contain documentation of the compliance assessment or written evidence of follow-up attempts made to obtain the positive airway pressure (PAP) therapy compliance assessment.

N. Disclosure of Persons Having Ownership, Financial or Control Interest

Standard

N-1 – Disclosure (MANDATORY)

The DME supplier must provide current information to the accrediting body for all individuals and joint venture companies holding an ownership or controlling interest (5% or more). The DME supplier must report to the accrediting body any agent relationship and managing employee interest in the DME supplier, and subcontractor relationships with another DME supplier.