

## **American Academy of Sleep Medicine**

# Public Comment Announcement: Proposed Changes to AASM Standards for Accreditation

Oct. 28, 2015

The American Academy of Sleep Medicine (AASM) is inviting public comments on proposed changes to the AASM Standards for Accreditation that include both substantial revisions to current standards and the addition of new draft standards. If implemented, the proposed changes will impact all currently accredited entities and future applicants.

Since 1977 the AASM accreditation programs have helped ensure that patients with a sleep disorder receive the highest quality of medical care. AASM accreditation has become the gold standard by which the medical community, insurers and the public evaluate sleep medicine providers.

Periodically, the AASM reviews the AASM Standards for Accreditation to verify that the standards remain relevant and reflect current practice models. By rigorously reviewing the standards, and revising them when necessary, the AASM ensures that its accreditation programs continue to promote high quality, patient-centered care.

Recognizing that the proposed changes represent a significant development for the field of sleep medicine, the AASM is requesting comments from AASM members, accredited entity staff and other stakeholders. The following pages contain a brief summary of the draft changes along with the proposed standards in their entirety.

The AASM greatly appreciates your feedback. Please send your comments by email to <a href="mailto:accreditation@aasmnet.org">accreditation@aasmnet.org</a> or by fax to (630) 737-9790 by the deadline of **Dec. 15, 2015**.

Comments also can be submitted by mail to:

American Academy of Sleep Medicine Attn: Accreditation Department 2510 North Frontage Road Darien, IL 60561-1511

If you have questions about the proposed standards, please call the AASM at 630-737-9700.

## **Summary of Proposed Changes: AASM Standards for Accreditation** Oct. 28, 2015

This overview introduces and summarizes the proposed changes to the current AASM accreditation standards. Minor changes in wording that do not alter a standard's meaning or applicability have not been included below. Standards not listed in this summary were not changed. To review the proposed changes in full, please see the complete draft of the proposed accreditation standards, which follows the summary. Comments about the proposed standards can be submitted to the AASM at <a href="mailto:accreditation@aasmnet.org">accreditation@aasmnet.org</a> by Dec. 15, 2015. If you have questions about the proposed standards, please call the AASM at 630-737-9700.

Current	New	Change	Change Summary
Standard	Standard	Type	,
A-2-FH: Medical Code of Conduct and Compliance with HIPAA	A-2-FH: Medical Code of Conduct and Compliance with HIPAA	Revision	Removed that Code of Ethics must be physically on-hand.
B-2-F: Medical Director Continued	B-2-F: Medical Director Continued	Revision	Simplified language regarding number of facilities/beds allowed but did not change intent of standard.
B-3-H: Medical Director Continued	B-3-FH:Medical Director Qualifications	Revision	The medical director for both facility and HSAT must be board certified in sleep medicine.
B-4-FH: Medical Director Responsibilities	B-4-FH: Medical Director Responsibilities	Revision/Merge	Merge responsibilities previously held by the designated Board Certified Sleep Specialist (under current Standard B-8-F)
B-5-H: Medical Director Responsibilities Continued	B-5-H: Medical Director Responsibilities Continued	Revision	Added requirement to be on site 8 hours a month
B-6-FH: Medical Director Continuing Education	B-6-FH: Medical Director Continuing Education	Revision	Exception for fellowship extended to facility
B-7-F: Board Certified Sleep Specialist	N/A	Removal	Standard has been removed as the medical director must now be board certified
B-8-F: Board Certified Sleep Specialist Responsibilities	N/A	Removal	Standard has been removed as the medical director must now be board certified
B-9-F: Board Certified Sleep Specialist Continuing Education	N/A	Removal	Standard has been removed as the medical director must now be board certified
B-10-H: Interpreting Physicians	B-7-FH: Interpreting Clinicians	Revision	For both facility and HSAT, any individual board certified in sleep may interpret studies.
B-11-H: Interpreting Physicians Qualifications	B-8-FH: Interpreting Clinicians Qualifications	Revision	Applies to both facility and HSAT; exams must be consecutive.
B-12-H: Interpreting Physicians Continuing Education	B-8-FH: Interpreting Clinicians Continuing Education	Revision	Applies to both facility and HSAT.

B-13-FH: Sleep Technicians and Technologists	B-10-FH: Sleep Technicians and Technologists	Revision	Medical director responsible for all technical staff training; scoring removed from HSAT training topics.
B-14-F: Registered Sleep Technologist	B-11-F: Registered Sleep Technologist	Revision	Registry exam must be passed within 1 year of acceptance.
B-15-F: Sleep Technician and Technologist Continuing Education	B-12-FH: Sleep Technician and Technologist Continuing Education	Revision	Applies to both facility and HSAT.
B-16-F: Non- registered Sleep Technologist	B-13-F: Non- registered Sleep Technologist	Revision	Removed "or scoring" as scorers are addressed in Standard B-14.
B-17-H: Scoring Personnel	B-14-FH: Scoring Personnel	Revision	Applies to both facility and HSAT; addresses non-registered scoring technicians.
B-18-H: Scoring Personnel Continuing Education	B-15-FH: Scoring Personnel Continuing Education	Revision	Applies to both facility and HSAT.
B-20-H: HSAT On- Call Coverage	B-16-H: Addressing Problems during HSAT	Revision	Program must set and implement its own policy regarding on-call coverage.
N/A	B-17-FH: Employee Background Checks	New Standard	Employee Background checks must be completed prior to hire.
C-1-FH: Patient Acceptance	C-1-F: Patient Acceptance for Incenter Testing	Revision	Full spectrum of sleep disorders must be accepted.
C-1-FH: Patient Acceptance	C-2-H: Patient Acceptance for HSAT	New Standard	HSAT acceptance criteria moved to this new standard.
C-2-FH: Record Review of Direct Referrals	C-3-FH: Record Review of Direct Referrals	Revision	Applies to both facility and HSAT; Communication with referring physician must be documented.
D-1-FH: Permanent Address	D-1-FH: Permanent Address	Revision	Simplify language.
D-2-FH: Phone Line	D-2-FH: Phone Line	Revision	Immediate communications access to emergency services is required.
D-5-F: Use of Space	D-5-F: Use of Space	Revision	Remove portion of standard addressing mixed use.
D-9-F: Handicap Testing Bedroom and Bathroom	D-9-F: Handicap Testing Bedroom and Bathroom	Revision	Simplify for current ADA requirements.
D-13-F: Polygraphic Equipment	D-13-F: Polysomnographic Equipment	Revision	Simplify language.
D-14-H: Portable Recording Equipment	D-14-F: Portable Recording Equipment	Revision/Merge	Merge current standards D-14 and F-3; Simplify language regarding allowable equipment.
E-4-FH: Equipment Maintenance	E-4-FH: Equipment Maintenance	Revision/Merge	Merge with current standards E-5 and E-6; Applies to both facility and HSAT
E-5-F: Facility Equipment Maintenance	N/A	Removal	This is now addressed in E-4.
E-6-H: HSAT Equipment Maintenance	E-5-H: HSAT Equipment Maintenance	Revision	Most of this standard is now addressed in E-4; the remainder applies to HSAT only.

F-1-F: Signals and	F-1-F: Signal	Revision	Removed equipment (addressed elsewhere) and
Equipment	Acquisition	Kevision	added additional direction regarding acceptable
Equipment	requisition		<u> </u>
E 0 E ====	EAF	D	montages.
F-2-F: PSG Reports	F-2-F: PSG	Revision	Additional language added regarding
	Reports		management consistent with AASM guidelines
F-3-H: HSAT	N/A	Removal	This is now addressed in Standard D-14.
Recording Equipment			
F-4-H: HSAT	F-3-H: HSAT	Revision	Revised to incorporate AASM Scoring Manual
Reports and	Reports and		HSAT rules.
Interpretations	Interpretations	D	
F-7-F: Computer-	F-6-F: Computer-	Revision	Qualified staff must complete this review.
assisted Scoring	assisted Scoring F-7-F: Inter-scorer	Revision	Desired for a relative service when to make you
F-8-F: Inter-scorer		Revision	Revised for consistency with other terms used
Reliability	Reliability		within standards (i.e. clinician)
F-9-F: Review of	F-8-F: Review of	Revision	Revised for consistency with other terms used
Raw Data	Raw Data		within standards (i.e. clinician); include
			consistency with AASM Scoring Manual
F-10-H: Review of	F-9-H: Review of	Revision	Revised for consistency with other terms used
HSAT Raw Data	HSAT Raw Data		within standards (i.e. clinician); Include
			consistency with AASM Scoring Manual;
			Board-certified psychologists may interpret
			HSAT.
NT/A	E 10 II.	N C4 1 1	
N/A	F-10-H:	New Standard	Subcontracted HSAT providers must be AASM
	Subcontracting HSAT Services		accredited unless dictated by payers
N/A	F-11-F:	New Standard	Subcontracted scorers must also meet applicable
IN/A	Subcontracting	New Standard	AASM Accreditation Standards
	Scoring		AASM Accreditation Standards
G-1-FH: Patient	G-1-FH: Patient	Revision	Simplify language.
Management	Management	1te vision	
G-2-FH: Patient	G-2-FH: Patient	Revision/Merge	Merge with Standard G-3 and simplify
Management	Management	Tre visions ividige	language.
Continued	Continued		language.
G-3-FH:	N/A	Removal	This is now addressed in G-2.
Documenting Patient			
Evaluation/			
Management			
H-1-FH: Medical	H-1-FH: Medical	Revision	Include interactions with referring provider and
Records	Records		insurance; serious medical conditions should be
			documented.
H-2-FH: PAP	H-2-FH: PAP	Revision	Assessment must be completed through review
Assessment	Assessment		of device download and subjective response;
			inadequate response necessitates follow-up
H-3-FH: Database	H-3-FH:	Revision	Raw data storage required for at least 5 years
11 5 111. Database	Database/ Storage	1.0 (101011	Tan. Jan Storage required for at least 5 years
I-2-H: HSAT	I-2-H: HSAT	Revision	Language revised for consistency with Standard
Emergency Procedure	Emergency	10,101011	I-1-F; program must have a written plan.
	Procedure		1 1 1, program mast have a written plan.
N/A	I-3-FH:	New Standard	Annual emergency drills are required.
	Emergency Drills		
I-3-FH: Emergency	I-4-FH:	Revision	Must maintain an AED.
Equipment	Emergency		
	Equipment		
J-1-FH: QA Program	J-1-F: Facility	Revision	Specific measures are required; use of AASM
	Quality Assurance		Quality Metrics is optional.
77/	Program		
N/A	J-2-H: HSAT	New Standard	HSAT QA must address specific measures; use
	Quality Assurance		of AASM Quality Metrics is optional.
	Program		

J-2-FH: Reporting QA Program	N/A	Removed	This is now addressed in J-3-FH.
J-3-FH: Quality Improvement	J-3-FH: Quality Improvement	Revised	Applies to both facility and HSAT.
N/A	K-1-FH: Facility Safety	New Standard	Must comply with all construction codes, fire safety and building codes
N/A	K-2-FH: Occupational Safety	New Standard	Must meet all applicable OSHA requirements
N/A	K-3-FH: Hazardous Materials	New Standard	Properly dispose of hazardous materials
N/A	K-4-FH: Patient Safety Risk Analysis	New Standard	Patient safety risk analysis must be completed every 5 years and reviewed annually
N/A	K-5-FH: Patient Safety Related Significant Adverse Events	New Standard	Significant Adverse Events must be documented
N/A	K-6-FH: Analysis of Significant Adverse Events	New Standard	Root cause analysis must be completed for each significant adverse event
N/A	K-7-F: Safety Risks Unique to Incenter Sleep Testing	New Standard	Safety risks within the sleep facility should be minimized
N/A	L-1-FH: Patients' Rights	New Standard	Patients' Bill of Rights must be implemented

## AASM Standards for Accreditation – Proposed for Public Comment Oct. 28, 2015

## Key

FH	The specific Standard applies to entities
	applying for facility and/or HSAT
	accreditation.
F	The specific Standard applies only to entities
	applying for facility accreditation.
Н	The specific Standard applies only to entities
	applying for HSAT accreditation.

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#### A. General Standards

#### Standard

#### A-1 – FH – Facility License (MANDATORY)

All entities must maintain a valid license to provide health care services. If a valid license is not required by applicable law, the entity may submit a certificate of occupancy and/or permit to provide health care services. If none of the above is required by applicable law, the Medical Director must submit a written attestation. It is the responsibility of all entities to maintain compliance with all licensing acts, local building codes and any other laws relevant to the entity's operation. Failure to comply with the stipulations in this standard is sufficient justification for denial and/or revocation of accreditation.

#### Standard

## $\begin{array}{l} \textbf{A-2-FH-Medical Code of Conduct and Compliance with the Health Insurance} \\ \textbf{Portability and Accountability Act (HIPAA) (MANDATORY)} \end{array}$

All entities are required to follow the Code of Medical Ethics of the American Medical

Association Council on Ethical and Judicial Affairs Current Opinions, which the AASM adopted as official policy in 1998. The sleep entity must have the ability to access easily the *Code of Medical Ethics*.

1. All entities must have or operate under written policies that govern the practices pertaining to maintaining confidentiality of patient health information (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, Durable Medical Equipment (DME) companies, employers or payers.
- 2. The Medical 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.
- 3. Entities must promptly notify all appropriate parties of any HIPAA violations. Entities must have or operate under written privacy breach notification policies and procedures that outline 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

Patient and employee safety and security must be insured to the greatest extent possible. The following standards pertain to the institution of a standard procedure for verifying the employment history, education, criminal record and other background 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 candidates who may not be an appropriate employee.

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

Entities must designate a single medical director who is a physician with a license valid in the state of the entity and in all states in which patients are seen. A copy of each state medical license must be submitted with the application. Exceptions to the requirement for a license valid in each state in which patients are seen are made for physician employees of federal facilities.

#### Standard

#### **B-2 – F – Medical Director Continued (MANDATORY)**

An individual can serve as medical director of up to three (3) sleep facilities, regardless of their accreditation status, with no limitation to the total number of beds. However, if an individual is medical director of more than three facilities, the total number of beds shall not exceed 16 beds. The medical director must be present in each sleep facility on a regular basis and not less than 8 hours each month.

#### Standard

#### **B-3** – FH – Medical Director Qualifications (MANDATORY)

The designated medical director must be a sleep specialist who meets at least one of the following requirements:

- A physician who is board certified in sleep medicine by the American Board of Sleep
   Medicine (ABSM) or an individual certified in sleep medicine by either a member board
   of the American Board of Medical Specialties (ABMS) or a member board of the
   American Osteopathic Association (AOA).
- 2. A physician who has been accepted by an American Board of Medical Specialties (ABMS) or American Osteopathic Association (AOA) approved board to sit for the examination in sleep medicine. To retain accreditation, the examination in sleep medicine must be passed within 2 consecutive examination cycles.

To meet this requirement, the individual must provide, in the application, a letter of acceptance to sit for the examination by the American Board of Medical Specialties (ABMS) or American Osteopathic Association (AOA) approved board. Upon completion of the examination, the individual must provide a copy of the official notification from the American Board of Medical Specialties (ABMS) or American Osteopathic Association (AOA) board indicating final status.

3. A physician who has completed a 12-month Accreditation Council for Graduate Medical Education (ACGME) accredited fellowship in sleep medicine and is awaiting the first available opportunity to apply to an American Board of Medical Specialties (ABMS) board to sit for the sleep medicine examination. To retain accreditation, the American Board of Medical Specialties (ABMS) examination in sleep medicine must be passed within 2 consecutive examination cycles.

#### Standard

## **B-4 – FH – Medical Director Responsibilities (MANDATORY)**

The medical director:

- 1. Is responsible for the direct and ongoing oversight of testing.
- 2. Is responsible for the qualifications of all medical and technical personnel.
- 3. Is responsible for assuring staff complies with the *Code of Medical Ethics* as well as any institutional ethics requirements.
- Must provide direct and ongoing oversight of the testing protocols and the quality of testing including the proper operation and calibration of the equipment.
- 5. Must review, report, and modify as necessary the facility's quality assurance program on a quarterly basis as mandated in Section J.

### **B-5** – H – Medical Director Responsibilities Continued

The HSAT medical director:

- Is responsible for the development of detailed job descriptions for all HSAT technical
  personnel that addresses their specific qualifications, duties and responsibilities, as well
  as the ongoing training requirements for HSAT.
- 2. Is responsible for the quarterly review, report, and modification as necessary of the HSAT program's quality assurance program.
- 3. Is responsible for ensuring that only licensed healthcare professionals with prescriptive authority in the state where the patient would be tested can request an HSAT.
- 4. Must be present in the HSAT facility a minimum of 8 hours a month.

#### Standard

## **B-6 – FH – Medical Director Continuing Education (MANDATORY)**

The medical director must earn 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.

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-7 – FH – Interpreting Clinician(s) (MANDATORY)

The interpreting physician(s) or ABSM-certified psychologist(s) must have a valid state license in all states where patients are evaluated. Rendering of diagnosis must adhere to state licensing laws.

## **B-8 – FH – Interpreting Clinician(s) Qualifications (MANDATORY)**

The physician(s) (or psychologists) responsible for interpretation of data and diagnoses of patients must be a sleep specialist who meets at least one of the following requirements:

- 1. A physician or psychologist who is board certified in sleep medicine by the American Board of Sleep Medicine (ABSM) or physician certified in sleep medicine by either a member board of the American Board of Medical Specialties (ABMS) or a member board of the American Osteopathic Association (AOA).
- 2. A physician who has been accepted by an American Board of Medical Specialties (ABMS) or American Osteopathic Association (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 consecutive examination cycles.
  To meet this requirement, the physician must provide in the application a letter of

acceptance to sit for the examination by the American Board of Medical Specialties (ABMS) or American Osteopathic Association (AOA) approved board. Upon completion of the examination, the physician must provide a copy of the official notification from the American Board of Medical Specialties (ABSM) or American Osteopathic Association (AOA) board indicating final status.

3. A physician who has completed a 12-month Accreditation Council for Graduate Medical Education (ACGME) accredited fellowship in sleep medicine and is awaiting the first available opportunity to apply to an American Board of Medical Specialties (ABMS) board to sit for the sleep medicine examination. To retain accreditation, the American Board of Medical Specialties (ABMS) examination in sleep medicine must be passed within 2 consecutive examination cycles.

## **B-9 – FH – Interpreting Clinician(s) Continuing Education**

All interpreting physicians (or ABSM-certified psychologists) must participate in at least 10 credits per year averaged over three years of *AMA PRA Category 1 Credit* or equivalent CE in sleep medicine. Compliance with continuing education requirements must be documented.

The AASM has adopted job descriptions that delineate the education, training, and responsibilities of sleep technologists, sleep technicians, and sleep technician trainees. All sleep technologists/technicians must be able to perform the duties listed in the AASM approved job descriptions. Standards B-10 through B-14 address requirements for sleep technologists, technicians and trainees. These standards do not differentiate between the various job descriptions or titles that sleep facilities may use for the employment of sleep technicians and technologists. For example, a sleep technologist or technician whose primary responsibility is to score a sleep study is subject to the same accreditation standards as a sleep technologist or technician whose primary responsibility is sleep test monitoring. Specifically, CPR certification is required for all sleep facility technical staff members, regardless of their duties.

#### Standard

## **B-10 – FH – Sleep Technicians and Technologists**

1. Entities must maintain appropriately trained, supervised, and, where required by state law, licensed sleep technologists. Technologist staffing at facilities must be adequate to address the workload of the sleep facility and assure the safety of patients. The AASM recommends a patient to technologist ratio of 2:1 under usual circumstances for attended polysomnography at accredited sleep facilities.

- Entities must maintain appropriately trained, supervised, and, where required by law, licensed personnel. It is the responsibility of the medical director to ensure that training is provided to technical personnel.
- 3. For programs that perform HSAT, technical staff must be trained on the proper use of HSAT devices including:
  - 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.

## B-11 – F – Registered Sleep Technologist

A minimum of one sleep technologist must be registered in sleep technology or accepted to sit for the registry examination through one of the following organizations:

- 1. American Board of Sleep Medicine (ABSM)
- 2. National Board for Respiratory Care (NBRC)
- 3. Board of Registered Polysomongraphic Technologists (BRPT)
- 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. The individual(s) fulfilling this standard must be present 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.

Note: An accredited facility that loses its sole registered technologist will have 120 days to fulfill this standard.

## B-12 – FH – Sleep Technician and Technologist Continuing Education

All technical staff must participate in at least 10 hours per year averaged over three years of sleep-related continuing education credits. This must be documented for each technical staff member. 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 entity's medical director.

Each sleep technician and technologist must have valid cardiopulmonary resuscitation (CPR) certification that includes skills training.

#### Standard

## B-13 – F — Non-registered Sleep Technologist

All technologists and technicians conducting sleep testing who are not registered by the American Board of Sleep Medicine (ABSM), Board of Registered Polysomnographic Technologists (BRPT), or National Board for Respiratory Care (NBRC):

Must be enrolled in or have completed the Accredited Sleep Technology Education
 Program (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

**B-14** – **FH** – **Scoring Personnel** 

Scoring personnel must be one of the following: Registered Sleep Technologists (RST), Registered Polysomnographic Technologists (RPSGT), Certified Polysomnographic Technicians (CPSGT), respiratory therapists with the sleep disorders specialist certification (either CRT-SDS or RRT-SDS), or interpreting clinicians who comply with the requirements of Standard B-8. Non-registered sleep technologists (as defined in Standard B-13) may score only under the supervision of one of the above while adhering to Standard B-13.

#### Standard

## **B-15** – FH – Center Staff Provider Continuing Education

All center staff providers, including licensed physicians, psychologists, advanced practice registered nurses and physicians assistants, must earn at least 10 credits per year averaged over three years of *AMA PRA Category 1 Credit* or equivalent in sleep medicine. Compliance with applicable continuing education requirements in sleep medicine must be documented. Providers who have 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. 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 entity's medical director.

#### Standard

#### B-16 – H – Addressing Problems during HSAT

 The program must have and comply with a written protocol that provides on-call coverage to address problems encountered during HSAT. 2. All patient and technical problems encountered during testing hours must be documented in a secure log. Quarterly audits must be conducted of these logs to identify trends related to device, sensor or service issues.

#### Standard

## **B-17 – FH – Employee Background Checks**

Prior to employing an individual, the sleep entity must obtain a criminal background check of the individual. For individuals who are subject to being reported to the National Practitioner Data Bank, the entity also must obtain the results of a query of the National Practitioner Data Bank prior to hiring and at least every two years thereafter. For site visits, each facility will attest to this being completed as specified.

#### C. Patient Policies

#### Standard

### C-1 – F – Patient Acceptance for In-center Testing

Facilities must maintain a Policy and Procedures Manual that addresses patient acceptance policies. Written policies for patient acceptance must include:

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

Facilities must demonstrate their acceptance of patients with the full spectrum of sleep diagnoses as delineated by the current version of the International Classification of Sleep Disorders (ICSD). Facilities must demonstrate their performance of the full spectrum of sleep tests including

polysomnography and MSLT. This standard can be met by providing a list of diagnoses or tests performed over a 6 month or longer period.

#### Standard

## C-2 – H – Patient Acceptance for Home Sleep Apnea Testing

HSAT programs must maintain a Policy and Procedures Manual that addresses patient acceptance policies. Written policies for patient acceptance must include:

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

Home sleep apnea tests should adhere to the criteria of high pretest probability according to the AASM guidelines. If the AASM guidelines are not used, as in the case of insurance mandate or medical exception, then a written protocol explaining acceptance criteria, rationale, and follow up procedure on negative tests and positive tests must be in place.

#### Standard

#### C-3 – FH – Record Review of Direct Referrals

For patients directly referred, the medical director or a designated sleep entity staff provider must review the information provided for each patient and determine if the requested test is indicated according to Standard C-1. Evidence of communication with the referring clinician should be recorded in the patient record for every PSG or HSAT. At a minimum, this should include a history and physical received from the referring clinician and a sleep study report sent back to the referring clinician.

## D. Facility and Equipment

#### Standard

#### **D-1** – **FH** – **Permanent Address**

Entities must have a permanent, physical address.

#### Standard

#### **D-2** – **FH** – **Phone Line**

Entities, including both the clinical and laboratory settings if they are separate, must have a designated phone line(s) to directly receive incoming calls. All entities must have immediate communications access to Emergency Services (medical, fire and security).

#### Standard

## D-3 – FH – Signage

Entities must have signage on the outside of the facility or in a directory identifying the sleep entity.

## Standard

#### **D-4** – **FH** – **Stationery**

Entities must have professional stationery that at a minimum includes the name, address, and phone number of the entity. For hospital-based sleep entities, this standard will be met provided the sleep entity is located in the building carrying the primary address listed on the hospital's stationery.

#### Standard

## D-5 - F - Use of Space

Accreditation is granted to a single sleep facility, generally defined by a physical space used primarily for conducting sleep testing. All of the elements required to conduct sleep tests must

be available within the defined testing spaceThe administrative office(s) and/or staff clinician office(s) of the sleep facility may be separate from the laboratory testing site.

#### Standard

## D-6 – F – Testing Bedrooms – Physical Characteristics

All testing bedrooms must be single occupancy, private and comfortable, 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.

#### Standard

## **D-7 – F – 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 3 sides of the bed,
- 2. Must include a testing bed with a mattress not smaller than a standard hospital bed.

#### Standard

#### **D-8** – F – Bathroom Facilities

The sleep facility 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.

## D-9 – F – Handicap Testing Bedroom and Bathroom

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

#### Standard

#### D-10 – F – 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

#### **D-11** – F – Communication

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

#### Standard

## D-12 – F – Video Recording

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

## Standard

#### D-13 – F – Polysomnographic Equipment

The facility 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.* 

## **D-14 – H – Portable Recording Equipment**

All HSAT equipment must be FDA-approved and meet the minimum requirements of the current AASM guidelines. Equipment must provide a measure of respiratory events per unit time (AHI, RDI or REI). Equipment must allow for the display of raw data for manual scoring and editing. All reusable equipment must have a unique identifier (ID) so that it may be assigned to a patient and tracked. The ID number must be recorded and used to assist in failure investigation and a plan for preventing future failures must be documented.

A process must be developed documenting that all PHI and physiologic data is erased from the HSAT equipment following each use of the device. Equipment used must have the capability to meet all HSAT accreditation standards outlined in Sections F.

#### Standard

## D-15 - F - PAP Therapy

The facility 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).

#### E. Policies and Procedures

Entities accredited by the AASM must maintain written protocols, in paper or electronic form, for all testing procedures conducted. There are additional standards in sections F, I and K that are required to be included in the Policy and Procedures Manual.

#### Standard

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

Entities must maintain a Policy and Procedures Manual. The manual must contain all policies, procedures, protocols specific to the sleep entity, and all current AASM Practice Parameters, AASM Clinical Guidelines and AASM Best Practice Guidelines.

### E-2 – FH – Protocols: PSG, HSAT, MSLT, MWT, and PAP Titration

All entities must maintain written, paper or electronic format, protocols. Facilities must maintain protocols for comprehensive polysomnography, multiple sleep latency test, maintenance of wakefulness test, and titration of positive pressure therapy. HSAT programs must maintain protocols for HSAT.

All entities are encouraged to use "Clinical Guidelines for the Manual Titration of Positive Airway Pressure in Patients with Obstructive Sleep Apnea" in constructing PAP titration protocols.

#### Standard

#### E-3 – F – Other Protocols

Facilities that conduct esophageal pressure monitoring, actigraphy, end-tidal CO2 monitoring or transcutaneous CO2 monitoring must maintain protocols for these procedures.

Facilities that test sleep patients under age 13 years must maintain population specific protocols in the Policy and Procedures Manual for comprehensive polysomnography, titration of positive pressure therapy and capnography.

#### Standard

## **E-4** – **FH** – **Equipment Maintenance**

The entity must have a written plan for monitoring of all 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.

- 1. The entity must have a written procedure for infection control including cleaning and inspecting 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 test (e.g. no data, inadequate data, or corrupt data) must be removed from service and tested for proper function prior to next use.
- 3. Reported or detected failures of devices, sensors or processes must be categorized and analyzed for cause and a plan for preventing future failures must be documented..
- 4. The entity must physically separate clean and dirty devices in compliance with its infection control plan.

#### E-5 – H – HSAT Equipment Maintenance

Specific instructions must exist for HSAT device and sensor packing, shipping and storage.

## F. Data Acquisition, Scoring and Reporting

#### Standard

### **F-1** – **F** – **Signal Acquisition**

The signals collected must meet the requirements of the current version of *The AASM Manual* for the Scoring of Sleep and Associated Events: Rules, Terminology, and Technical Specifications. The facility must use either the recommended or acceptable montages in the scoring manual.

## F-2 - F - PSG Reports

Reports of polysomnography must include all the "RECOMMENDED" and/or "ACCEPTED" parameters from section II of the current version of *The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology, and Technical Specifications*. When the scoring manual allows for options in scoring, the report must indicate which option is used.

#### Standard

## F-3 – H – HSAT Reports and Interpretations

Reports of HSAT must include all the "RECOMMENDED" and/or "ACCEPTED" parameters from the HSAT section of the current version of *The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology, and Technical Specifications*. 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-4- F - Conducting MSLT and MWT

The multiple sleep latency test and maintenance of wakefulness test must be conducted using the protocol described in the most current version of the AASM Practice Parameters.

#### Standard

#### F-5 – F – PSG Scoring

Each epoch of each polysomnogram must be scored for sleep staging, arousals, respiratory events and limb movement in accordance with the most current version of *The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology, and Technical Specifications.* 

## F-6 – F – Computer-assisted Scoring

If used, computer-assisted scoring of polysomnography must be reviewed epoch-by-epoch and edited by staff as defined in Standard B-14 for accuracy.

#### Standard

## F-7 – F – Inter-scorer Reliability

Inter-scorer reliability (ISR) must be determined between each scorer and an interpreting clinician as defined in Standard B-7 or a corporate-appointed board certified sleep specialist; such individual must be an employee of the corporation and serves as the reference sleep specialist. ISR assessment must be conducted for each individual sleep facility. In cases where a corporate sleep specialist serves as the reference standard for inter-scorer reliability, the sleep facility's interpreting clinician must attest in writing that he/she has reviewed the results of the inter-scorer reliability assessment and will take corrective action when results fall below the sleep facility's level of acceptable agreement as defined in its quality assurance program. For comprehensive polysomnography, 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 interpreting clinician and to all other scoring technicians. Comparisons between each scorer and the facility's interpreting clinician 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 polysomnography studies must report agreement between scorer and the facility's interpreting clinician 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 polysomnography must at minimum include analysis by total number of events

and by the following event types: Obstructive apnea, central apnea and hypopnea. If the sleep facility 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.

#### Standard

#### F-8 – F – Review of Raw Data

The interpreting clinician 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. The interpreting clinician must over-read the raw data and sign interpretations of in-center testing interpreted by staff physicians who do not meet the requirements to be an interpreting clinician. Review must be consistent with *The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology, and Technical Specifications.* 

#### Standard

#### F-9 – H – Review of HSAT Raw Data

Only physicians or ABSM-certified psychologists meeting the requirements of an interpreting clinician can interpret an HSAT. Review must be consistent with *The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminilogy and Technical Specifications.* 

#### Standard

#### F-10-H-Subcontracting HSAT Services

When equipment or personnel are not available in an accredited entity, the entity must utilize an AASM-accredited entity to perform services and/or score and interpret sleep studies. The entity must have a written agreement with the subcontractor that enumerates the performance expectations of the subcontractor. The accredited entity is responsible for assessing at least annually the performance of the subcontractor in meeting contractual obligations.

Entities may depart from this standard when directed by the patient's payer or insurer to utilize specific subcontractors to perform and/or interpret HSAT testing. When so directed, the mandate to utilize a non-AASM-accredited entity must be noted in the patient's medical record.

#### Standard

## F-11-F 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 Accredited facility is responsible for assessing at least annually the performance of the subcontractor in meeting contractual obligations.

## G. Patient Evaluation and Care

#### Standard

### **G-1 – FH – Patient Management (MANDATORY)**

Entities must document in the medical record ongoing evaluation, management and follow-up of each patient with sleep disorders. Entities must be able to show medical records to demonstrate management of the typical range of sleep disorders as defined by the current version of the International Classification of Sleep Disorders (ICSD).

#### Standard

#### G-2 – H – Patient Management Continued (MANDATORY)

When clinically indicated and in compliance with current AASM guidelines, the HSAT program provides access to in-center polysomnography and other tests. The HSAT program must

demonstrate in writing an existing relationship with an accessible AASM-accredited sleep facility that can provide this care.

#### H. Patient Records

#### Standard

#### H-1 - FH - Medical Records

All entities must maintain appropriate medical records for every patient evaluated and/or tested in the facility. Medical records of patients seen by medical staff 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, with or without consultation by medical staff of testing facility.

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 facility should be noted and carefully reviewed. The record must be reviewed and approved for study by sleep facility medical director or sleep entity staff provider.

#### Standard

## H-2 – FH – PAP Assessment

Patients prescribed positive airway pressure treatment by the 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 as determined by both of the following requirements:

 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 positive airway pressure 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

## H-3 – FH – Database/Storage

The entity maintains a cumulative database or spreadsheet of all patients' sleep diagnoses, using current code numbers from the International Classification of Sleep Disorders (ICSD). The entity must store the raw data (excluding video) from all sleep tests (including PSG, MSLT, and HSAT) for a minimum of 5 years or as required by law if longer. Electronic copies may be provided to other treating sleep physicians who are not affiliated with the entity in accordance with patients' request for release of medical information.

### **I. Emergency Procedures**

#### Standard

#### I-1 – F – Emergency Plan

Facilities must have a written emergency plan accessible in paper or electronic format delineating the following:

- 1. Mechanisms and specific details for contacting emergency personnel;
- 2. The sleep facility personnel to be contacted in an emergency; and

3. Specific responsibilities of the technical staff.

Emergency policies must include, at minimum, policies and procedures for the following:

- 1. Cardio-pulmonary emergencies
- 2. Neurologic emergencies, particularly seizures
- 3. Psychiatric emergencies, particularly suicidal ideation
- 4. Environmental emergencies including fire, weather, belligerent patients, and bomb threats

#### Standard

## I-2 – H – HSAT Emergency Procedure

HSAT programs must have a written plan accessible in paper or electronic format to address emergencies, delineating the following:

- 1. Mechanisms and specific details for contacting emergency personnel; and
- 2. Responsibilities of personnel in an emergency.

The HSAT program must instruct the patient to call emergency services (911) in the event of an emergency during a HSAT.

## **Standard**

## **I-3-FH**—Emergency Drills

The entity conducts and documents annual drills of their emergency procedures. At a minimum, the facility conducts and documents annual drills of their response to cardiopulmonary emergencies.

## I-4 – FH – Emergency Equipment

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

## J. Quality Assurance

#### Standard

## J-1 – F – Facility Quality Assurance Program

Facilities must have a quality assurance (QA) program that addresses at least the following indicators:

- 1. A process measure for OSA;
- 2. An outcome measure for OSA;
- 3. An outcome measure for another sleep disorder (e.g. RLS, Insomnia or Narcolepsy); and
- 4. Interscorer Reliability as outlined in Standard F-7.

These measures may be chosen from the AASM Quality Measures.

#### Standard

## J-2 – H – HSAT Quality Assurance Program

The HSAT program must have a quality assurance (QA) program that addresses two process measures and one outcome measure. These measures may be chosen from the AASM Quality Measures.

## J-3 – FH – Quality Improvement

The entity must establish minimal thresholds for the quality assurance metrics. Quarterly, the entity's medical 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 medical director and maintained for at least 5 years.

## K. Safety

#### Standard

## K-1-FH — Facility Safety

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

#### Standard

## K-2-FH — Occupational Safety

The entity 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;
- 2. Availability of Personal Protective Equipment; and
- 3. Eyewash Stations when required.

#### Standard

#### **K-3-FH** — Hazardous Materials

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

## K-4-FH — Patient Safety Risk Analysis

The entity must complete and document an analysis of safety risks to patients related to the facility, patient populations served, and/or the procedures performed by the entity. This analysis must be updated whenever significant changes occur and no less frequently than every five years. The risk analysis must be reviewed, and the review documented, at least annually. Examples of risks may include: patient falls after receiving hypnotics, slippery shower surfaces, and uneven ground to/from the facility. The entity must implement policies and procedures to mitigate any risks identified.

#### Standard

#### K-5-FH — Patient Safety Related Significant Adverse Events

The entity must define and document significant adverse events for its patient population. At a minimum, the following events must be considered significant adverse events:

- Patient or staff death
- Permanent loss of function or of a body part by a patient or staff
- An event that leads to the hospitalization of a patient or staff
- An event that requires activation of an emergency medical response
- Sexual or physical assault of a patient or staff or allegations thereof
- Release of a minor or a patient lacking capacity or competency to an unauthorized individual
- Elopement of a patient
- Complications arising from the effects of hypnotics used for the purpose of sleep testing
- Any event required by the applicable jurisdiction to be reported to a government agency

#### Standard

#### K-6-FH — Analysis of Significant Adverse Events

The entity must create policies and procedures for performing a root cause analysis of any significant adverse events. The entity must conduct an investigation of all significant adverse events that occur.

## K-7-F — Safety Risks Unique to In-center Sleep Testing

Recognizing the unique vulnerability of patients and staff in a sleep testing environment, facilities must have explicit policies and procedures to minimize the risk for assault or allegations of inappropriate behavior during the testing timeframe. This may include the use of continuous video monitoring throughout the patient encounter in the lab and/or specific training for the use of chaperones during interactions between patients and staff.

## L. Patients' Rights

#### Standard

## L-1-FH Patients' Rights

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

- 1. You have the right to respectful care by credentialed and competent providers.
- 2. You have the right to know, on your request, the names of your providers and their roles in your healthcare.
- 3. You have the right to privacy in all matters pertaining to your healthcare.
- 4. You have the right to emergency care without delay when and if emergent care is needed.
- 5. You have the right to current, evidence-based care according to the standards of the American Academy of Sleep Medicine.
- 6. You have the right to be informed, in understandable terms, of your diagnosis, treatment options, prognosis and complication risks.
- 7. You have the right to refuse any medical care (drugs, treatments, or procedures) if allowed by law. You have the right to be informed of any risks from refusing care.
- 8. You have the right to hear about any possible medical research and to refuse participation in medical research.

- 9. You have the right to a second medical opinion at your own expense.
- 10. You have the right to medical care without discrimination based on race, color, religion, ancestry, national origin, sex, genetics, sexual orientation, gender identity, marital status, familial status, disability, veteran status, or any legally protected group status.
- 11. You have the right to an interpreter when English is not your preferred language.
- 12. You have the right to your medical information to the extent allowed by law.
- 13. You have the right to timely provision of care and efforts to minimize discomfort to you.
- 14. You have the right to transfer your care to an alternate sleep center at any time.
- 15. You have the right to examine and receive a detailed explanation of any medical bill.
- 16. You have the right to any information we may have about financial assistance.
- 17. You have the right to have your medical records from the sleep center sent to the medical provider of your choice.