

Standards for Accreditation

Final Draft - July 2022

The American Academy of Sleep Medicine (AASM) developed *Standards for Accreditation* with the primary purpose of ensuring that the highest quality of care is delivered to patients with sleep disorders. The constant evolution of sleep medicine necessitates an update to the *AASM Standards for Accreditation* to reflect the models of clinical practice that have emerged in recent years.

New research, policy and technology are shifting the field toward comprehensive patient management. Accreditation of entities that offer diagnostic testing and comprehensive management for sleep disorders is increasingly important as care focuses on improving population health and engaging patients while containing costs. The importance of quality clinical care has become the foundation for improving outcomes and continuum of care. For this reason, the AASM is releasing these *Standards for Accreditation* which includes accreditation of a clinical component required for Sleep Clinic, Sleep Facility and Sleep Practice accreditation types. Durable Medical Equipment (DME) Supplier accreditation has also moved to requiring a Sleep Clinic component.

Accreditation Network

In the field of sleep medicine, it is becoming common place for accreditation programs to be associated with one another either under a hospital, large health system or multi-clinic sleep practice. To accommodate the changing state of sleep medicine and to more efficiently mold to current practice models, the AASM has moved to a component-based system and released the implementation of an Accreditation Network. Accredited components (Sleep Clinic, Lab, HSAT, DME) associated with each other will form an Accreditation Network. This Accreditation Network made up of various components, will allow for commonalities to be shared in application (policies, procedures, staff, etc.) and allow for syncing of site visits and expiration dates.

Standards for Accreditation

To accommodate the component-based system, Standards for Accreditation are divided into the following sections:

- <u>Network</u>: Standards included in this section apply to the entire accreditation network. The accreditation network, as a whole, needs to make sure that they are compliant with the standards included in this section.
- <u>Site</u>: Standards included in this section apply to the physical location of each component within the Accreditation Network. Each component must individually meet the standards that are included in this section.
- <u>Sleep Clinic Component</u>: Standards included in this section apply to the Sleep Clinic Component. It is the responsibility of the Sleep Clinic component to fulfill the responsibilities in this section.
- <u>Lab Component</u>: Standards included in this section apply to the Lab Component. It is the responsibility of the Lab component to fulfill the responsibilities in this section.
- <u>HSAT Component</u>: Standards included in this section apply to the HSAT Component. It is the responsibility of the HSAT component to fulfill the responsibilities in this section.
- <u>DME Component</u>: Standards included in this section apply to the DME Component. It is the responsibility of the DME component to fulfill the responsibilities in this section.

Note: An Accreditation Network that only consist of a single component (Sleep Clinic) must still comply with the Network, Site-Specific and appropriate component standards.

Accreditation Types

An accreditation type is determined by the components that make up the Accreditation Network:

- Sleep Clinic Accreditation consist of an Accreditation Network that only includes Sleep Clinic component(s). "Sleep Clinic" is used to refer to a sleep clinic where patient evaluation and management occur.
- Sleep Practice Accreditation consist of an Accreditation Network that includes Sleep Clinic component(s) with HSAT component(s). "HSAT" is used to refer to where diagnostic testing through the use of home sleep apnea testing (HSAT) is administered.
- Sleep Facility Accreditation consist of an Accreditation Network that includes Sleep Clinic component(s) with Lab(s) and HSAT component(s). "Lab" is used to refer to where diagnostic testing through the use of in-center sleep studies is administered.

Minimally, an accreditation type must include 1 of each corresponding component. Additional components may be added to an Accreditation Network by submitting the component application under the Accreditation Network.

Accreditation Add-on(s)

DME Accreditation is an accreditation add on. It requires association with a Sleep Clinic component
and can be added to any of the above accreditation types. "DME" is used to refer to where PAP
therapy and PAP equipment is supplied to patients.

High Quality Patient Care and Management

All qualified sleep medicine physicians and providers must be committed to providing quality patient care. Patients benefit greatly from direct personal interaction with the diagnosing/treating physician and other center staff providers. It is therefore the general position of the AASM that, in ideal circumstances, all patients evaluated and treated should be seen by a board-certified sleep physician or medical staff member prior to testing and the initiation of treatment. In appropriate instances, sleep facilities also may use telemedicine tools in the provision of sleep medicine services to expand interactions between sleep physicians and sleep patients.

However, the AASM recognizes that patient consultations may be restricted by some health plans or prevented by a variety of other reasonable and unavoidable circumstances. Every effort should be made to manage these conditions in the best interests of the patient and in a way that promotes high-quality care. It is the recommendation of the AASM that accredited entities should include in its policies a description of any circumstances that prevent patient consultations.

In the context of these accreditation standards, sleep study interpretation includes reviewing the raw data from a sleep study and explaining what the data show. Interpretation is not the same as diagnosis. Diagnosis includes assessment of patient symptoms, examination of signs, and, when clinically appropriate, interpretation of diagnostic testing.

Clinical Recommendations

The AASM uses a rigorous, evidence-based process to establish practice guidelines on a variety of topics that are relevant to the practice of sleep medicine. AASM accredited programs must adopt and follow all STRONG and STANDARD level recommendation statements in all active AASM Clinical Practice Guideline, Practice Parameter, Clinical Guideline and Best Practice Guide papers. In addition, it is recommended that accredited entities adopt and follow all other recommendation statements (i.e., Good Practice, WEAK, GUIDELINE, OPTION, and CONSENSUS level recommendations) in all active AASM Clinical Practice Guideline, Practice Parameter, Clinical Guideline and Best Practice Guide papers. It is also recommended that accredited entities follow applicable AASM Consensus and Position Statements.

Clinical Judgement

The AASM recognizes that the practice of sleep medicine, like all other medical disciplines, is dynamic and complex, requiring clinical judgment. AASM Clinical Practice Guidelines, Practice Parameters and Clinical Guidelines are not designed to limit physicians from using their medical judgment. Therefore, unique circumstances may require deviation from AASM clinical recommendations for the appropriate evaluation and management of select patients. However, in such instances, the accredited entity is expected to keep documentation on file that provides justification for the deviation in standard clinical practice.

Compliance

Facilities accredited by the AASM must be in compliance with all accreditation standards at the time of application and throughout the accreditation period. If it is determined in the application review process that an accredited entity is not in compliance with the required standards, the application will be returned, and the entity will need to resubmit its application once the required standards are met. The AASM reserves the right to revoke accreditation for entities that are found to be non-compliant with the *Standards for Accreditation* during the period of accreditation.

Denial or Revocation

Denial or revocation 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 entity fails to meet any of the accreditation standards that are indicated as "MANDATORY." Entities will not be issued provisos for accreditation standards indicated as MANDATORY. (If granted accreditation with provisos, the entity receives a letter that describes certain stipulations that must be met by a specified deadline to retain accreditation.)
- 2. The entity is determined to be non-compliant with more than ten (10) non-mandatory accreditation standards.
- 3. The entity fails to resolve provisos within the period of time allotted to correct the provisos.
- 4. The AASM has evidence that the entity submitted falsified documents or misrepresented information in seeking to achieve or retain accreditation.

Disclaimer

The AASM is one of multiple bodies that offer accreditation to entities that offer sleep medicine services. Accreditation by the AASM is a voluntary program offered to entities that meet the standards contained in this document. The AASM reserves the right to modify, add or remove accreditation standards at its own discretion and without notice. In addition, the AASM reserves the right to interpret the *Standards for Accreditation* as deemed appropriate.

Entities accredited by the AASM must comply with all applicable local, state and federal laws and regulations. If any law or government regulation conflicts with these *Standards for Accreditation*, the law or regulation supersedes the accreditation standard.

Acknowledgments

The American Academy of Sleep Medicine acknowledges all current and past AASM Accreditation Committee members and staff who helped develop and evaluate the accreditation standards and recommended updates that were reviewed and approved by the AASM Board of Directors.

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Glossary

AASM	American Academy of Sleep Medicine
AASM	The AASM Manual for the Scoring of Sleep and Associated Events: Rules,
SCORING	Terminology and Technical Specifications
MANUAL	
ABMS	American Board of Medical Specialties
ABSM	American Board of Sleep Medicine
ACGME	Accreditation Council for Graduate Medical Education
ADA	Americans with Disabilities Act
AED	Automated External Defibrillator
AHI	Apnea-Hypopnea Index
AOA	American Osteopathic Association
APRN	Advanced Practice Registered Nurse
A-STEP	Accredited Sleep Technologist Education Program
BRPT	Board of Registered Polysomnographic Technologists
CAAHEP	Commission on Accreditation of Allied Health Education Programs
CEC	Continuing Education Credit
CME	Continuing Medical Education
COARC	Commission on Accreditation for Respiratory Care
CPR	Cardiopulmonary Resuscitation
CPSGT	Certified Polysomnographic Technician
CRT	Certified Respiratory Therapist
DME	Durable Medical Equipment
HIPAA	Health Insurance Portability and Accountability Act
HITECH	The Health Information Technology for Economic and Clinical Health Act
HSAT	Home Sleep Apnea Test
ICSD	International Classification of Sleep Disorders
ISR	Inter-Scorer Reliability
MSLT	Multiple Sleep Latency Test
MWT	Maintenance of Wakefulness Test
NBRC	National Board for Respiratory Care
OSA	Obstructive Sleep Apnea
OSHA	Occupational Safety and Health Administration
PA	Physician Assistant
PAP	Positive Airway Pressure
PHI	Protected Health Information
PSG	Polysomnography
QA	Quality Assurance
RDI	Respiratory Disturbance Index
REI	Respiratory Event Index
RLS	Restless Legs Syndrome
RN	Registered Nurse
RPSGT	Registered Polysomnographic Technologist
RRT	Registered Respiratory Therapist
RST	Registered Sleep Technologist

AASM Continuing Education Appendix

CME opportunities include:

• AASM Courses: aasm.org/events/

• SLEEP Journal: <u>aasm.org/clinical-resources/journals/</u>

 Journal of Clinical Sleep Medicine jcsm.aasm.org/

• AASM Online Learning Opportunities: <u>aasm.org/professional-development/cme/</u>

• AASM MOC Modules: aasm.org/professional-development/maintenance-of-certification/

CEC opportunities include:

 AASM ISR Record Review: isr.aasm.org/

*AMA PRA Category 1 Credit or equivalent type of continuing education credit accepted/maintained by your profession will be accepted.

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NETWORK

Standards included in this section apply to the entire accreditation network. The Accreditation Network, as a whole, needs to make sure that they are compliant with the standards included in this section.

STANDARD

N-1 Network Director (MANDATORY)

Entities must appoint a Network Director who is a sleep specialist and meets one of the following requirements:

- 1. A physician or PhD who is board-certified in sleep medicine by the ABSM or a physician certified in sleep medicine by either a member board of the ABMS or a member board of the AOA.
- 2. A physician who has completed a 12-month ACGME-accredited or AOA-accredited fellowship in sleep medicine, is eligible to sit for the sleep medicine board examination, and is awaiting the first available opportunity to apply to an ABMS member board or AOA member board to sit for the sleep medicine examination. To retain accreditation, the ABMS or AOA examination in sleep medicine must be passed within two consecutive examination cycles.

The entity must appoint one Network Director, to serve across all components; individual components may appoint separate local Site Directors (reference Standard N-3 and N-4). The Network Director may also serve as the Site Director.

STANDARD

N-2 Network Director Responsibilities

The Network Director:

- 1. Is responsible for serving as or designating a primary contact for the AASM and apprise the AASM of any changes to the accreditation network.
- 2. Must review, report, and manage the entity's quality assurance program on a quarterly basis as mandated in the Sleep Clinic Component Standards.
- 3. Must annually review and provide oversight all of policies and protocols for the accreditation network.
- 4. Must review and assess all safety related issues, perform risk analysis, and communicate with stakeholders.
- 5. Must have access, as needed, to the information in electronic medical records (EMRs) utilized by each component.
- 6. Must be medically licensed in each state of the network, should the network encompass an area larger than a specific state or locale.
- 7. It is recommended that the Network Director spend a minimum of 4 hours per month (in larger Networks 2 hours per month per component may be required) fulfilling the above responsibilities. The Network Director may fulfill this requirement by either physical presence in the center, and/or regular conference calls, virtual meetings, and webinars with the professional and technical staff.

STANDARD

N-3 Site Director (MANDATORY)

Entities must appoint a Site Director who is a sleep specialist and meets one of the following requirements:

1. A physician or PhD who is board-certified in sleep medicine by the ABSM or a physician certified in sleep medicine by either a member board of the ABMS or a member board of the AOA.

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

The entity may appoint one Site Director, to serve across all components, additionally each component may appoint separate Site Directors that meet this standard. The Site Director may also serve as the Network Director.

STANDARD

N-4 Site Director Responsibilities

The Site Director:

- 1. Is responsible for ensuring there is a process for determining that only licensed health care professionals with prescriptive authority in the state where the patient would be tested can request testing.
- 2. Is responsible for the qualifications and training of all medical, technical and administrative support personnel.
- 3. Is responsible for the supervision and oversight of entity medical technical and administrative personnel.
- 4. Is responsible for assuring staff complies with the Code of Medical Ethics as well as any institutional ethics requirements.
- 5. Must provide oversight of proper operation and calibration of the equipment mandated in the Lab and/or HSAT Component Standards.
- 6. It is recommended that the Site Director spend a minimum of 4 hours per month fulfilling the above responsibilities. The Site Director may fulfill this requirement by either physical presence in the center, and/or regular conference calls, virtual meetings, and webinars with the professional and technical staff.

STANDARD

N-5 Network and Site Director Continuing Education (MANDATORY)

The director must earn at least 30 credits (averaged 10 credits per year over the past 36 months) of AMA PRA Category 1 CME credit in sleep medicine. Compliance with CME requirements must be documented. See appendix for CME opportunities.

Physicians recently completing a sleep medicine fellowship or initial board certification in sleep medicine will have the CME requirement waived for 36 months from the end date of the program.

STANDARD

N-6 Medical Staff Member (MANDATORY)

Entity medical staff members include physicians, licensed psychologists, and advanced practice providers (NP, PA, APRN), all of whom may or may not be board-certified in sleep medicine, must hold a valid, unrestricted state license in states where patients are evaluated, diagnosed, or treated. The AASM recommends medical staff members be board certified in sleep medicine.

STANDARD

N-7 Medical Staff Member Continuing Education

Medical staff members must earn at least 30 credits (averaged 10 credits per year over the past 36 months) of AMA PRA Category 1 CME credit in sleep medicine. Compliance with CME requirements must be documented.

Medical staff members who have completed a sleep medicine fellowship or initial board certification in sleep medicine will have the CME requirement waived for 36 months from the end date of the program.

Medical staff members who completed a formal 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 medicine will be prorated based on the end date of the program. Proration based upon date of hire is acceptable for advanced practice provider (NP, PA, APRN) medical staff members. Education sessions conducted by the entity are acceptable for fulfilling this standard provided the session has defined educational objective(s) and attendance is documented by a roster signed by the Site Director. See appendix for additional CME opportunities.

STANDARD

N-8 Technical Staff Requirements

Entities must maintain appropriately trained, supervised, and, where required by state law, licensed sleep technologists. It is the responsibility of the Site Director to ensure that training is provided and documented for technical personnel.

STANDARD

N-9 Registered Sleep Technologist

For those that have a diagnostic component (Lab and/or HSAT) a registered sleep technologist is registered or accepted to sit for the registry exam by one of the following:

- 1. American Board of Sleep Medicine (ABSM)
 - a. Registered Sleep Technologist (RST)
- 2. National Board for Respiratory Care (NBRC)
 - a. Registered Respiratory Therapist Sleep Disorder Specialist (RRT-SDS)
- 3. Board of Registered Polysomnographic Technologists (BRPT)
 - a. Registered Polysomnographic Technologist (RPSGT)
- 4. Another organization that offers an equivalent examination accepted by the AASM

The registry exam must be passed within one year from acceptance to sit for the examination; otherwise, the individual will be considered a non-registered technologist.

STANDARD

N-10 Sleep Technician and Technologists Continuing Education

For those that have a diagnostic component (Lab and/or HSAT) all technical staff must participate in at least 30 credits (averaged 10 credits per year over the past 36 months) of sleep-related continuing education credits. This must be documented for each technical staff member. Proration based upon date of hire is acceptable for sleep technician and technologists. Education sessions conducted by the entity are acceptable for fulfilling this standard provided the session has defined educational objective(s) and attendance is documented by a roster signed by the Site Director.

Each sleep technician and technologist must have valid CPR certification that includes skills training.

N-11 Non-Registered Sleep Technologist

For those that have a diagnostic component (Lab and/or HSAT) all technologists and technicians performing technical duties (except scoring) who are not registered by the ABSM, BRPT, or NBRC (as defined in Standard N-9):

 Must be enrolled in or have completed the A-STEP Online Self Study Modules. Non-registered technologists and technicians must complete A-STEP Online Self Study Modules within two years of enrollment.

OR

2. Must be enrolled in or have completed training in polysomnography in a program accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP) or a Commission on Accreditation for Respiratory Care (CoARC) program with the polysomnography option.

STANDARD

N-12 Administrative Support Staff

The accreditation network may utilize additional administrative staff in a supporting role (e.g. prior authorizations, download PAP machines, provide HSAT equipment) that is not directly involved in the evaluation or treatment of a patient. Administrative support staff must be appropriately trained to perform these supportive duties, but do not require any specific continuing education requirements.

STANDARD

N-13 Scoring Personnel

For those that have a diagnostic component (Lab and/or HSAT) scoring personnel must be one of the following: RST, RPSGT, CPSGT, respiratory therapists with the sleep disorders specialist certification (either CRT-SDS or RRT-SDS), or medical staff members/PhDs board-certified in sleep medicine (as defined in Standard N-1 and Standard N-1. Scoring personnel not sleep credentialed as identified above may score only under the supervision of one of the above while adhering to Standard N-11.

STANDARD

N-14 Individual Licensure

All professional staff (including MDs, DOs, PhDs, advanced practice providers and RNs) and technical staff (including RRTs, RSTs, RPSGTs and non-registered technologists) must maintain valid, unrestricted licenses commensurate with the services they perform in the state(s) where patients are seen, when required by state law. Each staff member must practice within the limits of his or her license. The AASM neither sanctions nor defends individuals practicing outside the scope of their license. Privileges and restrictions of licenses are contained in the practice act related to each license.

STANDARD

N-15 Employee Background Checks

Entities shall comply with all background check requirements which may be required by federal, state, or local law. In the absence of such requirements, the component shall conduct criminal background checks of all new employees. The component shall utilize information obtained in this process only to the extent such information is relevant to the job duties of a particular person.

N-16 Medical Code of Conduct (MANDATORY)

Entities and their physician staffs are required to follow the current opinions in the *Code of Medical Ethics* of the American Medical Association Council on Ethical and Judicial Affairs. The entity must have the ability to easily access the *Code of Medical Ethics*.

STANDARD

N-17 HIPAA Rules and Regulations (MANDATORY)

- 1. Entities are required to abide by all current, applicable Health Insurance Portability and Accountability Act ("HIPAA") and the Health Information Technology for Economic and Clinical Health ("HITECH") rules and regulations.
- 2. Entities must operate under written policies that govern the practice of maintaining the confidentiality of Protected Health Information ("PHI"). It is the responsibility of the Network Director that these policies are in place. Written policies must address the importance of protecting PHI. Protecting PHI must be the responsibility of all personnel employed by the entity, and all employees must attest to their awareness that federal and state privacy laws, along with any additional privacy rules, protect PHI. Except as permitted by law, personnel shall not share any PHI with any party, including but not limited to other health care providers, health care institutions, DME companies, employers, or payers.
- 3. Entity policies shall reflect that patients have a right to:
 - o Review a privacy notice to inform them how PHI will be used and disclosed;
 - Request that uses and disclosures of PHI be restricted (facilities are not required to agree to the restrictions);
 - o Inspect, copy, and amend their medical records; and
 - o Get an accounting of the disclosure of their PHI.
- 4. The Site Director is responsible for ensuring that all appropriate personnel are trained regarding HIPAA regulations and that patients are informed of their rights under HIPAA, including the unauthorized solicitation of PHI by any person or company, through distribution of privacy practices notices. Proof of training shall be maintained by the entity.
- 5. The Site Director must promptly notify all appropriate parties, including but not limited to a hospital compliance officer, attorney, or other appropriate office within a hospital, of any HIPAA violations. Entities must have or operate under written privacy breach notification policies and procedures which outline the processes to determine whether there has been the acquisition, access, use or disclosure of PHI in a manner not permitted under the HIPAA regulations which compromise the security or privacy of the PHI ("Breach"). If it is determined there is more than a low probability that PHI is compromised, notification shall be made in accordance with applicable law.

STANDARD

N-18 Medical Records

Entities must maintain appropriate medical records for every patient evaluated and/or tested. Medical records of patients seen by the medical staff members must document all interactions with the patient, referring provider or provider's representative, and insurance company. Medical records must include the referral letter/prescription for testing.

Prior to testing, all patient medical records must include patient questionnaires or other screening assessment, history and physical, as well as medications record. Potential serious medical conditions that might lead to medical emergencies while at the testing component should be noted and carefully reviewed.

N-19 Record Review of Direct Referrals

For patients directly referred, a medical staff member or appropriately trained technical or administrative support staff member must review the information provided for each patient and determine if the requested action is indicated according to the component's patient acceptance policy. Evidence of communication with the referring clinician should be recorded in the patient record for every PSG or HSAT. This should include a history and physical received from the referring clinician and a sleep study report sent back to the referring clinician.

STANDARD

N-20 Emergency Policies

Emergency policies must include policies and procedures for the following:

- 1. Cardio-pulmonary emergencies with equipment required in Standard S-6.
- 2. Neurologic emergencies, particularly seizures and strokes.
- 3. Psychiatric emergencies, particularly suicidal ideation.
- 4. Environmental emergencies including fire, weather, belligerent patients, and bomb threats.

STANDARD

N-21 Analysis of Significant Adverse Events

Entities must create a policy and procedure for performing a root cause analysis of any significant adverse events. Significant adverse event may include:

- 1. Patient or staff death.
- 2. Permanent loss of function or of a body part by a patient or staff.
- 3. An event that leads to the hospitalization of a patient or staff.
- 4. An event that requires activation of an emergency medical response.
- 5. Sexual or physical assault of a patient or staff or allegations thereof.
- 6. Release of a minor or a patient lacking capacity or competency to an unauthorized individual.
- 7. Elopement of a patient.
- 8. Complications arising from the effects of hypnotics used for the purpose of sleep testing.
- 9. Incident, injury or infection caused by component equipment.
- 10. Any event required by the applicable jurisdiction to be reported to a government agency.

STANDARD

N-22 Quality Assurance Program

Sleep Clinics must have a Quality Assurance program that addresses three sleep medicine indicators from a qualified clinical data registry (QCDR) and inter-scorer reliability as outlined in <u>Standard N-24</u>. The indicators may be chosen from the AASM Sleep CDR (available at https://aasm.org/sleep-clinical-data-registry/).

STANDARD

N-23 Quality Improvement

Sleep Clinics must establish minimal thresholds for the quality assurance metrics. Quarterly, the Network Director must attest to the effectiveness of quality improvement efforts and address plans for remediation of metrics that do

not meet the minimal threshold. Quarterly reports must be signed and dated by the Network Director and maintained for at least five years.

STANDARD

N-24 Inter-scorer Reliability

Inter-scorer reliability (ISR) applies to any accreditation network that has a lab component. ISR must be determined between each scorer and the Network Director or a medical staff member board-certified (as defined in Standard N-1) in sleep medicine. In cases where a medical staff member board-certified (as defined in Standard N-1) in sleep medicine serves as the reference standard for ISR, the Network Director must attest in writing that he/she has reviewed the results of the ISR assessment and will take corrective action when results fall below the lab's level of acceptable agreement as defined in its quality assurance program (reference Standard N-21 and Standard N-21 and Standard N-21 and Standard N-22).

For comprehensive PSG, the following parameters must be compared: sleep staging epoch-by-epoch agreement, respiratory events, leg movements and arousals. Sleep technologists must be blinded to the scoring of the Network Director/medical staff member and to all other scoring technicians. Comparisons between each scorer and the Network Director/medical staff member must be made on 200 consecutive 30-second epochs in each of three polysomnograms per quarter, for a total of 12 polysomnograms per year. Comprehensive PSG studies must report agreement between scorer and the Network Director/ medical staff member as percent concordance defined as the quotient of the total number of epochs of agreement for a given parameter and the total number of epochs in the analysis sample multiplied by 100. Sleep-related breathing event comparisons for laboratory PSG must include analysis by total number of events and by the following event types: obstructive apnea, central apnea, and hypopnea. If the lab reports respiratory effort related arousals, this event must be included in the comparison. Use of the AASM Inter-Scorer Reliability program fulfills the requirements of this standard.

SITE

Standards included in this section apply to the physical location of each component within the Accreditation Network. Each component must individually meet the standards that are included in this section.

STANDARD

S-1 Component Licensing (MANDATORY)

Components must maintain a valid state license to provide health care services. If a valid state license is not required by applicable law, the component may submit a certificate of occupancy and/ or permit to provide health care services. If no license, certificate, or permit is required by applicable law, the Site Director must submit a written attestation that the above is not required.

STANDARD

S-2 Permanent Address

Components must have a permanent, physical address.

STANDARD

S-3 Phone Line

Components must have a phone to receive incoming or make outgoing calls. Components must have immediate communications access to emergency services (medical, fire and security).

S-4 Policy and Procedures Manual

Components must maintain a Policy and Procedures Manual. The manual must contain all policies, procedures, and protocols specific to the component, and must be consistent with all current AASM Practice Parameters, AASM Clinical Guidelines and AASM Best Practice Guidelines (available at https://aasm.org/clinical-resources/practice-standards/practice-guidelines/?cid=120). The manual must contain all policies and procedures required within these Standards for Accreditation.

STANDARD

S-5 Patient Acceptance

Entities must maintain a Policy and Procedures Manual that addresses patient acceptance policies for sleep clinics, in-center testing, HSAT and DME. Written policies for patient acceptance must include:

- Adherence to all applicable, current AASM guidelines:
- Age limitations;
- A mechanism for acceptance;
- Evidence based criteria for exclusion; and
- Information required from a referring health care provider prior to all sleep testing.

Sleep Clinic component must be able to evaluate, manage and provide follow up for an adequate range of sleep disorders (as defined in Standard C-1). Sleep Clinic(s) associated with a diagnostic component (lab and/or HSAT) must accept the full spectrum patient acceptance of the diagnostic component(s).

Lab component must be able to provide diagnostic sleep testing for all sleep disorders requiring lab-based testing for diagnosis (including but not limited to central sleep apnea, parasomnias and central hypersomnias). The testing portion of this standard can be met by providing a list of tests performed (reference Standard L-17) over a period of at least six months.

STANDARD

S-6 Emergency Drills

Components must conduct and document drills of their emergency procedures on an annual basis. At a minimum, the component conducts and documents annual drills of their response to cardio-pulmonary emergencies.

STANDARD

S-7 Emergency Equipment

Components must have appropriate equipment to address possible emergencies. At a minimum, all entities must have immediate access to either an automated external defibrillator (AED) or access to an on-site medical emergency response team. The component maintains and documents the maintenance of all emergency equipment according to manufacturers' recommendations. The component maintains and documents training of personnel on emergency equipment.

S-8 Physical Safety

The physical space used by the component complies with all required standards, regulations and codes for construction, fire safety and building codes applicable in the jurisdiction where the component is located and appropriate to the component type.

STANDARD

S-9 Occupational Safety

Components must demonstrate compliance with all applicable OSHA requirements as well as appropriate state authorities. This includes but is not limited to:

- 1. Access to safety data sheets for hazardous materials; and
- 2. Availability of personal protective equipment.

STANDARD

S-10 Hazardous Materials

Components disposes of all hazardous materials in compliance with the manufacturer's recommendations and applicable laws and regulations.

STANDARD

S-11 Patient Safety Risk Analysis

Components must complete and document an analysis of safety risks to patients related the procedures performed by the component. This analysis must be updated periodically and no less frequently than every five years. The risk analysis must be reviewed, and the review documented, on an annual basis. The component must implement policies and procedures to mitigate risks identified. Risks may include:

- 1. Patient falls after receiving hypnotics.
- 2. Slippery surfaces.
- 3. Uneven ground to/from the premises.

STANDARD

S-12 Reporting of Significant Adverse Events

Consistent with the Significant Adverse Events policy (reference Standard N-21), each site must investigate all significant adverse events that occur, document findings in a formal report, and have the report analyzed by the Network Director.

STANDARD

S-13 Patients' Rights

Components must have a patients' bill of rights and ensure patients are informed of these rights. If the component is part of a larger organization, it may use its organization's bill of rights. Otherwise, the component must have a patients' bill of rights that addresses at least the following:

- 1. The right to accurate and easily understood information proposed about the patient's health care and the providers of such care. If the patient speaks another language, has a physical or mental disability, or just does not understand something, help should be given so that the patient can make informed health care decisions.
- 2. The right to know treatment options and take part in decisions about care. Parents, guardians, family members, or others can speak for the patient, if the patient cannot make his/her own decision.

- 3. The right to considerate, respectful care from your doctors and other health care providers that does not discriminate against the patient.
- 4. The right to talk privately with health care providers and to have health care information protected.
- 5. The right to read and copy your own medical record, the right to ask that your doctor change the record if it is not correct, relevant, or completed.
- 6. The right to examine and receive a detailed explanation of any medical bill and the right to information regarding financial assistance the component may offer.

S-14 Storage

Components collecting patient data must store data, including the raw data (excluding video) from all sleep tests (including, but not limited to, PSG, MSLT and HSAT), for a minimum of five years or as required by law if longer. Electronic copies may be provided to other treating physicians who are not affiliated with the component in accordance with patients' request for release of medical information.

STANDARD

S-15 Signage

Entities must have signage, identifying themselves, on the outside or in a directory; if components are housed in separate physical locations, each component must have signage.

STANDARD

S-16 Stationery

Entities must have paper or electronic professional stationery that includes the name and/or address, and phone number of the entity. For hospital-based entities/components, this standard will be met provided the entity is located on the site carrying the primary address listed on the hospital's stationery; if components are housed in separate physical locations, each component must have stationary.

SLEEP CLINIC COMPONENT

Standards included in this section apply to the Sleep Clinic Component. It is the responsibility of the Sleep Clinic component to fulfill the responsibilities in this section.

STANDARD

C-1 Patient Management (MANDATORY)

Sleep Clinics must document in the medical record ongoing evaluation, management, and follow-up of each patient with sleep disorders. Sleep Clinics must be able to show medical records to demonstrate management of an adequate range of sleep disorders. All sleep disorders are defined by the current edition of the *International Classification of Sleep Disorders*.

STANDARD

C-2 Patient Management Continued (MANDATORY)

Sleep Clinics with an HSAT component but no lab component must demonstrate, in writing, an existing relationship with an accessible AASM accredited facility that can provide full diagnostic sleep testing in a laboratory when needed for the continued management of practice patients.

C-3 Diagnosis by Medical Staff (MANDATORY)

Only a licensed medical provider can diagnose a medical condition.

STANDARD

C-4 Medical Staff Member Staffing

Sleep Clinics must have, at minimum, one physician (MD or DO) medical staff member with a valid, unrestricted license in the state where the component is located. The Site Director may fulfill this requirement.

STANDARD

C-5 PAP Assessment

Patients prescribed PAP treatment by the entity's medical staff members must be offered a follow-up positive airway pressure assessment within 12 weeks of treatment initiation. PAP assessment must minimally include a measurement of treatment use and clinical response to the therapy as determined by both of the following requirements:

- 1. Documentation of review of device download confirming response to therapy and adequate adherence as defined by the AASM; and
- 2. Documentation of subjective response to therapy such as a questionnaire or patient report during face-to-face encounter.

The patient medical record must contain documentation of the assessment as described above or written evidence of follow- up attempts to obtain the PAP treatment assessment. If inadequate response to therapy is present on the device download or the patient's subjective report, there must be follow up visits scheduled or offered to the patient. These visits should include assessment of causes of intolerance or non-acceptance of the device and review of device download and device-patient interface.

STANDARD

C-6 Controlled Substance Prescribing

All professional staff (including MDs, DOs, PhDs, advanced practice providers) must maintain valid, unrestricted DEA licenses(s) in each state where they administer, dispense or prescribe controlled substances, adhering to the federal and state-controlled substance regulations.

LAB COMPONENT

Standards included in this section apply to the Lab Component. It is the responsibility of the Lab component to fulfill the responsibilities in this section.

STANDARD

L-1 Medical Staff Member Staffing

Labs must have, at minimum, one physician (MD or DO) medical staff member with a valid, unrestricted license in the state where the component is located. The Site Director may fulfill this requirement.

L-2 Sleep Study Interpretation (MANDATORY)

An individual board-certified in sleep medicine (as defined in <u>Standards N-1</u> and <u>Standard N-3</u>) must either perform the sleep study interpretation or review the sleep study interpretation.

STANDARD

L-3 General Technologist Staffing

Technologist staffing must be adequate to address the workload of the lab and assure the safety of patients. The AASM recommends a patient to technologist ratio of 2:1 under usual circumstances for attended PSG at facilities.

STANDARD

L-4 Registered Technologist Staffing

Labs must have on staff at least one sleep technologist (as defined in <u>Standard N-9</u>). The individual(s) fulfilling this standard must be present (virtually or in person) at the facility at least 30 hours per week. If the facility is open fewer than 40 hours per week, then the registered technologist(s) must be present at the facility for 75% of operating hours.

A lab that loses its sole registered technologist will have 120 days to fulfill this standard.

STANDARD

L-5 Use of Space

There needs to be a clearly defined physical space used primarily for conducting sleep testing. All of the elements required to conduct sleep tests must be available within the defined testing space.

STANDARD

L-6 Testing Bedrooms – Physical Characteristics

All testing bedrooms must be single occupancy, private, comfortable, and quiet, have hard floor-to-ceiling walls, and a privacy door that opens directly to a corridor or common use area such that the patient can access the testing bedroom without having to pass through another testing bedroom. Caregivers staying overnight at the lab must have a space to sleep (e.g. recliner, cot).

STANDARD

L-7 Testing Bedrooms & Emergency Care

Patient testing bedrooms must not have any impediments to the delivery of emergency care. The patient testing rooms:

- 1. Must be of sufficient size to accommodate emergency personnel access with a minimum of 24 inches of available clear space on three sides of the bed;
- 2. Must include a testing bed with a mattress not smaller than a standard hospital bed.

STANDARD

L-8 Bathrooms

Labs must have clean bathrooms with a minimum ratio of one bathroom for every three testing rooms; these bathrooms must each contain a toilet and a sink. Each bathroom must have a working privacy door. Sole access to a shared bathroom shall not be through a testing bedroom.

L-9 Handicap Testing Bedroom and Bathroom

At least one testing bedroom and bathroom at each lab must be handicap accessible as defined by local building regulations and the Americans with Disabilities Act (ADA).

STANDARD

L-10 Control Room

The dimensions of the control room must not be less than 40 square feet total or 20 square feet per testing bedroom, whichever is larger.

STANDARD

L-11 Communication

Labs must maintain a two-way communication system between the patient bedroom and the control room and/or personnel.

STANDARD

L-12 Video Recording

Labs must have continuous visual monitoring and video recording of patients during testing. Time-delayed photographs will not be considered compliant with this standard.

STANDARD

L-13 Polysomnographic Equipment

Labs must use polysomnographic equipment that meets all of the "RECOMMENDED" minimal technical and digital specifications in the current version of *The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology, and Technical Specifications* (AASM Scoring Manual).

STANDARD

L-14 PAP Therapy

Labs must maintain equipment for the delivery of positive airway pressure therapy for sleep apnea, including remote control of the device (e.g., pressure output, device mode).

STANDARD

L-15 Equipment Maintenance & Procedures

Labs must have a written plan for monitoring of all in-lab patient-related equipment for electrical and mechanical safety. The written plan must include specific instructions regarding documentation of compliance in an equipment maintenance log. The plan must address monthly visual inspection of equipment by staff for apparent defects; adhering to manufacturer's recommendations for monitoring and maintenance of recording equipment; and annual electrical safety testing by a certified electrician or biomedical engineer.

Labs must have a written procedure for infection control including cleaning and inspecting all patient-related equipment; this includes sterilization, high-level disinfection, or the application of germicidal agents after each use that is consistent with the manufacturers' recommendations, federal and state health policy regulations and institutional standards.

L-16 Required Protocols: PSG, MSLT, MWT and PAP Titration

Labs must maintain written protocols in paper or electronic form for all of the following tests: comprehensive PSG, MSLT, MWT and titration of PAP therapy. The MSLT and MWT must be conducted using the protocol described in the most current version of the AASM Clinical Practice Guidelines.

STANDARD

L-17 Other Protocols

If labs conduct esophageal pressure monitoring, actigraphy, end-tidal CO_2 monitoring or transcutaneous CO_2 monitoring, then they must maintain protocols for these procedures. If labs conduct other testing or therapeutics (e.g. CO_2 titration, upper airway stimulation system titration, MRD titration) not specifically mentioned in Standard CO_2 or CO_2 to the procedure consistent with applicable standards of care.

STANDARD

L-18 Pediatric Protocols

Labs that test sleep patients under the age of 13 years must maintain age-specific protocols in the Policy and Procedures Manual for comprehensive PSG, titration of PAP therapy and capnography.

STANDARD

L-19 Signal Acquisition

The signals collected must meet the requirements of the current version of AASM Scoring Manual. The lab must use either the "RECOMMENDED" or "ACCEPTABLE" montages in the AASM Scoring Manual.

STANDARD

L-20 PSG Scoring

Each epoch of each PSG must be scored for sleep staging, arousals, respiratory events and limb movement in accordance with the most current version of AASM Scoring Manual.

STANDARD

L-21 PSG Reports

Reports of polysomnography must include all the "RECOMMENDED" and/or "ACCEPTABLE" parameters from Parameters to be Reported for Polysomnography of the current version of the AASM Scoring Manual. When the AASM Scoring Manual allows for options in scoring, the report must indicate which option is used.

STANDARD

L-22 Computer-assisted Scoring

If used, computer-assisted scoring of PSG must be verified and edited by a RST, RPSGT, CPSGT, respiratory therapists with the sleep disorders specialist certification (either CRT-SDS or RRT-SDS), or medical staff members/PhDs board-certified in sleep medicine (as defined in Standard N-3) before interpretation (as defined in Standard L-2 and Standard N-3).

L-23 Emergency Plan

An emergency plan must be accessible in paper or electronic format delineating the following:

- 1. Mechanisms and specific details for contacting emergency personnel;
- 2. The lab personnel to be contacted in an emergency; and
- 3. Specific responsibilities of the medical and technical staff.

Entities using hospital code teams may use hospital-based policies for medical emergencies.

STANDARD

L-24 Safety Risks Unique to In-Center Sleep Testing

Recognizing the unique vulnerability of patients and staff in a sleep testing environment, labs must have explicit policies and procedures to minimize the risk for assault or allegations of inappropriate behavior during the attended sleep testing encounter. This may include the use of continuous video monitoring in high risk areas during the attended sleep testing encounter (patient bedrooms, hookup areas) and/or specific training for the use of chaperone during interactions between patients and staff.

STANDARD

L-25 Subcontracting HSAT

Entities may subcontract home sleep apnea testing. The subcontract may not include diagnosis of a medical condition; this must remain the responsibility of the entity's appropriately licensed physician or advanced practice providers, as appropriate. The entity must have a written agreement with the subcontractor to this effect that clearly identifies the specific expectations of the subcontractor and requiring the subcontractor to meet all applicable AASM HSAT Standards. The entity is responsible for assessing the performance of the subcontractor in meeting contractual obligations on an annual basis.

STANDARD

L-26 Subcontracting Scoring

When a subcontractor scores sleep studies, the entity must have a written agreement with the subcontractor that enumerates the performance expectations of the subcontractor. The scorers of the subcontractor must meet all applicable AASM Accreditation standards for scoring personnel. The entity is responsible for assessing the performance of the subcontractor in meeting contractual obligations including meeting applicable standards on an annual basis.

HSAT COMPONENT

Standards included in this section apply to the HSAT Component. It is the responsibility of the HSAT component to fulfill the responsibilities in this section.

STANDARD

H-1 Medical Staff Member Staffing

HSAT components must have, at minimum, one physician (MD or DO) medical staff member with a valid, unrestricted license in the state where the component is located. The Site Director may fulfill this requirement.

H-2 Sleep Study Interpretation (MANDATORY)

An individual board-certified in sleep medicine (as defined in <u>Standards N-1</u> and <u>Standard N-3</u>) must either perform the sleep study interpretation or review the sleep study interpretation.

STANDARD

H-3 HSAT Staff Training

HSAT staff must be trained on the proper use of HSAT devices. Evidence of training must be maintained by the entity. Training must include:

- Device operations, application of sensors, use, maintenance, warnings, and safety.
- Instruction of patients in the use of HSAT devices.
- Troubleshooting of HSAT problems; and
- Infection control.

STANDARD

H-4 Addressing Problems during HSAT

The component must have and comply with a written protocol that provides on-call coverage to address problems encountered during HSAT.

STANDARD

H-5 Home Sleep Apnea Tests (HSAT)

All HSATs must be FDA-cleared or approved and meet the minimum requirements of the current AASM guidelines and AASM Scoring Manual. Equipment must provide a measure of respiratory events per unit time (AHI, RDI or REI). Equipment must allow for the display of raw data to be reviewed and edited.

All reusable equipment must have a unique identifier so that it may be assigned to a patient and tracked. The identifier must be recorded and used to assist in failure investigation and a plan for preventing future failures must be documented. HSATs must have the capability that all PHI and physiologic data can be erased following each use of the device.

STANDARD

H-6 HSAT Equipment Maintenance & Procedures

There must be a written plan for monitoring of all HSAT patient-related equipment for electrical and mechanical safety.

- 1. The component must have a written procedure for infection control including cleaning and inspecting all patient-related equipment; this includes sterilization, high-level disinfection, or the application of germicidal agents after each use that is consistent with the manufacturers' recommendations, federal and state health policy regulations, and institutional standards.
- 2. All devices and sensors associated with a failed HSAT (e.g. no data, or corrupt data) must be tested for proper function prior to next use.
- 3. Reported or detected failures of HSATs, sensors or processes must be categorized and analyzed for cause and a plan for preventing future failures must be documented.

- 4. The component must physically separate clean and dirty devices in compliance with its infection control plan.
- 5. Specific instructions must exist for HSATs and sensor packing, shipping and storage.
- 6. Entities must have a policy in place that documents the procedure(s) used to delete all PHI and physiologic data from an HSAT following each use of the device.

H-7 HSAT Reports and Recommendations

Reports of HSAT must include all the "RECOMMENDED" and/or "ACCEPTED" parameters from chapter IX. Home Sleep Apnea Testing (HSAT) Rules for Adults in the current version of the AASM Scoring Manual. Any recommendations for next management steps (based upon test results and clinical information), if provided, must be consistent with applicable AASM practice guidelines.

STANDARD

H-8 Subcontracting HSAT

Entities may subcontract home sleep apnea testing. The subcontract may not include diagnosis of a medical condition; this must remain the responsibility of the entity's appropriately licensed physician or advanced practice providers, as appropriate. The entity must have a written agreement with the subcontractor to this effect that clearly identifies the specific expectations of the subcontractor and requiring the subcontractor to meet all applicable AASM HSAT Standards. The entity is responsible for assessing the performance of the subcontractor in meeting contractual obligations on an annual basis.

STANDARD

H-9 Subcontracting Scoring

When a subcontractor scores sleep studies, the entity must have a written agreement with the subcontractor that enumerates the performance expectations of the subcontractor. The scorers of the subcontractor must meet all applicable AASM Accreditation standards for scoring personnel. The entity is responsible for assessing the performance of the subcontractor in meeting contractual obligations including meeting applicable standards on an annual basis.

DME COMPONENT

Standards included in this section apply to the DME Add-on Component. It is the responsibility of the DME Add-on component to fulfill the responsibilities in this section.

STANDARD

D-1 DME Supplier Availability

DME suppliers must maintain a designated contact person accessible to the patient and/or caregiver(s) via telephone 24 hours a day, 7 days a week, 52 weeks per year.

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

D-2 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:

- 1. Continuous Positive Airway Pressure (CPAP) and Auto Adjusting Positive Airway Pressure devices.
- 2. 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.
- 3. PAP humidifiers.
- 4. PAP supplies (e.g. mask, hoses, filters, etc.).
- 5. 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.

STANDARD

D-3 Staff Training

DME staff which may include licensed personnel, where required by state law, must be trained to deliver, set-up and train patients/caregivers on all equipment, items and/or services included in <u>Standard D-2</u> that are offered by the supplier. DME 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.

STANDARD

D-4 Patient Education

DME suppliers must provide appropriate education to patients/caregivers on all aspects of equipment use including initial equipment set-up and use. Education includes but is not limited to:

- Functionality of PAP equipment.
- Proper fitting for mask/pillow.
- Troubleshooting PAP equipment.
- PAP cleaning.
- PAP equipment maintenance/replacement schedule.
- Contact for routine and emergency situations.

STANDARD

D-5 Equipment Maintenance & Procedures

There must be a written plan for monitoring of all returned or on loan PAP equipment for electrical and mechanical safety, including:

- DME suppliers must have a written procedure for infection control including cleaning and inspecting all
 equipment; this includes sterilization, high-level disinfection, or the application of germicidal agents after
 each use that is consistent with the manufacturers' recommendations, federal and state health policy
 regulations, and institutional standards.
- Reported or detected failures of equipment must be categorized and analyzed for cause and a plan for preventing future failures must be documented.
- 3. DME suppliers must physically separate clean and dirty equipment in compliance with its infection control plan.

4. DME suppliers must have a policy in place that documents the procedure(s) used to delete all PHI and physiologic data from equipment that stores data.

STANDARD

D-6 Financial and Billing Policies

DME suppliers must implement financial management practices and policies that ensure accurate accounting and billing to insurance companies and patients. This includes maintaining:

- 1. Accounts that link equipment and/or item(s) to the patient.
- 2. Procedure for identifying and correcting billing discrepancies.
- 3. Charity policy (if applicable).
- 4. Loaner equipment policy.
- 5. Fraud, waste, and abuse policies, where required by state law.
- 6. Use of most current CPT/ICD codes.

STANDARD

D-7 Consultation with Ordering Healthcare Professional

DME suppliers 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, items and/or services and must document interactions in the patient's chart. Any changes in the patient's medical equipment necessitate an updated prescription, which must be kept unaltered in the patient's chart. Any certificates of medical necessity must also be maintained in the patient's chart.

STANDARD

D-8 Collaboration with Ordering Healthcare Professional

DME suppliers must maintain a working relationship with the ordering healthcare professional. DME suppliers must provide pertinent information to the ordering healthcare professional which will allow the ordering healthcare professional to monitor patient treatment. This may include but not be limited to confirmation of equipment delivery, delays in service and PAP compliance data.

STANDARD

D-9 Sleep Clinic Relationship

DME suppliers must maintain a relationship with an AASM-accredited Sleep Clinic.

STANDARD

D-10 On-going Patient Management

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