

Standards for Accreditation of **Out of Center Sleep Testing (OCST) in Adult Patients** 

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#### Introduction

Accreditation by the American Academy of Sleep Medicine (AASM) is a voluntary program offered to sleep programs that meet the standards contained in this document. These standards have been developed for the primary purpose of ensuring the highest quality care be delivered to patients with a sleep disorder. These standards address out of center sleep testing for adults.

For the purpose of clarity and brevity the remainder of this document will use the term "sleep service entity" when referring to entities performing Out of Center Sleep Testing (OCST). Out of Center Sleep Testing is defined as sleep testing performed outside of the sleep center. Remotely monitored studies performed independent of other testing are not covered by these standards.

In broad terms, the Standards for Accreditation describe the required structural, professional and human resources, clinical and technical standards, and emergency and quality assurance methods required for accreditation by the AASM. Sleep service providers achieving accreditation are recognized in the community as a resource for expertise in sleep medicine.

The AASM uses a rigorous evidence-based process to establish Practice Parameters on a variety of topics that are relevant to the practice of Sleep Medicine. Accredited sleep service entities must adopt and follow the standards in all active AASM Practice Parameter papers. Standards can easily be identified as they are all in bolded print in every Practice Parameter paper. In addition, it is recommended that accredited sleep service entities adopt and follow all active AASM Clinical Guidelines and Best Practices.

The AASM recognizes that the practice of Sleep Medicine, like all other medical disciplines, is dynamic, complex and requires clinical judgment. AASM Practice Parameters are not designed to limit physicians from using their medical judgment which, in individual patients, may require deviation from AASM Practice Parameters. AASM accredited sleep service entities are expected to document instances requiring deviation from AASM Practice Parameters.

The AASM reserves the right to modify, add, or remove accreditation standards at its own discretion without notice.

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#### Preamble

AASM accredited sleep service entities must be in compliance with all accreditation standards at the time of application. If it is determined in the application review process that a sleep service entity is not in compliance with the required standards, the application will be returned and the sleep service entity will need to resubmit it with the required standards being met.

Denial of accreditation will be recommended by the site visitor, reviewers, accreditation committee, or staff when one or more of the following conditions are identified:

- 1. The sleep service entity fails to meet any of the accreditation standards that are indicated as "MANDATORY." Sleep service providers will not be issued provisos for accreditation standards indicated as MANDATORY.
- 2. The sleep service entity is determined to be non-compliant with more than thirteen (13) accreditation standards provisos.
- 3. The sleep service entity fails to resolve proviso(s) within the period of time allotted to correct the proviso(s).
- 4. The AASM has evidence that the sleep service entity submitted falsified documents or misrepresented information in seeking to achieve or retain accreditation.

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#### A. General Standards

#### Standard

# A-1 – Provider License (MANDATORY)

AASM accredited sleep service entities must maintain a valid license, certificate of occupancy, and/or permit, when required by applicable law and regulation, to provide health care services. It is the responsibility of AASM accredited sleep service entities to maintain compliance with all licensing acts, local building codes and Federal and State laws relevant to the entity's operation. Failure to comply with the stipulations in this paragraph is sufficient for denial and/or revocation of accreditation. An entity's valid health care license, certificate of occupancy or business permit fulfills this standard. If applicable law does not require a sleep service entity to have a healthcare license, certificate of occupancy or business permit, written attestation of such by the Medical Director is required.

The accredited sleep service entity must maintain a professional office with a physical, stationary address recognized by the United States Post Office.

#### A-2 – Medical Code of Ethics (MANDATORY)

AASM accredited sleep service entities are required to follow the *Code of Medical Ethics* of the American Medical Association which the AASM adopted as official policy in 1998. The sleep service entity must have on hand the *Code of Medical Ethics* of the American Medical Association Council on Ethical and Judicial Affairs Current Opinions.

#### B. Personnel

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

#### Standard

#### B-1 – Medical Director (MANDATORY)

AASM accredited sleep service entities must designate a single medical director who is a physician with a valid state medical license. A copy of the medical director's state medical license must be submitted with the application.

# **B-2 – Medical Director Qualifications (MANDATORY)**

The designated medical director must be a sleep specialist. This requirement is defined by at least one of the following:

 A physician who is board-certified in sleep medicine by the American Board of Sleep Medicine or an individual certified in sleep medicine by either a member board of the American Board of Medical Specialties or a member board of the American Osteopathic Association.

 A physician who has been accepted by an ABMS or AOA approved board to sit for the examination in sleep medicine. To retain the accreditation, the examination in sleep medicine must be passed within 2 examination cycles.

To meet this requirement, the individual must provide, in the application packet, a letter of acceptance to sit for the examination by the ABMS or AOA approved board. Upon completion of the examination, the individual must provide a copy of the official notification from the ABMS or AOA board indicating final status.

3. A physician who has completed a 12 month ACGME accredited fellowship in sleep medicine and is awaiting the first available opportunity to apply to an ABMS board to sit for the sleep medicine examination. To retain accreditation, the ABMS examination in sleep medicine must be passed within 2 examination cycles.

# B-3 – Medical Director Responsibilities (MANDATORY)

The medical director:

- a. is responsible for the ongoing oversight of testing, including ongoing oversight of the testing protocols, the quality of testing and the proper operation and calibration of the equipment;
- is responsible for the qualifications of all medical and technical personnel;
   and
- c. is responsible for the quarterly review, report, and modification as necessary of the sleep service entities' quality assurance program.

#### B-4 – Medical Director Continuing Medical Education (MANDATORY)

The medical director must participate in at least 10 credits per year averaged over three years of AMA PRA Category 1 CME credit in sleep medicine. Compliance with CME requirements must be documented.

#### B-5 – Interpreting Physician(s) (MANDATORY)

The interpreting physician(s) must have a valid state license in all states for which the physician provides interpretation of studies and diagnoses of patients.

# B-6 – Interpreting Physician(s) Qualifications (MANDATORY)

The physician(s) responsible for interpretation of OCST data and diagnoses of patients must be a sleep specialist. This requirement is defined by at least one of the following:

1. A physician who is board-certified in sleep medicine by the American

Board of Sleep Medicine or an individual certified in sleep medicine by either a member board of the American Board of Medical Specialties or a member board of the American Osteopathic Association.

- 2. A physician who has been accepted by an ABMS or AOA approved board to sit for the examination in sleep medicine. To retain the accreditation, the examination in sleep medicine must be passed within 2 examination cycles. To meet this requirement, the individual must provide, in the application packet, a letter of acceptance to sit for the examination by the ABMS or AOA approved board. Upon completion of the examination, the individual must provide a copy of the official notification from the ABMS or AOA board indicating final status.
- 3. A physician-who has completed a 12 month ACGME accredited fellowship in sleep medicine and is awaiting the first available opportunity to apply to an ABMS board to sit for the sleep medicine examination. To retain accreditation, the ABMS examination in sleep medicine must be passed within 2 examination cycles.

**B-7 – Interpreting Physician(s) Continuing Medical Education (MANDATORY)** All interpreting physicians must participate in at least 10 credits per year averaged over three years of *AMA PRA Category 1 Credit*™ in sleep medicine. Compliance with CME requirements must be documented.

#### B-8 - Technical Personnel

AASM accredited sleep service entities must maintain appropriately trained, supervised, and, where required by state and federal law, licensed technical personnel to perform the sensor application and/or patient education. Technical staffing must be adequate to address the workload of the sleep service entity, and assure the patient's safety and understanding of the test.

# B-9 – Scoring Personnel

Appropriate scoring technical personnel include sleep technicians, sleep technicians with the CPSGT certification or other board approved certifications, sleep technologists, respiratory therapists with the sleep disorders specialist (SDS) certification, or electroneurodiagnostic technicians with additional sleep certification.

#### B-10 – Technical Personnel Continuing Education

The sleep service entities' technical scoring personnel must each participate in an average of 10 hours per year of *AMA PRA Category 1 Credit*™ or CEC sleep-related educational activities over a three year period. This must be documented for each technical personnel member. Education sessions conducted by the service entities are acceptable for fulfilling this standard provided the session has defined educational objective(s) and attendance is documented by a roster signed by the sleep service entities' medical director.

# **B-11 – OCST Technical Personnel Training**

Either the medical director, board certified sleep physician, or a sleep technologist must provide education to the technical personnel on the proper use of OCST devices including:

- a. application of sensors;
- b. instruction of patients in the use of OCST devices;
- c. troubleshooting of OCST problems; and
- d. scoring of data.

# **B-12 – OCST On-call Coverage (MANDATORY)**

Sleep service entities must provide nighttime (on-call) coverage by the medical director or a licensed physician board certified in sleep medicine or appropriately trained technical personnel addressed in standard B-8 to address problems encountered in OCST.

#### C. Patient Policies

#### Standard

### C-1 – Patient Acceptance

The sleep service entities' Policy and Procedures Manual must address patient acceptance policies. Written policies for patient acceptance must include:

- a) age limitations;
- b) a mechanism for acceptance:
- c) criteria for exclusion; and
- d) information required from a referring health-care provider prior to all out of center sleep tests that adhere to the criteria of high pretest probability for OSA with limited co-morbidities as described in the current versions of AASM practice parameters, AASM clinical guidelines and AASM best practice guidelines pertaining to the diagnosis of obstructive sleep apnea syndrome in adults (see Appendix A).

# C-2 – Practice Parameter Requirements

The clinical evaluation of patients accepted for sleep testing conducted in the sleep service entity and OCST must comply with the current versions of AASM practice parameters, AASM clinical guidelines and AASM best practice guidelines pertaining to the diagnosis of obstructive sleep apnea syndrome in adults (see Appendix A). Evidence of compliance with this standard must be included in the medical record.

# D. Facility and Equipment

#### Standard

#### D-1 - Phone Access

The program must have 24 hour telephone access to the personnel defined in standard B-8.

# D-2 – Stationery

AASM accredited sleep service entity must have stationery identifying the sleep service entity and, at a minimum, include the sleep service entity address and phone number. For hospital-based sleep service entities this standard will be met provided the sleep service entity is located in the building carrying the primary address listed on the hospital's stationery.

# D-3 – Portable Recording Equipment

The OCST equipment must meet the minimum definitions described in at least one of the CPT codes 95800, 95801 or 95806.

95800 Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (eg, by airflow or peripheral arterial tone), and sleep time

95801 Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and respiratory analysis (eg, by airflow or peripheral arterial tone)

95806 Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (eg, thoracoabdominal movement)

Equipment used must have the capability to meet all OCST accreditation standards outlined in Sections F and J.

#### E. Policies and Procedures

The sleep service entity must maintain written protocols, in paper or electronic form, for all testing procedures conducted by the entity. There are additional standards in sections I and J that are required to be included in the Policy and Procedure Manual.

#### Standard

#### E-1 – Policy and Procedures Manual

AASM accredited sleep service entities must maintain a Policy and Procedures

Manual that is easily accessible, in paper form or digital form, to all professional and technical staff. The manual must contain all policies, procedures and protocols specific to the sleep service entity, and the current versions of AASM practice parameters, AASM clinical guidelines and AASM best practice guidelines pertaining to the diagnosis of obstructive sleep apnea syndrome in adults (see Appendix A).

#### E-2 - Protocols

The sleep service entity must maintain written, paper or electronic format protocols for OCST for obstructive sleep apnea.

#### E-3 – Equipment Maintenance

The entity must have a written protocol for cleaning and inspecting equipment after each use that is consistent with the manufacturers' recommendations, federal and state health policy regulations and institutional standards.

# E-4 – Equipment Maintenance Continued

A written plan for yearly monitoring of all patient-related equipment for electrical and mechanical safety is required. The written plan must include specific instructions regarding documentation of compliance, including an equipment maintenance log. The plan must address: visual inspection of equipment for apparent defects; adhering to manufacturer's recommendations for monitoring and maintenance of recording equipment.

# F. Data Acquisition, Scoring and Reporting

#### Standard

#### F-1 – OCST Reports

OCST reports must include at minimum:

- a) an RDI (an estimate of the apnea and hypopneas per unit time);
- b) evaluation of oxygen saturation during recording period;
- c) recording duration of test; and
- d) technical adequacy of test.

# F-2 – OCST Recording Equipment

Equipment must provide an RDI based on measures that approximates an AHI based on full polysomnography. Equipment must also measure oxygen saturation and heart rate and meet the criteria for the codes designated in standard D-3. Equipment must allow for the display of raw data for manual scoring or editing.

#### F-3 – RDI Scoring Equivalency

Sleep service entities performing OCST must use equipment that provides a measure of respiratory events per unit time (RDI). The Medical Director must

determine that the device provides a measure that is equivalent to an apneahypopnea index (AHI) based on full polysomnography.

# F-4 – Computer-assisted Scoring

If used, computer-assisted scoring of OCST recordings must be reviewed and edited for accuracy by a board certified sleep physician.

#### F-5 - Review of Raw Data

The board certified sleep physician interpreting an OCST must conduct an epoch by epoch review of the entire raw data recording for every study interpreted. The review of the data must assure that the quality of the recording and the scoring of sleep and associated events is sufficient to allow for interpretation. Signed attestation of this review must be kept in the patient record in the form of a signature or on the report of the test.

#### **G. Patient Evaluation and Care**

#### Standard

# G-1 – Patient Management (MANDATORY)

A follow-up in-person visit with a physician, nurse practitioner or physician assistant must be performed on all patients undergoing OCST to discuss the results of the test and treatment options. Appropriate follow-up for patients who require continued management must be available from the sleep service entity or by referral.

Options for treatment of OSA found on OCST may include:

- Referral to an accredited AASM sleep center for a PAP titration or splitnight study;
- b) APAP home trial; and
- c) Determination of an alternate to PAP therapy

If continued management is not provided by the sleep service entity, it must demonstrate, in writing, an existing relationship with an accessible AASM accredited sleep center that can provide this care. The sleep service entity must demonstrate that either the treating physician, nurse practitioner, physician assistant or the AASM accredited sleep center have reviewed the sleep study results with the patient. The entity must supply the referring physician with contact information regarding the local AASM accredited center(s) in their network.

#### G-2 – Post-test Follow-up and Management

Technical failures due to equipment malfunction must be documented (See Standard J-1) and the study repeated.

In-center polysomnography must be recommended in cases where OCST fails to establish the diagnosis of OSA in patients with a high pre-test probability. If incenter testing is not provided by the sleep service entity, the entity must provide written documentation of a relationship with an AASM accredited sleep center.

# **G-3 - Documenting Patient Evaluation and Management**

The sleep service entity's medical staff must document ongoing evaluation and management of patients with sleep disorders. The documentation must be part of the patient's medical record.

# G-4 – PAP Titration or Therapy During OCST (MANDATORY)

PAP titration or therapy initiated or performed by the OCST entity must be conducted in accordance with the standards described in the current AASM practice parameters pertinent to autotitrating continuous positive airway pressure (See Appendix A).

G-5 – Follow-up After PAP Titration or Therapy During OCST (MANDATORY) Patients being treated with fixed CPAP on the basis of APAP titration or being treated with APAP must have clinical follow up within 30 days of initiation of PAP to determine treatment effectiveness and safety. This is especially important during this period of PAP use. A reevaluation must be scheduled and, if necessary, a standard attended PAP titration must be performed if symptoms are not resolved or if the APAP treatment otherwise appears to lack effectiveness.

If the patient doesn't accept or adhere to therapy following an APAP trial, they must have an evaluation with a sleep specialist or at an accredited AASM sleep center for further management.

Appropriate follow-up for patients who require continued management must be available within the sleep service entity or by referral. If continued management is not provided by the sleep service entity, they must demonstrate, by written documentation, an existing relationship with an AASM accredited sleep center that can provide this care. Documentation of referral must be maintained in the patient record.

# G-6 – PAP Assessment of Patients by OCST Entities Prescribing PAP (MANDATORY)

Patients prescribed positive airway pressure treatment by the sleep service entity medical staff must be offered a follow-up positive airway pressure assessment within 12 weeks of treatment initiation. Positive airway pressure assessment must minimally include a measurement of treatment use and clinical response to the therapy such as:

- a) direct patient inquiry;
- b) office encounter with sleep service entity technical or medical staff;

- c) office encounter with the referring physician;
- d) questionnaires;
- e) telephone inquiry to the referring physician or the patient; or
- f) an informatic system capable of obtaining positive airway pressure use and a metric of clinical response.

The patient's medical record must contain documentation of the assessment as described above or written evidence of follow-up attempts to obtain the positive airway pressure treatment assessment.

#### H. Patient Records

#### Standard

#### H-1 – Medical Records

AASM accredited sleep service entities must maintain appropriate medical charts for each patient evaluated by the sleep service entity.

Medical charts of patients seen by sleep service entity medical staff must document all patient interactions with the sleep service entity, including testing, diagnosis, and any initial evaluation, treatment, PAP assessment and follow-up.

Prior to testing, all patient medical records must contain documentation consistent with Standard C-1. Written indication that a sleep service entity physician has reviewed and approved the proposed evaluation must be noted in the record.

#### H-2 - Database

The sleep service entity must maintain a cumulative document or database of the final diagnosis, using the most current ICD-9 codes, and procedures performed for each patient evaluated using the most current CPT codes. For sleep service entities affiliated with AASM accredited sleep centers, a single document or database tracking both OCST and in-center patients is sufficient.

# I. Emergency Procedures

#### Standard

#### I-1 – Emergency Plan

The accredited sleep service entity must instruct the patient to call emergency services 911 in the event of an emergency.

# J. Quality Assurance

#### Standard

# J-1 – Quality Assurance Program

The sleep service entity must have a quality assurance program that ensures appropriate patient evaluation and management. Specific measures must be determined by the Medical Director. The program must include at a minimum the following measures:

- 1. Study failure rate;
- 2. Number of retests required including the reason for retesting;
- 3. Written criteria for assessing adequacy of data for clinical decision making; and
- 4. CPAP compliance for treated patients at 12 week follow-up (see standard G-6).

# J-2 - Quality Assurance Reporting

All quality assurance metrics must be reported and reviewed by the sleep service entity's medical director a minimum of once each quarter. The medical director must sign and date the report. Quality assurance reports must be retained for the duration of the accreditation cycle.

# J-3 – Quality Improvement

The sleep service entity must establish thresholds for quality assurance metrics and a written policy for remedial action when minimal standards are not met. Remedial actions may include technologist training; changes to set up or take down protocols; equipment modification, replacement or failure; determination of cause of failure; or changes to patient follow-up procedures.



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