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 “OCST program” when referring to programs 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 testing programs 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 OCST programs 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 OCST programs 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 OCST programs 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 OCST programs must be in compliance with all accreditation standards at the time of application. If it is determined in the application review process that an OCST program is not in compliance with the required standards, the application will be returned and the OCST program will need to resubmit it with the required standards being met. For Accredited Sleep Centers applying for OCST accreditation, the most recent version of applicable standards at the time of application applies.

It is the responsibility of the AASM accredited facility to ensure that all sleep facility clinical and technical personnel, regardless of their role, work as regulated by their primary field's scope of practice, and as consistent with their education, expertise, and state licensure. Only an appropriately licensed MD, DO, PA, or NP should render medical diagnoses and provide medical care.

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 OCST program fails to meet any of the accreditation standards that are indicated as "Mandatory." OCST programs will not be issued provisos for accreditation standards indicated as Mandatory.
2. The OCST program is determined to be non-compliant with more than thirteen (13) accreditation standards provisos.
3. The OCST program fails to resolve proviso(s) within the period of time allotted to correct the proviso(s).
4. The AASM has evidence that the OCST program submitted falsified documents or misrepresented information in seeking to achieve or retain accreditation.
5. The sleep facility fails to notify the AASM within 30 days of initiation of any government investigation or adverse action taken against the facility that impacts the ability to meet any standards.

Table of Contents of AASM Out of Center Sleep Testing in Adult Patients Accreditation Standards

**indicates the standards that are OCST-specific and do not overlap with the sleep center standards*

A. General Standards

Standard

A-1 – Provider License (Mandatory)

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

The accredited OCST program must maintain a professional office with a physical, stationary address recognized by the United States Post Service.

Standard

A-2 – Medical Code of Conduct and Compliance with the Health Insurance Portability and Accountability Act (HIPAA)

AASM accredited OCST programs are required to conduct themselves in a manner consistent with the *Code of Medical Ethics* of the American Medical Association, which the AASM adopted as official policy in 1998. The OCST program must have on hand the *Code of Medical Ethics* of the American Medical Association Council on Ethical and Judicial Affairs Current Opinions. A signed statement of attestation will meet compliance with this standard.
Protection of the privacy of healthcare information is a paramount ethical concern. OCSTs interact with referring healthcare providers, patients, and vendors of health care equipment (e.g., testing services, durable medical equipment, etc). Therefore, the need for increased vigilance to protect patient health information (PHI) has never been greater. Employers and payers are now more sensitive to the protection of PHI than ever before and as a result, all AASM Accredited OCST programs must demonstrate compliance.

A-2 HIPAA Compliance

1. Sleep Center must have or operate under written policies that govern the practices pertaining to maintaining confidentiality of patient medical information. PHI must be the responsibility of all personnel at the OCST, and all must attest to their awareness that federal and state privacy laws, along with any additional privacy rules of the OCST, protect PHI. Sleep Center personnel shall not share any PHI with any party, including but not limited to other health care providers, health care institutions, DME companies, employers, payers, etc., except as permitted by law.

2. The Medical Director is responsible for assuring that all appropriate sleep center personnel are trained regarding HIPAA regulations and OCST policies, and that patients are informed of their rights under HIPAA including the unauthorized solicitation of PHI by any person or company.

3. Sleep Centers must promptly notify all appropriate parties of any HIPAA violations. OCSTs must have or operate under a written privacy breach notification policy and procedure that outlines the actions necessary to notify patients when a breach of their unsecured PHI has occurred that compromises the security or privacy of such information.

B. Personnel

Standards B-1 through B-4 relate to the appointment, responsibilities and continuing medical education of a physician medical director. Patient and employee safety and security must be insured to the absolute extent possible. The AASM recommends that Accredited Sleep Centers institute a standard procedure for verifying the employment, education, criminal background and other information of all applicants and employees, prior to and during employment. These checks are required for employees who have direct patient contact, unsupervised access to patients or their belongings, or access to PHI. Such checks can identify potential employees who may not be an appropriate employee for the center.

Standard

B-1 – Medical Director (Mandatory)

AASM accredited OCST programs must designate a single medical director who is a MD/DO with a valid state medical license in the state where the permanent facility or office is located. A copy of the medical director's state medical license must be submitted with the application.

Standard

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:

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.

Standard

B-3 – Medical Director Responsibilities

The medical director:

- 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 development of detailed job descriptions for all technical personnel that addresses their specific qualifications, duties and responsibilities, and ongoing training requirements for OCST.
- Is responsible for establishing the required qualifications and on-going training of all medical and technical personnel.
- Is responsible for the quarterly review, report, and modification as necessary of the OCST program's quality assurance program.

Standard

B-4 – Medical Director Continuing Medical Education

The medical director 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. Physicians recently completing a sleep medicine fellowship will have the CME requirement waived for 36 months from the end date of the program.

Standard

B-5 – Interpreting Physician(s)

The interpreting physician(s) must have a valid state license in all states where the patient is tested.

Standard

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.

Standard

B-7 – Interpreting Physician(s) Continuing Medical Education

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.

Standard

B-8 – Technical Personnel

AASM accredited OCST programs must maintain appropriately trained, supervised, and, where required by state and federal law, licensed personnel.

Standard

B-9 – Scoring Personnel

Scoring personnel include Registered Sleep Technologist (RST), Registered Polysomnographic Technologists™ (RPSGT), Certified Polysomnographic Technicians (CPSGT), or respiratory therapists with the sleep disorders specialist certification (either CRT-SDS, or RRT-SDS), Sleep Specialists, or other AASM recognized certifications.

Standard

B-10 – Scoring Personnel Continuing Education

The sleep service program's 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 OCST program are acceptable for fulfilling this standard provided the session has defined educational objective(s) and attendance is documented by a roster signed by the OCST program's medical director.

Standard

B-11 – OCST Technical Personnel Training

It is the responsibility of the medical director to ensure that training is provided to the technical personnel (see Standard B-8) on the proper use of OCST devices including:

- Device, application of sensors, use, warnings and safety;
- Instruction of patients in the use of OCST devices;
- Troubleshooting of OCST problems;
- Infection Control; and
- Scoring of data

Please refer to the OCST Policy Statement, which includes additional language under the "Properly Trained Personnel" heading.

Standard

B-12 – Center Staff Provider Continuing Education

A center staff provider is a licensed physician (MD/DO), psychologist, nurse practitioner or physician assistant who provides the evaluation and management of patients within their scope of practice as part of the sleep medicine program.

All center staff providers must participate in at least 10 credits per year averaged over three years of *AMA PRA Category 1 Credit*™ in sleep or equivalent. Compliance with applicable continuing education requirements in sleep must be documented. Providers who have completed a training program within the previous 12 months will have their credit requirements waived. Upon completion of a training program, the applicable continuing education requirement in sleep will be prorated based on the end date of the program. 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 sleep facility's medical director.

Standard

B-13 – OCST On-call Coverage

1. Sleep service programs 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.

2. All calls received during testing hours must be documented in a secure log. Quarterly audits will be conducted of on-call logs to identify trends of device, sensor or service issues, which will be used in QA reporting, see Section J.

C. Patient Policies

Standard

C-1 – Scope of Practice

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

- Age limitations;
- A mechanism for acceptance;
- Criteria for exclusion; and
- 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).

Only appropriately licensed healthcare professionals (MD, DO, NP or PA) with prescriptive authority in the state where the patient would be tested can request an OCST.

Standard

C-2 – Practice Parameter Requirements

The clinical evaluation of patients accepted for sleep testing conducted in the OCST program 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.

Standard

D-2 – Stationery

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

Standard

D-3 – Portable Recording Equipment

The OCST equipment must be FDA approved and 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 (e.g., by airflow or peripheral arterial tone), and sleep time
- 95801 Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and respiratory analysis (e.g., by airflow or peripheral arterial tone)
- 95806 Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (e.g., thoracoabdominal movement)

All reusable equipment must have a unique identifier (ID) so that it may be assigned to a patient and tracked. The ID number will be included in the patient medical record and used to assist in failure investigation and quality reporting.

A process must be developed documenting that all PHI and physiologic data is erased following each use of the device.

Equipment used must have the capability to meet all OCST accreditation standards outlined in Sections F and J. For additional information, reference the paper "Obstructive Sleep Apnea Devices for Out-Of-Center (OOC) Testing: Technology Evaluation."

E. Policies and Procedures

The program should develop appropriate businesses policies and procedures that will aid in a successful, high quality OCST program. 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 OCST programs 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 and procedures 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).

Standard

E-2 – Equipment Maintenance

6. The OCST program must have a written procedure for infection control including cleaning and inspecting equipment and the application of germicidal agents after each use that is consistent with the germicidal manufacturers' recommendations, federal and state health policy regulations and institutional standards.
7. Specific instructions must exist for device and sensor packing, shipping or storage. An area must be designated for clean versus dirty devices
8. All devices and sensors associated with a failed test, i.e. no data, inadequate data, or corrupt data must be removed from service and tested for proper function prior to its next use.
9. Reported or detected failures of devices, sensors or processes must be categorized and analyzed for cause (see Section J).

Standard

E-3 – Equipment Maintenance Continued

An annual written plan for ongoing 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.

Recommendations
The AASM recommends that device failure or design that result in harm to the patient, show the potential for harm to the patient, or that result in systematic diagnostic errors should be reported to the FDA via the MedWatch program (https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm).

F. Data Acquisition, Scoring and Reporting

Standard

F-1 – OCST Reports and Interpretations

The data included in OCST reports must include at minimum:

- Type of Device Used
- Date of testing
- Duration of test recording
- Respiratory Event Index (REI) and total number of respiratory events
- A summary of oxygen desaturations (which may be ODI, % of time below certain thresholds, mean, minimum and/or maximum O2 saturations) during recording period
- Heart rate during the recording period
- Technical adequacy of test
- Interpretation (based upon test results and clinical information), including at a minimum whether the test results support a diagnosis of obstructive sleep apnea or not
- Signature (electronic or ink) of interpreting sleep physician

Any recommendations for next management steps (based upon test results and clinical information), if provided, must be consistent with applicable AASM Standards of Practice, AASM Practice Guidelines, and AASM Best Practice papers.

Standard

F-2 – OCST Recording Equipment

Accredited OCST programs must use FDA approved equipment that provides a measure of respiratory events per unit time (REI). The Medical Director must determine that the device provides a measure that is equivalent to an apnea-hypopnea index (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. For more information please reference Collop NA; Tracy SL; Kapur V; Mehra R; Kuhlmann D; Fleishman SA; Ojile JM. Obstructive sleep apnea devices for out-of-center (OOC) testing: technology evaluation. J Clin Sleep Med 2011;7(5):531-548.

Standard

F-3 – Review of Raw Data

The board certified sleep physician interpreting an OCST must conduct a 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 on the report (See F-2).

G. Patient Evaluation and Care

The AASM recommends that it is optimal for patients to be evaluated by a sleep specialist in concert with, and preferably prior to and after, any sleep testing as part of a comprehensive sleep center's program. However, the AASM acknowledges that OCST may be performed at independent diagnostic testing facilities, or by request of primary care or medical specialists. All OCST programs must adhere to standards G-1 through G-2. Whenever patient evaluation and management extends beyond the rendering of diagnostic testing and interpretation only, standards G-3 through G-5 apply.

Standard

G-1 – Patient Management (Mandatory)

Appropriate follow-up must be available from the OCST program or by referral. A record of any patient management must be included in the patient's medical record.
Options for treatment of OSA found on OCST may include:

- Referral to an accredited AASM sleep center for a PAP titration or split-night study;
- APAP home trial; and
- Determination of an alternate to PAP therapy

If continued management is not provided by the OCST program, it must demonstrate, in writing, an existing relationship with an accessible AASM accredited sleep center that can provide this care, and the OCST program must supply the referring physician with contact information regarding the local AASM accredited center(s) in their network.

Standard

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 adequately performed OCST does not establish the diagnosis of OSA in patients with a high pre-test probability. If in-center testing is not provided by the OCST program, the OCST program must provide written documentation (such as a letter of understanding that both parties have signed) of a relationship with an AASM accredited sleep center.

Standard

G-3 - Documenting Patient Evaluation and Management

The OCST program'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.

Standard

G-4 – PAP Titration or Therapy After OCST

PAP titration or therapy initiated or performed by the OCST program must be conducted in accordance with the standards described in the current AASM practice parameters or guidelines pertinent to PAP titration or auto-titration. (See Appendix A).

Standard

G-5 –Assessment of Patients by OCST Entities Prescribing PAP

Patients prescribed positive airway pressure treatment by the OCST program medical staff should have a face-to-face follow-up positive airway pressure assessment within the first few weeks but within no longer than 12 weeks of treatment initiation. Positive airway pressure assessment should be face-to-face and minimally include an objective measurement of treatment use and clinical response to the therapy. The patient's medical chart 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 OCST programs must maintain appropriate medical records for each patient evaluated by the sleep service program.

Medical records of patients seen by OCST program medical staff must document all patient interactions with the OCST program, 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 an OCST program physician has reviewed and approved the proposed evaluation must be noted in the record.

Standard

H-2 – Database

The OCST program must maintain a cumulative document or database of the final diagnosis, using the most current ICD codes, and procedures performed for each patient evaluated using the most current CPT codes. For sleep service programs 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 AASM accredited OCST program 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 OCST program 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 (e.g., device, sensor or service issues);

3. Written criteria for assessing adequacy of data for clinical decision making;
4. For patients managed at the OCST, CPAP compliance and patient-reported outcomes (such as sleepiness or quality of life) for treated patients at follow-up (see standard G-5).
5. Patient satisfaction measures
6. Number of days between receipt of request for services and provision of interpretation/management plan to referring healthcare provider.

Standard

J-2 – Quality Assurance Reporting

All quality assurance metrics must be reported and reviewed by the OCST program'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.

Standard

J-3 – Quality Improvement

The OCST program must establish thresholds for quality assurance metrics expressed as a minimum of achievement. Effectiveness of quality improvement efforts must be made at least quarterly, as attested to by the OCST program's medical director.

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