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General Standards

Standard

A-1 – Address (MANDATORY)

American Academy of Dental Sleep Medicine (AADSM) accredited dental sleep medicine (DSM) facilities must have a permanent, physical address recognized by the United States Postal Service. The DSM facility address may include a P.O. Box for mailing purposes only.

A-2 – Facility License (MANDATORY)

AADSM accredited DSM facilities must maintain a valid license, certificate of occupancy, and/or permit, when required by applicable law and regulation, to provide health care services and/or durable medical equipment (DME). It is the responsibility of the DSM facility to maintain compliance with all licensing acts, local building codes and any other laws relevant to the facility's operation.

Failure to comply with the stipulations in this paragraph is sufficient for denial and/or revocation of accreditation. A DSM facility's valid healthcare license, certificate of occupancy or business permit fulfills this standard. Where additional licenses or permits are required for providers of DME, evidence of such is required to fulfill this standard. If applicable law does not require a dental sleep medicine facility to have a healthcare license, certificate of occupancy or business permit, or DME license or permit, written attestation of such by the dental director of the facility is required.

A-3 – ADA Code of Ethics (MANDATORY)

AADSM accredited sleep medicine facilities are required to follow the *American Dental Association Principles of Ethics and Code of Professional Conduct.* The DSM facility must either have a hard copy on hand or have the ability to access easily an updated copy of the *American Dental Association Principles of Ethics and Code of Professional Conduct* electronically.

A-4 – Dental Sleep Medicine Activity (MANDATORY)

The dental director must have been providing DSM services within this dental sleep medicine facility for a minimum of one year prior to submitting an accreditation application. DSM services must include a minimum of 12 appliance insertions, as well as documentation of post-delivery follow-up and short-term follow-up for each. Documentation of long-term follow-up is required for a minimum of 5 of these cases.

B. Personnel

Standards B-1 through B-4 relate to the appointment, responsibilities and continuing education of a dental director.

Standard

B-1 - Dental Director (MANDATORY)

- a) AADSM accredited DSM facilities must designate a single professional dentist as dental director. The dental director must have a license valid in the state of the facility and in all states in which patients are seen.
- b) An individual can serve as dental director of up to three (3) DSM facilities, including satellite locations, regardless of their accreditation status.

B-2 – Dental Director Qualifications (MANDATORY)

The dental director must be either

- 1. A qualified dentist who is a Diplomate of the American Board of Dental Sleep Medicine (ABDSM)
 - OR
- 2. A qualified dentist who:
 - a. has completed a required 30 credits of continuing education within the past three years. A minimum of 20 credits must be in dental sleep medicine. The additional credits must be sleep medicine related. After January 1, 2017, dental directors must complete, within the past two years, a minimum of 25 hours of recognized continuing education in dental sleep medicine (e.g., American Dental Association Continuing Education Recognition Program [ADA CERP] or Academy of General Dentistry Program Approval for Continuing Education [AGD PACE]) provided by a dental sleep medicine focused non-profit organization or accredited dental school; and
 - b. has delivered a minimum of twelve appliances within the previous 12 months.
 - c. To retain the accreditation, the dental director must obtain ABDSM certification within 2 board certification cycles. The dental director must provide a copy of the official notification from the ABDSM attesting to successful completion of all requirements including but not limited to the board examination.

B-3 – Dental Director Responsibilities (MANDATORY)

The dental director:

- a. is responsible for the direct or indirect and ongoing oversight of patient evaluation, treatment, and follow-up care;
- b. is responsible for proper handling, storage, maintenance, and ongoing assessment of oral appliances;
- c. is responsible for the qualifications of all dentists and auxiliary personnel,
- d. must provide direct and ongoing oversight of the evaluation and testing protocols, as permitted under local laws and regulations;
- e. must review, report, and modify as necessary the facility's quality assurance program on a quarterly basis; and
- f. must be present in the dental sleep medicine facility on a regular basis and not less than 40 hours each month.

B-4 – Dental Director Continuing Education (MANDATORY)

The dental director must participate in at least 10 credits per year averaged over three years of continuing education. A minimum of 5 credits per year must be ADA CERP recognized or AGD PACE approved credit in dental sleep medicine. The additional five credits may be sleep medicine related AMA PRA Category 1 CME. After January 1, 2017, dental directors must complete, within the past two years, a minimum of 25 hours of recognized continuing education in dental sleep medicine (e.g., American Dental Association Continuing Education Recognition Program [ADA CERP] or Academy of General Dentistry Program Approval for Continuing Education [AGD PACE]) provided by a dental sleep medicine focused non-profit organization or accredited dental school. Compliance with CE requirements is required for all dental directors, regardless of whether they are certified by the ABDSM. Compliance with this standard must be documented.

Standards B-5 through B-7 address requirements for DSM clinical auxiliaries, which may include dental assistants, dental hygienists, nurses, and other auxiliary personnel as allowed under state law. Each must be licensed where required by state law. These standards do not differentiate between the various job descriptions or titles that dental sleep medicine facilities may use for the employment of various clinical auxiliaries. CPR certification is required for <u>all</u> clinical staff members, regardless of their duties or titles. These requirements are in addition to any state or local requirements.

B-5 – Dental Sleep Medicine Clinical Auxiliaries

Clinical auxiliary staffing at dental sleep medicine facilities must be adequate to address the workload of the dental sleep medicine facility and assure the safety of patients. If the dental sleep medicine facility employs clinical auxiliary staff, they must be appropriately trained, supervised, and, where required by state law, licensed.

B-6 – Dental Sleep Medicine Clinical Auxiliaries Continuing Education

The dental sleep medicine facility's clinical auxiliary staff must each participate in an average of 5 hours per year of ADA CERP recognized credit, AGD PACE approved credit, or sleep-related in-service educational activities over a three year period. Education sessions conducted at the facility are acceptable for fulfilling this standard provided the session has defined educational objective(s) and attendance is documented by a roster signed by the dental sleep medicine facility's dental director. Documentation of continuing education must be maintained for each clinical auxiliary staff member.

B-7 – Dental Sleep Medicine Clinical Auxiliaries Additional Certification

Each dental sleep medicine clinical auxiliary must have valid American Heart Association or American Red Cross certification, or its equivalent, in cardiopulmonary resuscitation. For the purpose of AADSM Accreditation requirements, the level of CPR training must be suitable for healthcare professionals. Valid certification in cardiopulmonary resuscitation includes skills training.

Standard B-8 relates to the training of all staff that performs coding and billing of services.

B-8 – Coding and Billing Personnel Training

A minimum of 5 hours of initial training must be provided for new staff responsible for coding and billing of services provided by the DSM facility. Some suggested areas of training include:

- a. Coding requirements related to the services provided.
- 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 for each coding and billing staff member. Training materials, attendance sheets and course outlines must be maintained for training offered at the facility. Certificates or letters of completion should be maintained for courses attended outside the DSM facility.

Standard B-9 – Dental Sleep Medicine Administrative Staff Continuing Education

New staff responsible for dental sleep medicine administrative responsibilities must each participate in 2 hours of initial training through either an ADA CERP recognized or AGD PACE approved provider. Education sessions conducted at the facility are acceptable for fulfilling this standard provided the session has defined educational objectives and attendance is documented by a roster signed by the dental sleep medicine facility's dental director. Documentation of continuing education must be maintained for each new administrative staff member.

C. Patient Acceptance and Records Policies

Standard

C-1 – Patient Acceptance

The DSM facility's Policy and Procedures Manual must address patient acceptance policies. Written policies for patient acceptance must include:

- a. a mechanism for acceptance;
- b. criteria for exclusion; and
- c. information required from a physician prior to treatment.

The AADSM recognizes that concern for patient safety, clinical judgment, or other appropriate reasons may limit a dental sleep medicine facility from accepting all patients.

C-2 - Patient Records Maintenance

The DSM facility must maintain accurate, pertinent, accessible, confidential and secure patient records for all patients evaluated and/or treated there. Records must be maintained 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 including initial evaluation, diagnosis, treatment, testing, follow-up and miscellaneous encounters including phone calls and letters related to treatment.

C-3 - Patient Records: Documentation from the Referring Physician

The DSM facility must receive an order from the referring physician documenting medical necessity of the oral appliance. The order must be maintained in the patient record.

Prior to initiating treatment, all patient medical charts must include: physician prescription, prior overnight sleep study results, patient questionnaires, patient history, clinical examination, and documentation of informed consent.

C-4 – Oral Appliance Therapy

Patients receiving an oral appliance for treatment of sleep-related breathing disorders must receive all of the following, and each must be documented in the medical record:

- 1. Review of sleep-related breathing disorders and potential consequences if left untreated.
- 2. Review of treatment alternatives for sleep-related breathing disorders.
- 3. Benefit of treatment recommendations.
- 4. Potential risks and complications related to treatment recommendations.
- 5. Oral appliance care and use instructions.
- 6. Follow-up care per the AASM Practice Parameters and AADSM Treatment Protocols.

C-5 – Combination Oral Appliance – Positive Airway Pressure

Patients prescribed positive airway pressure (PAP) treatment in combination with oral appliance therapy must be managed in coordination with a treating physician. The patient's dental sleep medicine record must include documentation of physician management of the PAP component as well as appropriate documentation of the oral appliance therapy.

D. Facility

Standard

D-1 – Use of Space

Accreditation is granted to a single DSM facility, generally defined by a physical space used for conducting services related to dental sleep medicine. All of the elements required to provide evaluation, treatment, and follow-up care related to dental sleep medicine are contained within the defined space. Up to 2 additional satellite clinical locations are permitted under the primary accreditation application as long as the Dental Director remains the same, and all criteria listed under D-4 are also met. The administrative office(s) of the DSM facility may be separate from the clinical site. In such circumstances, the administrative office(s) must also meet the AADSM *Standards for Accreditation*, as they function as a part of the broader DSM program.

D-2 - Dental Sleep Medicine Facility Availability

The DSM facility 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 posted hours of operation.

If the DSM facility chooses to distribute patient education materials and advertising, this information must display the facility contact information including address and phone number.

D-3 - Treatment and Consultation Rooms - Physical Characteristics

All treatment rooms must be hygienic. They must be suitably equipped to provide good light and oral access for a thorough intraoral and extraoral evaluation. Patient consultations must be provided in a private environment.

D-4 - Satellite Clinical Locations

DSM satellite clinical facilities may cumulatively provide no more than 20% of the total monthly available DSM patient care hours (for primary and satellite facilities combined) and must operate under the same federal tax ID number as the main dental sleep medicine facility. The Dental Director must be physically present within each DSM satellite clinical facility during dental sleep medicine patient care hours for a minimum of 25% of each satellite facility's available patient care hours. Each DSM satellite clinical facility must meet all other accreditation requirements.

E. Oral Appliances

Standard

E-1 – Appropriate Oral Appliances (MANDATORY)

The DSM facility must provide appropriate, 510K FDA cleared, quality oral appliances (orthotics) to patients. Appliances are utilized to reposition the tongue, mandible and/or other pharyngeal tissues in an effort to create and maintain a patient's airway during sleep. For this accreditation, such appliances may include any of the devices listed below:

- a. Tongue-retaining devices devices used to treat sleep-disordered breathing using a vacuum bulb or other mechanism to maintain the tongue in a more anterior position.
- b. Mandibular advancement devices oral appliances used to treat sleepdisordered breathing that reposition the mandible in a forward position.

E-2 – Materials for Oral Appliances

The DSM facility must have the available manufacturer features, warranties and instructions for the oral appliance(s) that it provides, including documentation of FDA clearance.

F. Policies and Procedures

Standard

F-1 – Policy and Procedures Manual

The DSM facility 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 DSM facility.
- 2. Include names and job descriptions for all DSM facility personnel.
- 3. Delineate education, training, responsibilities, certifications and licensures.
- 4. Document continuing education requirements related to the specialized equipment it provides to patients.
- 5. Include evidence of annual review of the manual, with periodic updates by the dental director 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), and all Medicare requirements.

Policies should indicate that the DSM facility follows all current AASM Practice Parameters and Clinical Guidelines and all current AADSM Treatment Protocols.

F-2 – Protocols: Treatment with and Titration of Oral Appliances

The dental sleep medicine facility must maintain written, paper or electronic format protocols for treatment of sleep related breathing disorders with oral appliance therapy and protocols for oral appliance titration.

F-3 - Fraud, Waste and Abuse Policies (MANDATORY)

The DSM facility 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.

F-4 – HCPCS/ICD-10 Codes Update

The dental sleep medicine facility must have guidelines in place to ensure that the most current HCPCS/ICD-10 codes are utilized in billing the services provided.

G. Oral Appliance Safety Procedures

Standard

G-1 – Oral Appliance Safety Program

The DSM facility must have a policy, in written or electronic format, which promotes the safe use of oral appliances and minimizes safety risks, infections and hazards both for its staff dispensing appliances and for its patients receiving the oral appliance for use.

G-2 – Adverse Event Investigation

The DSM facility must investigate adverse events that result in acute injuries, accidents or hospitalization in which the dental sleep medicine facility may have contributed to the event.

- a. The number of adverse events, event outcomes and resolutions must be maintained in a written log or electronic database.
- b. The investigation must be initiated as soon as possible and within two business days after the dental sleep medicine facility becomes aware of any adverse event.
- c. The investigation must include documentation of all necessary information, pertinent conclusions, and whether changes in the system(s) or processes are needed.

d. The dental sleep medicine facility must provide subsequent written followup to the adverse event to prevent future occurrences.

G-3 – Oral Appliance Failure, Repair and Maintenance Plan

The DSM facility must have, in written or electronic format, a policy for identifying, monitoring and reporting (where indicated) failure, repair and preventive maintenance of oral appliances provided to the patient.

H. Consumer Services

Standard

H-1 - Oversight (MANDATORY)

A qualified dentist member of the DSM facility staff must provide a face-to-face meeting prior to the fitting of an appliance.

A qualified dentist member of the DSM facility staff must physically be present in the DSM facility at all times while patients are being seen.

This standard can be met by either the dental director or additional qualified dentist staff.

H-2 – Patient Rights

Patient rights must be protected during all interactions with the DSM facility. The patient has the right to considerate and respectful service without regard to race, creed, national origin, sex, age, disability, diagnosis, or religious affiliation. DSM facility staff must provide patients and prospective patients with sufficient information to base a decision regarding facility selection.

H-3 - Plan of Care/Informed Consent

The DSM facility must provide the patient with a written plan of care following the initial evaluation and prior to fabricating an oral appliance for treatment of sleep related breathing disorders. The patient must also give informed consent before initiating oral appliance therapy.

H-4 - Receipt of Oral Appliances

The DSM facility must:

- a. Provide information to the patient regarding expected delivery time for receipt of the prescribed oral appliance.
- b. Document that the appliance was personally checked by the treating dentist for structural integrity.

- c. Provide a written warranty for the appliance that delineates what support is included in the appliance fee and what services are likely to be needed at additional cost.
- d. Verify and document in the patient's chart the patient's receipt of the appliance.
- e. Provide daytime and after-hours contact information to each patient at the time of delivery of the prescribed appliance.

H-5 – Verification of Training

The DSM facility must, as applicable:

- a. Provide, or coordinate the provision of, appropriate information related to the set-up, features, routine use, troubleshooting and maintenance of the appliance provided to the patient.
- b. 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, the oral appliance as appropriate.

H-6- Patient Complaints

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

I. Emergency Procedures

Standard

I-1 – Emergency Plan

AADSM accredited DSM facilities must have a written emergency plan accessible in paper or electronic format that delineates the following:

- a. mechanisms and specific details for contacting emergency personnel;
- b. the dental sleep medicine facility personnel to be contacted in an emergency;
- c. personnel and procedures for responding to after work hours questions and technical problems encountered by patients; and
- d. outline the specific responsibilities of the clinical staff.

At a minimum, emergency policies must include procedures for the following:

- a. Medical emergencies.
- b. Environmental emergencies such as fire, weather, belligerent patients, and bomb threats.

I-2 – Emergency Equipment

The DSM facility must have accessible all appropriate emergency equipment to address all possible emergencies outlined in their emergency plan.

J. Follow-up

Standard

J-1 – Follow-up Care

The DSM facility must provide appropriate follow-up services to the patient and/or caregiver(s) consistent with the type(s) of oral appliance and/or service(s) provided.

J-2 – Post Delivery Follow-up

A member of the dental sleep medicine facility staff must place a phone call, send an email, or otherwise attempt to directly contact the patient 1-3 days after delivering a new oral appliance. The patient is given the opportunity to review instructions, express concerns, and provide feedback. This contact is documented in the patient chart.

J-3 – Short-term Follow-up

The DSM facility must offer face-to-face follow-up to patients who are prescribed oral appliance therapy to ensure adherence, address patient concerns, assess appliance fit, and check for complications within four weeks of initiating therapy. Additional follow-up visits must be provided every 1-12 weeks until the oral appliance home titration phase is successfully completed, the oral appliance has reached its maximum limit of mandibular advancement, or the patient has reached his/her tolerable limit of mandibular advancement. Documentation of short-term follow-up is to be documented in the patient chart.

J-4 – Long-term Adherence with Oral Appliance Therapy

The DSM facility must encourage long-term follow-up to patients who are prescribed oral appliance therapy. The facility must maintain a follow-up protocol which includes a face-to-face patient evaluation at six months after successful titration and at least annually thereafter.

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The annual recall exam must evaluate efficacy, patient adherence, side effects, symptoms as well as the structural integrity of the oral appliance and the need for possible additional titration.

Long-term follow-up must be documented in the patient record. Progress notes and follow-up reports, as well as other pertinent information, must be shared with the patient's physician and appropriate healthcare providers on a regular basis.

The DSM facility should document notification of the treating physician whenever its staff or dentist(s) become aware that any patient has discontinued oral appliance therapy for a sleep related breathing disorder.

K. Claims Submission Audit

Standard

K-1 – Patient Records Audit

A minimum of five patient records must be self-audited at least annually by the DSM facility. The audit must demonstrate:

- a. Accurately coded bills for oral appliances documented in the patient chart.
- b. Reasonable and medically necessary oral appliances have been provided to the patient.

The DSM facility must maintain documentation of annual audits for the duration of the accreditation period.

K-2 – Billing Discrepancies Procedure

The DSM facility must have a procedure for identifying and correcting billing discrepancies. This procedure must include:

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

L. Quality Assurance

Standard

L-1 – Quality Assurance Program and Reporting

The Dental Sleep Medicine (DSM) facility must implement a quality assurance program that measures patient satisfaction, oral appliance adherence and billing practices.

- 1. The DSM facility must track patient satisfaction in relation to access to care, delivery of appliance, and service. A patient survey must be completed by a minimum of 80% of the patients treated.
- 2. The DSM facility must track patient adherence for oral appliance use. The DSM facility must have a system in place to track patient adherence and follow up care.
- 3. The DSM facility must track frequency of billing and coding errors (e.g. number of insurance claims denied, errors resulting in claims denial).

All three quality assurance indicators must be reported and reviewed at least once per quarter. The quality assurance report must be reviewed and signed by the DSM facility dental director quarterly.

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

Standard

M-1 - Disclosure (MANDATORY)

The DSM facility 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 DSM facility must report to the accrediting body any agent relationship and managing employee interest in the DSM facility, and subcontractor relationships with another DSM facility.