

American Academy of Sleep Medicine
Proposal for an Integrated Sleep Management Delivery Model

September 2011

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This is a proposal describing an integrated sleep management delivery model (from this point forward, referred to as “integrated delivery model”), to be tested through an accreditation program administered by the American Academy of Sleep Medicine (AASM), a membership organization representing a specialty designated by CMS, with the support of the Center for Medicare and Medicaid Innovation.

I. Introduction

The AASM requests the opportunity to partner with the Center for Medicare and Medicaid Innovation on a project designed to test the effectiveness of an integrated delivery model for the treatment of sleep disorders with the AASM serving as the accrediting body for project test locations. In order to be able to provide all the necessary accreditation elements of an integrated delivery model, **the AASM requests the following:**

- The AASM requests that CMS open the application process for approval of the AASM as a CMS deemed authority for DME supplier accreditation.
- The AASM requests that CMS provide a carve-out for test locations of the integrated delivery model, reversing the CMS ruling, which currently prevents a single facility from providing both diagnostic and therapeutic services including positive airway pressure therapy for patients with obstructive sleep apnea.
- The AASM requests that, for the purposes of the testing of the integrated delivery model, CMS provide a carve-out permitting independent diagnostic testing facilities (IDTFs) which are exclusively performing sleep testing to be allowed to treat patients and provide therapeutic DME.

CMS has identified the need for an accreditation to be awarded to an integrated delivery model that combines the diagnosis and treatment of sleep disorders obstructive sleep apnea (OSA). As was stated in the November 19, 2008 Federal Register, “*we are unaware of any current model (of a disease management program) that encompasses accreditation for both OSA diagnosis and CPAP under a single accreditation certificate.*”¹ However, as also stated in the November 19, 2008 Federal Register, facilities providing the diagnostic testing for sleep disorders cannot provide the therapeutic care necessary to treat sleep disorders. Additionally, because CPAP is a designated health service, facilities providing diagnostic testing for sleep disorders cannot provide CPAP without running afoul of the self-referral law and regulations. These issues currently prevent a truly integrated delivery model from being established without a carve-out from CMS.

At this time, the AASM offers all of the individual elements required to create such an integrated delivery model accreditation program: 1) sleep center accreditation; 2) durable medical equipment (DME) supplier accreditation (the AASM has not been able to become a deemed authority by CMS); and 3) out of center sleep testing (OCST) accreditation. The integrated delivery programs will be led by a board certified sleep physician (BCSP) primarily responsible for the direction of the program. Additionally, the AASM considers

¹ Centers for Medicare & Medicaid Services (CMS). Medicare Program; payment policies under the physician fee schedule and other revisions to Part B for CY 2009; e-prescribing exception for computer-generated facsimile transmissions; and payment for certain durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). Final rules. Fed Regist. 2008 Nov 19;73(224):69858

the following components to also be critical to an integrated delivery model: a partnership with a dental sleep medicine practitioner; a partnership with a surgeon experienced in upper airway surgery to treat OSA; a mechanism to track follow-up and outcomes of all patients diagnosed with OSA; and a compliance program to minimize fraud and abuse. The AASM is uniquely qualified to offer all the elements required to establish an integrated delivery model accreditation program and to offer a single certificate to programs meeting the accreditation requirements. The overarching goal of this model is to improve outcomes in patients with sleep disorders.

Using a number of test locations able to provide the components described above, CMS could confirm if there are improved outcomes and cost savings resulting from the improved care received when a single entity provides *“comprehensive diagnostic and therapeutic services...that commonly includes ongoing assessment of the patient’s response to therapy and modifications to therapy as needed.”*²

The body of this proposal, as well as appendices A-D, supports the AASM’s recommendation of an integrated delivery model. The AASM leadership hopes for a favorable review of this proposal in keeping with the previous positive interactions between CMS and the AASM.

II. Accreditation Components of the Integrated Delivery Model

The proposed accreditation of integrated delivery models is comprised of three main existing AASM accreditation programs: sleep center accreditation, non-Medicare DME supplier accreditation, and OCST provider accreditation. Currently, the AASM offers voluntary accreditation for these three programs, though all three accreditation programs would be required for locations testing the integrated delivery model. Applicants for all three accreditation programs are required to meet a set of standards including a number of mandatory standards (noted as such in the standards documents provided in Appendix A). Programs failing to meet one or more of the mandatory standards will not be granted accreditation by the AASM.

Standards for accreditation of sleep centers, non-Medicare DME suppliers and OCST providers require compliance with the **AASM Practice Parameters and Clinical Guidelines**. The AASM has developed Practice Parameters which specify criteria for sleep testing and the diagnosis and treatment of obstructive sleep apnea and other sleep disorders. For more information about the AASM’s Science and Research department and the development of AASM Practice Parameters and Clinical Guidelines, please see Appendix D.

Sleep Center Accreditation: Currently, over 2200 sleep centers are actively accredited by the AASM, making the AASM the largest sleep center accrediting body in the country. The AASM began accrediting sleep centers in 1977. AASM sleep center accreditation includes a

² Centers for Medicare & Medicaid Services (CMS). Medicare Program; payment policies under the physician fee schedule and other revisions to Part B for CY 2009; e-prescribing exception for computer-generated facsimile transmissions; and payment for certain durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). Final rules. Fed Regist. 2008 Nov 19;73(224):69857

rigorous application process with an extensive review of sleep center policies and procedures as well as a detailed on-site visit. Applicants are required to abide by the standards for accreditation, which were developed and approved under the authority of the AASM Board of Directors. Sleep centers open for less than six months are given the opportunity to apply for provisional accreditation, an accreditation which is granted for a period of six months. Programs serving as test locations of the integrated delivery model would be required to be a fully accredited sleep disorders center in order to participate; provisionally accredited programs would be excluded. For a more detailed description of the AASM sleep center accreditation program and a copy of the standards for sleep center accreditation, please see Appendix A.

Durable Medical Equipment Supplier Accreditation: In 2010, the AASM began offering a durable medical equipment (DME) accreditation program. Similar to the AASM sleep center accreditation program, AASM DME supplier accreditation requires a detailed application process and on-site review. The AASM is not a deemed authority through CMS because we developed this accreditation after CMS closed the application process. However, the AASM standards for DME accreditation were modeled on CMS's requirements and, therefore, the program can easily be transitioned to meet the CMS requirements. For a more detailed description of the AASM DME supplier accreditation program, a copy of the standards for AASM DME supplier accreditation and a comparison chart describing the differences between the AASM DME supplier standards and the CMS standards, please see Appendix A.

Out of Center Sleep Testing Entity Accreditation: Early in 2011, the AASM began offering an accreditation program for sleep service entities performing out of center sleep testing (OCST). The accreditation is offered as an add-on to the AASM sleep center accreditation or as an individual program for stand-alone facilities offering OCST. Centers participating as test locations of the integrated delivery model would be required to obtain this add-on accreditation for the out of center portion of their sleep testing. For a more detailed description of the AASM OCST accreditation program, including a copy of the standards for OCST accreditation, please see Appendix A. Test locations of the integrated delivery model will be required to use one of four validated tools to determine a patient's pretest probability and the appropriateness of in-center or out of center sleep testing for a given patient. These tools are described in further detail in the "Test Location Preparation and Responsibilities" section below as well as in the OCST section of Appendix A.

III. Additional Components of the Integrated Delivery Model

In addition to obtaining AASM accreditation for their sleep center, DME program and OCST program, test locations of the integrated delivery model will be required to have four components in order to participate in the Center for Medicare and Medicaid Innovation project and receive integrated sleep management accreditation. Additional requirements include 1) a partnership with a dental sleep medicine professional experienced in oral appliance therapy, 2) a partnership with a surgeon experienced in upper airway surgery to treat OSA 3) a tracking mechanism for recording follow-up and outcomes for all patients diagnosed with OSA, and 4) a compliance program designed to prevent fraud and abuse.

Partnership with a Dental Sleep Medicine Provider: “Although not as efficacious as CPAP, oral appliances are indicated for use in patients with mild to moderate OSA (obstructive sleep apnea) who prefer OAs (oral appliances) to CPAP, or who do not respond to CPAP, are not appropriate candidates for CPAP, or who fail attempts with CPAP or treatment with behavioral measures such as weight loss or sleep-position change.”³ Because oral appliances are now considered an important alternative treatment for OSA, integrated delivery model test locations will be required to maintain a partnership with a licensed dentist with experience in dental sleep medicine and the fitting of oral appliance for the treatment of OSA. To meet the AASM integrated accreditation requirement, this dentist must be certified by the American Board of Dental Sleep Medicine (ABDSM) and must serve as the dental director of a facility accredited by the American Academy of Dental Sleep Medicine (AADSM) by January 2014. The continued participation of the board certified sleep physician (BCSP) in monitoring of outcomes and treatment adherence is important for patients referred for oral appliance therapy (OAT). For additional information about dental sleep medicine including information about the dental sleep medicine certification and dental sleep medicine facility accreditation, please see Appendix A. For information about tracking follow-up and measuring outcomes for patients referred for OAT, see Appendix B.

Partnership with a Surgeon Experienced in Upper Airway Surgery: In a 2010 AASM Practice Parameters, Aurora et. al. described the inclusion of upper airway surgery as a viable alternative to PAP therapy.⁴ Patients who do not respond to or fail CPAP, and for whom oral appliances are contraindicated or undesired, may be considered for upper airway surgery. These patients can be referred by the sleep specialist to an appropriately trained surgeon. To meet the AASM integrated accreditation requirements, the test location must establish a referral pathway for patients who are appropriate candidates for upper airway surgery. Referrals for surgery must meet the requirements outlined in the above mentioned 2010 AASM Practice Parameters. For more information about measurement of outcomes for patients referred for upper airway surgery, please see Appendix B.

Follow-up and Outcomes Tracking Mechanism: CMS now requires that PAP adherence be monitored for the first 90 days.⁵ For the AASM integrated delivery model the AASM proposes that encounters with patients diagnosed with OSA are monitored on a more chronic basis to provide continuing care for PAP users as well as patients prescribed oral appliance therapy (OAT) and referred for upper airway surgery (see the “Eligible Beneficiaries/Patients” section below for more information.) Using the tracking mechanism outlined in Appendix B, the test locations will be required to monitor all follow-up encounters with patients diagnosed with OSA.

³ Kushida CA, Morgenthaler TI, Littner MR, Alessi CA, Bailey D, et al. Practice Parameters for the Treatment of Snoring and Obstructive Sleep Apnea with Oral Appliances: An Update for 2005, SLEEP. 2006;29(2):240-243.

⁴ Aurora RN, Casey KR, Kristo D, Auerbach S, et al. Practice Parameters for the Surgical Modifications of the Upper Airway for Obstructive Sleep Apnea in Adults, SLEEP 2010;33(10):1408-1413.

⁵ Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Continuous Positive Airway Pressure (CPAP) Therapy For Obstructive SLEEP Apnea (OSA) (240.4). Effective March 13, 2008. Available at: <https://www.cms.gov/medicare-coverage-database/>. Accessed April 20, 2011.

Follow-up and outcomes for patients prescribed PAP therapy – Integrated delivery model test locations will track baseline PAP pressure and outcomes measures results at initial visits as well as PAP adherence and outcomes measures at follow-up visits three months, six months, one year and two years after initiation of therapy.

Follow-up and outcomes for patients prescribed OAT – Integrated delivery model test locations will track baseline outcomes measures results at initial visits as well as OAT adherence and outcomes measures at the patient's return visit to the board certified sleep physician (BCSP) for a follow-up sleep study and review of study results, as well as at follow-up visits one year and two years after initiation of therapy.

Follow-up and outcomes for patients referred for upper airway surgery – Integrated delivery model test locations will track baseline outcomes measures results at initial visits as well as outcomes measures at the patient's return visit to the BCSP for a follow-up sleep study and review of study results, as well as at follow-up visits one year and two years after initiation of therapy.

Some patients with mild to moderate sleep apnea (AHI of 5-15) are considered for behavioral modification treatments of OSA such as weight loss and change of body position during sleep. While these methods of treatment are effective in some patients and may be used by the BCSP of test locations, outcomes will not be measured for patients treated with behavioral modification techniques.

The implementation of a mechanism for tracking therapy adherence, interventions, outcomes and health indicators will help to ensure that each beneficiary/patient is consistently engaged and made an integral partner in his/her improved health outcomes.

Compliance Program: Approval by CMS of a carve-out allowing testing locations to provide diagnostic testing as well as therapeutic services for sleep disorders patients is necessary to allow the integrated delivery model to be tested. However, the AASM recognizes that CMS may have concerns about fraud and abuse, specifically with respect to physician self-referral for the provision of the equipment and delivery of PAP therapy. To diminish these concerns, the AASM will mandate that all test locations of the integrated delivery model implement a compliance program. Appendix C includes a detailed outline of the compliance program that all test locations will be required to implement in order to be accredited as an integrated delivery model. The compliance outline includes instructions for developing the following key components of the compliance program: policies and procedures; designation of a compliance officer and compliance committee; conducting effective training and education; developing effective lines of communication; enforcing standards through well-publicized disciplinary guidelines; auditing and monitoring; and responding to detected offenses and developing corrective action initiatives.

IV. Test Location Selection and Eligible Beneficiaries/Patients

Selection of Test Locations: The AASM requests that a selection of 1-2% of the sleep centers currently accredited by the AASM participate as test locations of the integrated

delivery model. This is approximately 25-50 centers. The AASM requests that participating test locations be offered a financial incentive for participation in the integrated delivery model project. This financial incentive could take the form of higher reimbursement for services offered to eligible beneficiaries/patients or a lump sum incentive based on the number of eligible beneficiaries/patients from each test location.

In order to test the effectiveness of the integrated model, the AASM recommends that a broad range of facilities treating a range of patient types be included as test locations. The project should include both rural and urban facilities; physician owned, hospital owned, hospital based facilities and those managed by outside contractors; and facilities that exclusively treat sleep patients as well as multi-specialty physician groups which include a sleep component. The AASM also proposes not limiting the testing of the integrated sleep management program model to Medicare beneficiaries. Every payer class should be incorporated into the testing of this model. The AASM suggests that independent diagnostic testing facilities (IDTFs) that have a licensed physician Board Certified in Sleep Medicine as its medical director be included in the testing of the integrated delivery model. Because of the limitations set by CMS on IDTFs with respect to treatment of patients, the AASM requests that, for the purposes of the testing of the integrated delivery model, CMS provide a carve-out allowing IDTFs with a medical director Board Certified in Sleep Medicine, exclusively performing sleep testing to be allowed to treat patients and provide DME.

Eligible Beneficiaries/Patients: Adult patients over the age of 18 years-old who are diagnosed with a sleep disorder are eligible for the integrated sleep management program delivery model.

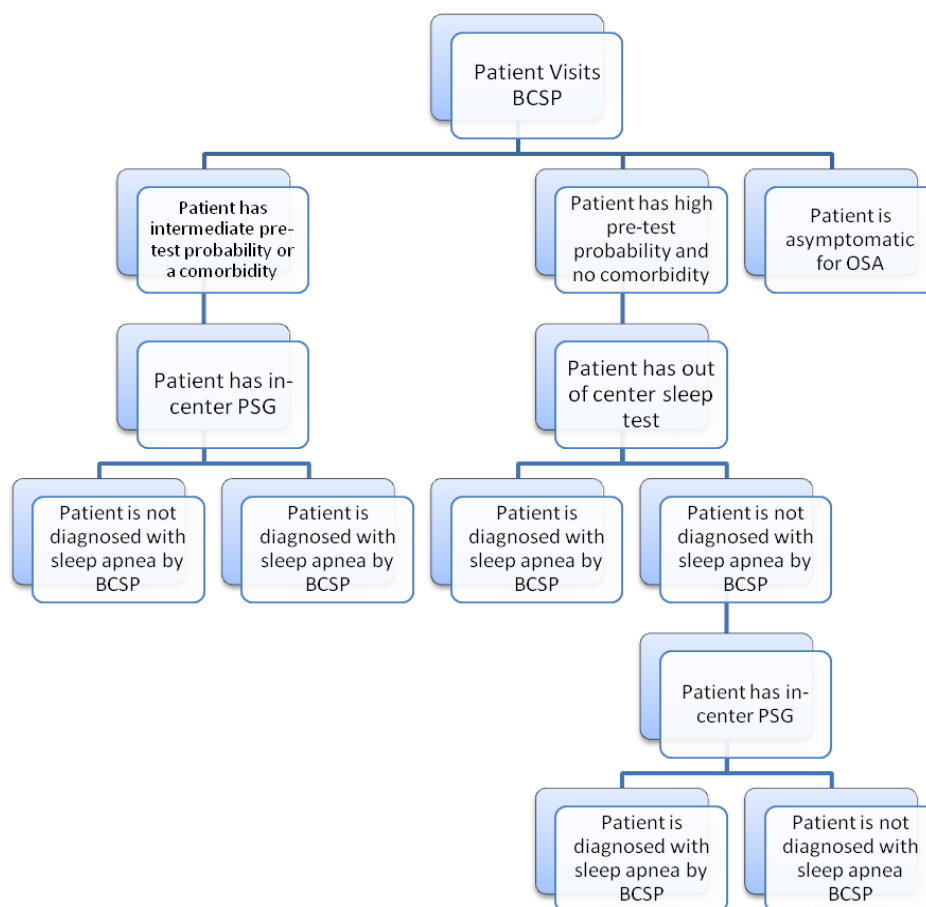
Patients tracked using the therapy tracking mechanism (described in detail in Appendix B) must have a diagnosis of obstructive sleep apnea (ICD-9-CM code 327.23) or hypersomnia with sleep apnea, unspecified (ICD-9-CM code 780.53) and must be prescribed a positive airway pressure device, an oral appliance or must be referred for upper airway surgery. The use of oral appliances as a first line of treatment is limited to patients with mild to moderate OSA. Patients referred for upper airway surgery must meet the requirements outlined in the 2010 *AASM Practice Parameters for the Surgical Modifications of the Upper Airway for Obstructive Sleep Apnea in Adults*.

V. Test Location Preparation and Responsibilities

Test Location Preparation: Test locations of the integrated delivery model will be required to have in place a number of components that may or may not be in operation at the time the location is selected to participate. For example, because of the November 2008 ruling, sites providing diagnostic testing cannot also provide DME for the treatment of OSA. As a result, the test locations will need to establish or affiliate with a DME program in compliance with AASM standards in order to participate as test locations of the integrated delivery model.

Test Location Responsibilities: Test locations of the integrated delivery model will be required to follow the same criteria to determine if patients should be tested in-center (e.g.

Type 1 in-lab polysomnography) or out of center. Patients with high pretest probability, with no significant comorbidities or suspected sleep disorders other than OSA, are acceptable candidates for out of center testing. At this time, there is no agreed upon definition for high-pretest probability. For the purposes of the testing of the proposed integrated delivery model, test locations will be allowed to select the tool they use to determine pretest probability from a list of four validated tools. These tools include: 1) OSA50; 2) Berlin Questionnaire; 3) Multivariable Apnea (MAP) Risk Index; and 4) STOP Questionnaire. Copies of articles documenting the validity of these tools follow the Out of Center Sleep Testing (OCST) Accreditation Standards in Appendix A. Test locations will be asked to document their methods and use a single tool consistently when determining pretest probability. The flow chart on the following page describes the process test locations will use to determine the most appropriate testing mechanism to use to diagnose a patient with symptoms of OSA. Similar flow charts describing treatment options can be found in Appendix B.



Test locations of the integrated delivery model must monitor outcomes in order to prove the success or failure of the project. These outcome measures are to be recorded in the

therapy tracking mechanism described above and in detail in Appendix B. A subjective measure of sleepiness (Epworth Sleepiness Scale) and two subjective measures of sleep quality (Functional Outcomes of Sleep Quality and 12 item Short Form Health Survey) will be tracked at each patient's initial visit and a number of additional times following initiation of treatment. Co-morbid conditions, as reported by each patient, will also be tracked initially and throughout the duration of treatment.

Integrated Delivery Model Project Timeline: The AASM estimates that, if approved, approximately one year will be needed to recruit test locations of the integrated delivery model from the list of programs currently accredited by the AASM. During the preparatory year, test locations will need to obtain all components required for the integrated delivery model. The AASM recommends that test locations be required to comply with all of the components of the integrated delivery model in order to participate. The AASM proposes to allow the test locations to operate under the integrated delivery model for a full two years to collect data on PAP adherence and outcomes. The AASM proposes a review and reporting to CMS of the data collected by the test locations in the standardized outcomes tracking mechanism at one year, 18 months, and two years to determine the effectiveness of the integrated delivery model.

VI. American Academy of Sleep Medicine Resources

The AASM has a unique history and a wide range of resources making it an ideal organization to initiate a project with the Center for Medicare and Medicaid Innovation to confirm the effectiveness of an integrated delivery model for the treatment of sleep disorders.

Governance: The AASM is governed by a twelve member Board of Directors including four officers (President, President-Elect, Immediate Past-President and Secretary/Treasurer) and eight at-large directors. Specialties represented on the Board of Directors include Research Scientists, Internal Medicine, Neurology, Otolaryngology, Pediatrics, Pulmonology and Psychiatry. The Board of Directors meets on a quarterly basis and at the SLEEP Annual Meeting. Additionally, a five member Executive Committee comprised of the four officers (President, President-Elect, Immediate Past-President and Secretary/Treasurer) and one at large member, meets monthly by conference call.

National Office: Located in Darien, Illinois, the AASM national office is a 30,000 square foot facility owned by the AASM and dedicated in October 2010. The national office houses the AASM's 55 full-time employees and supports 30 additional part-time employees. The AASM national office is also home to a number of other organizations, which are managed by the AASM, including:

- The American Academy of Dental Sleep Medicine (AADSM)
- The American Board of Dental Sleep Medicine (ABDSM)
- The American Association of Sleep Technologists (AAST)
- American Board of Sleep Medicine (ABSM)
- Associated Professional Sleep Societies (APSS)
- American Sleep Medicine Foundation (ASMF)

- Sleep Research Society (SRS)
- Sleep Research Society Foundation (SRSF)
- Society of Behavioral Sleep Medicine (SBSM)

AASM Membership: The AASM, founded in 1975, is a professional membership organization dedicated to the advancement of sleep medicine and related research. AASM membership has grown significantly since its inception. Over the past ten years alone the membership has more than doubled to reach its 2010 level of close to 9000 members. In addition to regular members who possess an MD, DO, PhD, DDS or other doctoral degree, the AASM also represents student and fellow members who are new to the field as well as affiliate and industry members. In serving such a broad membership, the AASM is uniquely committed to establishing new models for patient care. Please see Appendix D for additional information about the AASM membership.

Science and Research and Standards of Practice: The AASM is fortunate to have a department, including two individuals with doctoral degrees, dedicated to sleep science and research. In addition to serving as a resource for the rest of the AASM staff, the Science and Research Department is responsible for working with the Standards of Practice Committee that develops AASM Practice Parameters, Clinical Guidelines and Best Practice Guides. Using a proven process for literature review and evaluation, the Standards of Practice Committee develops parameters and guidelines that set standards for the field of sleep medicine. For additional information about the Science and Research Department as well as the development of the Practice Parameters, Clinical Guidelines and Best Practice Guides, please see Appendix D.

Educational Courses and Products: The AASM has always been committed to the education of its members. The SLEEP annual meeting, a joint conference of the AASM and Sleep Research Society (SRS), will be celebrating its 25th Anniversary in June 2011. Since the first meeting in 1986, the SLEEP annual meeting has grown from 739 attendees to 5850 attendees in 2010. Since 1995 the AASM has been accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide attendees with credit for attending AASM-developed courses. Beginning with a National Sleep Medicine Course and the SLEEP meeting, the AASM eventually expanded its offering of educational opportunities. In 2010 alone, over 1500 individuals attended AASM courses, not including those who attended the SLEEP meeting.

In addition to courses and training programs, the AASM has encouraged the education of its members by offering a number of educational products. Please see Appendix D for additional information about the educational courses and products offered by the AASM.

Sleep Medicine Training and Certification: The AASM supports standardized training and certification of sleep medicine physicians. In 2005, at the request of the AASM, the Accreditation Council for Graduate Medical Education (ACGME) began accrediting sleep medicine fellowship programs. To date, 71 accredited sleep fellowships have been accredited providing training for approximately 100 individuals each year.

In 2007, the AASM transitioned sleep certification to the American Board of Medical Specialties (ABMS). The ABMS has five member boards which are currently sponsoring the sleep certification examination: the American Board of Internal Medicine, the American Board of Pediatrics, the American Board of Family Medicine, the American Board of Otolaryngology, and the American Board of Psychiatry and Neurology. Recently, the American Board of Anesthesiology has also joined as the sixth member board. For more information about the growth and development of sleep medicine training and certification, please see Appendix D.

In January 2011, the AASM received notification from CMS that a specialty designation for sleep was approved. This designation will only be available to individuals who are board certified in sleep medicine. In the letter of approval, CMS indicated that the designation would be available for providers after October 2011.

Journal *SLEEP* and the *Journal of Clinical Sleep Medicine*: The AASM began publishing the journal *SLEEP* in 1978. *SLEEP* is a peer-reviewed joint publication of the AASM and SRS with an impact factor of 5.402. In 2005 the number of issues of *SLEEP* increased to 12 per year and commencing in 2011, *SLEEP* transitioned to an online-only publication.

In 2005 the AASM began publishing the *Journal of Clinical Sleep Medicine (JCSM)*. Targeted to sleep clinicians, *JCSM* is a peer-reviewed publication which features manuscripts such as clinical trials, clinical reviews, medical economic/practice perspectives and case reports. The *JCSM* leadership plans to move from a six issue per year schedule to an eight issue per year schedule beginning in 2011.

The continued publication of the journal *SLEEP* and *JCSM* reflect the AASM's commitment to continued research and further clinical development of the field of sleep medicine. Please see Appendix D for additional information about journal *SLEEP* and *JCSM*.

American Sleep Medicine Foundation: The American Sleep Medicine Foundation (ASMF) was founded in 1998 to further the AASM's mission to advance the fields of sleep research and sleep medicine. Since its inception, the AASM has invested more than \$10.5 million in the ASMF, much of which has translated into grants for sleep research and education. In addition to research, the ASMF funds one-year grants to support physician trainees. Through its financial commitment to the ASMF, the AASM confirms its investment in the development of improved future sleep care models. Please see Appendix D for additional information about the ASMF.

Internet Technology Staff and Online Resources: In order to serve the membership, accreditation, education, science and research arms of the AASM, the AASM national office has a large in-house internet technology staff. The IT department administers 16 websites integral to the AASM's mission. Additionally, the department has created new online experiences to help members to receive education in sleep. Please see Appendix D for additional information about the AASM national office and online resources.

VII. Conclusion

The AASM is committed to helping its members find ways to improve the diagnosis, treatment, and clinical outcomes of patients with sleep disorders. By adopting the AASM's proposal for a new Center for Medicare and Medicaid Innovation project, CMS is likewise showing its commitment to considering new models for healthcare delivery. The AASM hopes to partner with CMS to test the integrated sleep management delivery model described in the above proposal to prove the value of providing diagnosis and continued management of patients with sleep disorders by a single entity.

As CMS indicated in the November 19, 2008 Federal Register: *"ideally, we would like to require that all entities that furnish both sleep testing and CPAP be accredited. We solicit public input on accreditation models that might support this option. Once we are made aware of appropriate accrediting models, we may readdress this issue in future rulemaking."*⁶

The AASM requests the following from CMS in order to test the integrated delivery model:

- The AASM requests that CMS open the application process for approval of the AASM as a CMS deemed authority for DME supplier accreditation.
- The AASM requests that CMS provide a carve-out for test locations of the integrated delivery model, reversing the CMS ruling, which currently prevents a single facility from providing both diagnostic and therapeutic services including positive airway pressure therapy for patients with sleep disorders including obstructive sleep apnea.
- The AASM requests that, for the purposes of the testing of the integrated delivery model, CMS provide a carve-out permitting IDTFs which are exclusively performing sleep testing to be allowed to treat patients and provide therapeutic DME.

The AASM trusts that CMS will look favorably upon the proposed integration of its three accreditation programs. The AASM anticipates that the required compliance program will resolve any anticipated concerns CMS may have with respect to fraud and abuse. Through the outcomes measures monitored in the therapy and outcomes tracking mechanism, test locations of the integrated delivery model will be able to document and report on the anticipated improved care patients receive under this new model which encourages a partnership between the sleep specialist and the patient. Further direction regarding the coordination of this proposal with the Center for Medicare and Medicaid Innovation is requested.

⁶ Centers for Medicare & Medicaid Services (CMS). Medicare Program; payment policies under the physician fee schedule and other revisions to Part B for CY 2009; e-prescribing exception for computer-generated facsimile transmissions; and payment for certain durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). Final rules. Fed Regist. 2008 Nov 19;73(224):69858

Appendix A: Accreditation Components

- AASM Sleep Center Accreditation
- AASM Non-Medicare Durable Medical Equipment Supplier Accreditation
- AASM Out of Center Sleep Testing Accreditation
- AADSM Dental Sleep Medicine Facility Accreditation

AASM Sleep Center Accreditation

American Academy of Sleep Medicine (AASM) Accreditation of Sleep Disorders Centers is a voluntary process for the assessment of sleep programs. By achieving accreditation, a sleep center demonstrates a commitment to the provision of quality diagnostic services and the longitudinal management of sleep patients. The AASM's dedication to the continued quality of these requirements has made AASM center accreditation the gold standard by which the medical community and the public evaluate sleep medicine facilities. In most states, accreditation is now required for reimbursement of many sleep medicine services.

The AASM anticipates the need to transition to an accreditation program that requires all patients tested by the sleep center to be seen by center staff physicians for evaluation and follow-up. Current accreditation standards, specifically standard D-2, allow accredited facilities to test 80% of their patients without evaluating or following up with them in person. Under the current accreditation standards, the center staff physicians evaluate patient files to determine appropriateness of the study, but evaluation and follow-up is provided by the patient's referring physician.

As outlined in Appendix B of this proposal, test locations of the integrated model are only required to track outcomes for the patients seen for evaluation and follow-up by center staff physicians. If CMS approves the integrated sleep medicine proposal, the AASM will review and consider implementation of a revision to the direct referral standard. The revision would take place over a five year transition period allowing facilities to gradually decrease the number of patients they test by direct referral. Eventually, because all patients of the accredited facility will be seen by staff physicians, outcomes will be measured for all patients diagnosed with obstructive sleep apnea.

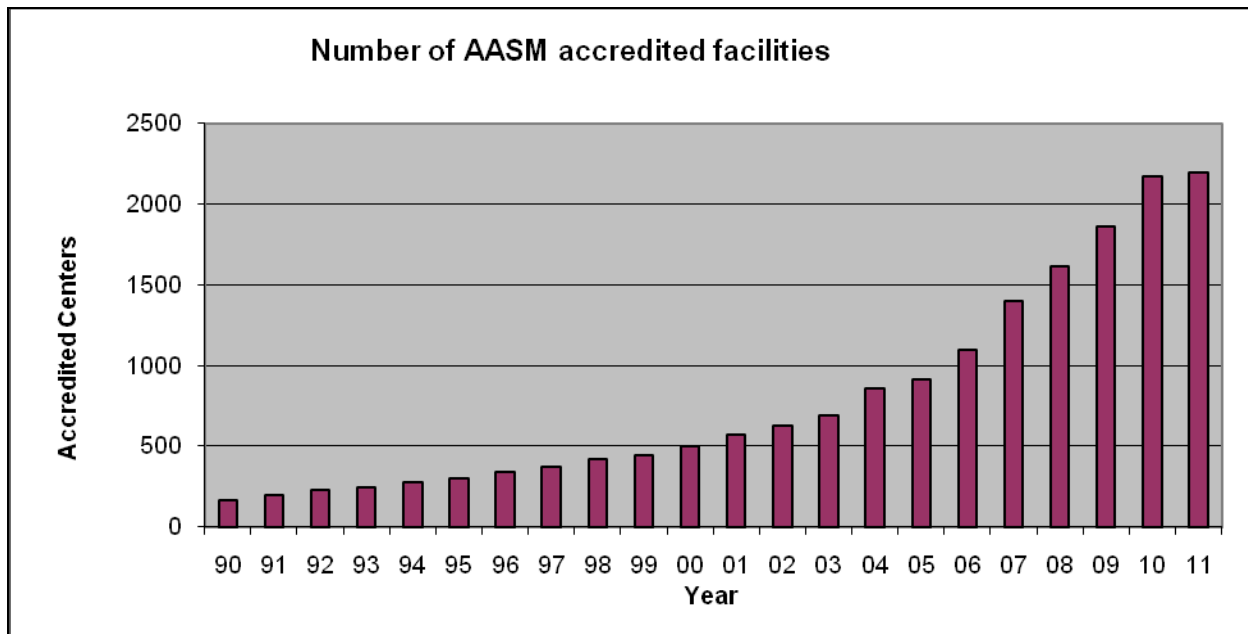
The first sleep facility was established in 1964 at Stanford University for the diagnosis and treatment of narcolepsy. In 1975, the Association of Sleep Disorders Centers (ASDC), a predecessor of the American Academy of Sleep Medicine (AASM), was formed and a Certification Committee was appointed to establish and maintain standards for the evaluation and treatment of patients with sleep disorders. The first draft of the accreditation guidelines was created in 1976 and the first site visit was conducted at Montefiore Hospital in New York, which was accredited in April of 1977. Five other facilities—Stanford, Ohio State, Cincinnati, Baylor and Memphis—all achieved accreditation within the first year. Within ten years, the number of ASDC-accredited centers had increased to fifty-four.

Today, the AASM Accreditation Committee writes and maintains the *Standards for Accreditation*. Final approval of the *Standards* rests with the AASM Board of Directors. The *Standards* are updated regularly to remain consistent with changes in technology and clinical practice.

The accreditation application process is a rigorous one. A thorough application and supporting materials must be submitted via the AASM online application system. The application is then reviewed by AASM clinical staff reviewers. Following review, a site

visitor board certified in sleep medicine surveys the applicant location and makes a report to the Accreditation Committee. The committee reviews these reports and makes accreditation recommendations to the AASM Board of Directors for a final decision. Since 1977, AASM Accreditation of Sleep Disorders Centers has grown to over 2200 accredited sleep centers across the United States with a reaccreditation rate of approximately 80%.

Figure A.1 – The expansion of accredited facilities since 1990.



AASM Sleep Center Accreditation Standards

A. General Standards

Standard

A-1 – Facility License (MANDATORY)

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

Standard

A-2 – Medical Code of Ethics (MANDATORY)

AASM accredited sleep facilities are required to follow the *Code of Medical Ethics* of the American Medical Association which the AASM adopted as official policy in 1998. The sleep facility must either have on hand or have the ability to access easily the *Code of Medical Ethics* of the American Medical Association Council on Ethical and Judicial Affairs Current Opinions.

B. Personnel

Standards B-1 through B-6 relate to the appointment, responsibilities and continuing education of a physician medical director and/or the appointment of a physician or PhD board certified sleep specialist.

A physician meeting all the requirements of B-1 through B-6 can fulfill both designations. A PhD can only fulfill the board certified sleep specialist designation.

Standard

B-1 – Medical Director (MANDATORY)

- a. AASM accredited sleep facilities must designate a single medical director who is a physician with a license valid in the state of the facility and in all states in which patients are seen. A copy of each state medical license must be submitted with the application.
- b. An individual can serve as medical director of three (3) sleep facilities, regardless of their accreditation status. If an individual is medical director of more than three facilities, the total number of beds shall not exceed 16 beds.

Standard

B-2 – Medical Director Responsibilities (MANDATORY)

The medical director:

- a. is responsible for the direct and ongoing oversight of testing,
- b. is responsible for the qualifications of all medical and technical personnel,
- c. must be present in the sleep facility on a regular basis and not less than 8 hours each month.

Standard

B-3 – Medical Director Continuing Education (MANDATORY)

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

Standard

B-4 – Board Certified Sleep Specialist (MANDATORY)

AASM accredited sleep facilities must designate a single professional sleep specialist defined by at least one of the following:

1. An individual who is board certified in sleep medicine by the American Board of Sleep Medicine or an individual certified in sleep medicine by either a member board of the American Board of Medical Specialties or a member board of the American Osteopathic Association.
2. An individual who has been accepted by an ABMS or AOA approved board to sit for the examination in sleep medicine. To retain the accreditation, the examination in sleep medicine must be passed within 2 examination cycles.
To meet this requirement, the individual must provide, in the application packet, a letter of acceptance to sit for the examination by the ABMS or AOA approved board. Upon completion of the examination, the individual must provide a copy of the official notification from the ABMS or AOA board indicating final status.
3. An individual who has completed a 12 month fellowship in sleep medicine and is awaiting the first available opportunity to apply to an ABMS board to sit for the sleep medicine examination. To retain accreditation, the ABMS examination in sleep medicine must be passed within 2 examination cycles.

Standard

B-5 – Board Certified Sleep Specialist Responsibilities (MANDATORY)

The designated board certified sleep specialist:

- a. must provide direct and ongoing oversight of the testing protocols and the quality of testing including the proper operation and calibration of the equipment,
- b. must review, report, and modify as necessary the facility's quality assurance program on a quarterly basis,
- c. must be on-site in the sleep facility on a regular basis and not less than 8 hours monthly,
- d. cannot serve as the board certified sleep specialist of more than three (3) sleep facilities, regardless of their accreditation status. If an individual is the designated board certified sleep specialist of more than three facilities, the total number of beds shall not exceed 16 beds.

Standard

B-6 – Board Certified Sleep Specialist Continuing Education (MANDATORY)

The board certified sleep specialist must participate in at least 10 credits per year averaged over 3 years of AMA PRA Category 1 CME (for a physician), CE (for a PhD) in sleep medicine. Compliance with CME/CE requirements must be documented. If a single individual serves as both the designated medical director and board certified sleep specialist, the individual must meet only the CME requirements of the medical director.

The AASM has adopted job descriptions which delineate education, training, and responsibilities of sleep technologists, sleep technicians, and sleep technician trainees. Standards B-7 through B-13 address requirements for sleep technologists, technicians and trainees. All sleep technologists/technicians must be able to perform the duties listed in the AASM approved job descriptions. 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 technical staff members, regardless of their duties.

Standard

B-7 - Sleep Technicians and Technologists

AASM accredited sleep facilities must maintain appropriately trained, supervised, and, where required by state law, licensed sleep technologists. Technologist staffing 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.

Standard

B-8 – 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:

- a. The American Board of Sleep Medicine (ABSM)
- b. The National Board of Respiratory Care (NBRC)
- c. The Board of Registered Polysomnographic Technologists (BRPT)
- d. An equivalent examination accepted by AASM

The individual(s) fulfilling this standard must be present at the facility a minimum total of 30 hours a week. If the facility is open fewer than 40 hours per week, the registered technologist must be present at the facility 75% of the time.

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

Standard**B-9 – Non-registered Sleep Technologist**

All technologists and technicians conducting sleep testing who are not registered by the ABSM, NBRC, BRPT, or other accepted certification body:

- a. must be enrolled in or have completed the A-STEP Online Self Study Modules,
- b. or must be enrolled in or have completed a CAAHEP accredited sleep technology training program, or electroneurodiagnostic (END) program, or respiratory therapy add-on track for sleep technology.

Standard**B-10 – Sleep Technician and Technologist Continuing Education**

The sleep facility's technical staff must each participate in an average of 10 hours per year of AMA PRA Category 1 CME or CEC sleep-related educational activities over a three year period. 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 sleep facility's medical director.

Standard**B-11 – Sleep Technician and Technologist Additional Certification**

Each sleep technician and technologist must have valid cardiopulmonary resuscitation. Valid certification in cardiopulmonary resuscitation includes skills training.

C. Patient Policies**Standard****C-1 – Patient Acceptance**

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

- a. age limitations,
- b. a mechanism for acceptance,
- c. criteria for exclusion,
- d. information required from a physician prior to all sleep testing in the sleep facility.

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

Standard**C-2 – Direct Referral (MANDATORY)**

Directly referred patients cannot exceed 80% of the patients tested by the sleep facility. A direct referral is defined as, all patients not seen in consultation by a sleep facility staff physician prior to or within three months following an in-laboratory sleep study or a portable monitoring study originally ordered by the patient's referring physician. Exceeding the direct referral threshold in any single calendar year is sufficient for denial of reaccreditation.

Standard**C-3 – Record Review of Direct Referrals**

For patients directly referred, the medical director or a designated sleep facility staff physician or the designated board certified sleep specialist must review the information provided for each patient and determine if the proposed evaluation conforms to established AASM Practice Parameters, or, if not, whether the evaluation is indicated for other reasons. Evidence of compliance with this standard must be included in the medical chart.

Standard**C-4 – Practice Parameter Requirements**

The clinical evaluation of patients accepted for sleep testing conducted in the sleep facility must comply with the AASM “Practice Parameters for the Indications for Polysomnography and Related Procedures”. Evidence of compliance with this standard must be included in the medical chart.

D. Facility and Equipment**Standard****D-1 – Permanent Address**

AASM accredited sleep facilities must have a permanent, physical address recognized by the United States Postal Service; such address may not include a P.O. Box. This standard is not intended to address the issue of mail delivery, rather identification and location of the sleep facility for patient access and convenience.

Standard**D-2 – Phone Line**

The program must have a separate phone line(s)/direct dial access into the sleep facility.

Standard**D-3 - Signage**

There must be appropriate signage identifying the program as “sleep facility.”

Standard**D-4 - Stationery**

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

Standard**D-5 – 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 space. The administrative office(s) and/or staff clinician office(s) of the sleep facility may be separate from the laboratory testing site. In such circumstances, the administrative and/or staff clinician office(s) must also meet the

AASM *Standards for Accreditation*, as they function as a part of the broader sleep disorders center.

In circumstances of mixed use, defined as testing rooms being used for other medical testing or examination during non-sleep testing (daytime) hours, the testing room(s) must meet all of the space and equipment standards of a single use sleep testing room.

Standard

D-6 – Testing Bedrooms – Physical Characteristics

All testing bedrooms must be single occupancy, private and comfortable, have hard walls, floor-to-ceiling, 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 – Testing Bedrooms & Emergency Care

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

- a. 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,
- b. must include a testing bed with a mattress not smaller than a standard hospital bed.

Standard

D-8 – 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 will have a working privacy door. Sole access to a shared bathroom shall not be through a testing bedroom.

Standard

D-9 – Handicap Testing Bedroom and Bathroom

At least one testing bedroom and bathroom must be handicap accessible as defined either by local building regulations or section 6.3 and 6.4 of the American with Disabilities Act (<http://www.access-board.gov/adaag/html/adaag.htm>).

Standard

D-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

D-11 - 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 – Video Recording**

Each testing bedroom in the facility must have a mechanism for visual monitoring and video recording of patients during testing. Time delayed photographs will not be considered compliant with this standard.

Standard**D-13 – Polygraphic Equipment**

The facility must maintain polygraphic equipment capable of recording and storing physiologic parameters using sensors, and recommended or alternative derivations as described in *The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology, and Technical Specifications*. The equipment must meet all of the “RECOMMENDED” minimal technical and digital specifications described in section III of the manual.

Standard**D-14 – PAP Therapy**

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

E. Policies and Procedures

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

Standard**E-1 – Policy and Procedures Manual**

AASM accredited sleep facilities must maintain a Policy and Procedures Manual that is easily accessible, in paper form or electronically, from the control room. The manual must contain all policies, procedures, protocols specific to the sleep facility, and all current AASM Practice Parameters and Clinical Guidelines.

Standard**E-2 – Protocols: PSG, MSLT, MWT, and PAP Titration**

The sleep facility must maintain written, paper or electronic format, protocols for comprehensive polysomnography, multiple sleep latency test, maintenance of wakefulness test, and titration of positive pressure therapy.

Sleep facilities 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 – Other Protocols**

AASM accredited sleep facilities that conduct portable monitoring for obstructive sleep apnea, esophageal pressure monitoring and actigraphy must maintain protocols for these procedures.

AASM accredited sleep 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 – Equipment Maintenance**

A written plan for monitoring of all patient-related equipment for electrical and mechanical safety is required. The written plan must include specific instructions regarding documentation of compliance. 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 electrical safety testing by a certified electrician or biomedical engineer to include at least annual testing for ground fault (resistance should be less than 0.5 ohms from chassis to ground) and chassis leakage current (amperage should be less than 100 microamps from equipment that will be in direct contact with the patient, and less than 300 microamps from equipment that will not be in direct contact with the patient, including the recording PCs).

F. Data Acquisition, Scoring and Reporting**Standard****F-1 – Signals and Equipment**

The signals collected and the equipment used for comprehensive polysomnography must be in compliance with *The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology, and Technical Specifications*.

Standard**F-2 – PSG Reports**

Reports of polysomnography must include all the "RECOMMENDED" parameters from section II of *The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology, and Technical Specifications*.

Standard**F-3 – Conducting MSLT and MWT**

The multiple sleep latency test and maintenance of wakefulness test must be conducted using the protocol described in Box 1 and Box 2 of the "Standards of Practice Committee of the American Academy of Sleep Medicine: Practice Parameters for Clinical Use of the Multiple Sleep Latency Test and the Maintenance of Wakefulness Test."

Standard**F-4 – PSG Scoring**

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

Standard**F-5 – Computer-assisted Scoring**

If used, computer-assisted scoring of polysomnography must be reviewed and edited for accuracy.

F-6 – Inter-scorer Reliability

Inter-scorer reliability must be determined between each scorer and a reference sleep specialist as defined in standard B-4 or a corporate appointed board certified sleep specialist; such individual must be an employee of the corporation and serves as the reference sleep specialist. Inter-scorer reliability assessment must be conducted for each sleep facility. In cases where a corporate sleep specialist serves as the reference standard for inter-scorer reliability, the sleep facility's designated board certified sleep specialist 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.

Use of the AASM Inter-Scorer Reliability program fulfills the requirements of this standard.

Standard**F-7 – Conducting Inter-scorer Reliability Assessment**

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 sleep facility designated reference specialist and to all other scoring technicians. Comparisons between each scorer and the facility's designated reference sleep specialist must be made on 200 consecutive 30-second epochs in each of three polysomnograms per quarter, for a total of 12 polysomnograms per year.

Use of the AASM Inter-Scorer Reliability program fulfills the requirements of this standard.

Standard**F-8 – SRBD Event Comparison**

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-9 – Inter-scorer Reliability Agreement**

Comprehensive polysomnography and portable monitoring studies must report agreement between scorer and the facility's designated reference sleep specialist 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.

Use of the AASM Inter-Scorer Reliability program fulfills the requirements of this standard.

Standard**F-10 – Review of Raw Data**

The physician or individual meeting B-4 interpreting a polysomnogram, multiple sleep latency test or maintenance of wakefulness test must conduct an epoch by epoch review the entire raw data recording for every study interpreted. Signed attestation of this review must be kept either in the patient record in the form of signature on the report of the test or in a separate journal.

Standard**F-11 – Review of Raw Data Continued**

The board certified sleep specialist must conduct an epoch-by-epoch review of the raw data of each record to assure that the quality of the recording and the scoring of sleep and associated events is sufficient to allow for interpretation. Specifically, this includes over-reading the raw data and interpretations of staff physicians who do not meet Standard B-4. Signed attestation of this review must be kept either in the patient record in the form of signature on the report of the test or in a separate journal.

G. Patient Evaluation and Care**Standard****G-1 – Patient Management**

In accordance with the sleep facility's patient acceptance policies, its physicians must demonstrate the capability and experience diagnosing and managing the full range of sleep disorders. This includes availability (within the sleep facility or by referral) of recognized and effective treatments for these disorders. Appropriate follow-up for patients who require continued management must be offered and available.

Standard**G-2 – Documenting Patient Evaluation/Management**

The sleep facility medical staff must document ongoing evaluation and management of patients with sleep disorders.

H. Patient Records**Standard****H-1 – Medical Charts**

AASM accredited sleep facilities must maintain appropriate medical charts for each patient evaluated by the sleep facility medical staff and for directly referred patients.

Standard**H-2 – Medical Charts Continued**

Medical charts of patients seen by sleep facility medical staff must document all patient interactions in the sleep facility, including initial evaluation, testing (if any), diagnosis, treatment, and follow-up.

Standard**H-3 – Medical Charts Continued**

Prior to testing, all patient medical charts must include: history and physical examination or patient questionnaires, or other screening assessment. Written indication that either a physician or the designated sleep specialist has reviewed and approved the proposed evaluation must be noted in the chart.

Standard**H-4 – PAP Assessment**

Patients prescribed positive airway pressure treatment by the sleep facility 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:

- a. direct patient inquiry,
- b. office encounter with sleep facility technical or medical staff,
- c. the referring physician,
- d. questionnaires,
- e. telephone inquiry to the referring physician or the patient,
- f. an informatic system capable of obtaining positive airway pressure use and a metric of clinical response.

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

Standard**H-5 - Database**

The sleep facility must maintain a cumulative database of the final diagnosis, using the most recent diagnostic and coding manual of the AASM, and procedures performed for each patient evaluated. This database must include cases seen by the facility's medical staff that did not require polysomnography.

I. Emergency Procedures**Standard****I-1 – Emergency Plan**

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

- a. mechanisms and specific details for contacting emergency personnel;
- b. the sleep facility personnel to be contacted in an emergency;
- c. outline the specific responsibilities of the technical staff.

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

- a. Cardiac emergencies;
- b. Neurologic emergencies, particularly seizures;
- c. Psychiatric emergencies, particularly suicidal ideation;
- d. Environmental emergencies such as fire, weather, belligerent patients, and bomb threats.

Standard**I-2 – Emergency Equipment**

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

J. Quality Assurance**Standard****J-1 – QA Program**

AASM accredited sleep facilities must have a quality assurance program that addresses inter-scorer reliability as outlined in standard F and at least three other quality assurance indicators.

Standard**J-2 – Reporting QA Program**

All quality assurance metrics must be reported and reviewed by the sleep facility's medical director or the designated board certified sleep specialist a minimum of once each quarter. The reviewer of the report must sign and date the report; a copy of the signed report must be kept on file for a minimum of one year.

AASM Durable Medical Equipment Supplier Accreditation

In November 2009, the AASM Durable Medical Equipment (DME) Accreditation Task Force (DATF) was charged with creating a DME accreditation program. Although the application period to apply for deemed authority status through CMS was closed, the DATF closely modeled the CMS DME supplier accreditation requirements when developing AASM standards. The intent was to create an accreditation program that would be easily transitioned to CMS regulations should the opportunity to become a deemed authority arise. Because of the DATF's attention to this issue, making this transition would be very simple for the AASM accreditation program. In April 2010, the AASM Board of Directors approved the Standards for DME Accreditation. Following beta-testing with two DME programs, the application for DME accreditation became publicly available in September 2010.

AASM DME accreditation program is a voluntary activity, providing recognition that a DME supplier meets rigorous standards set forth by the AASM. The AASM Standards of DME Supplier Accreditation have been tailored to ensure that they meet the unique needs of sleep disorders patients utilizing the services of a DME supplier. Integrating AASM DME Supplier Accreditation into a sleep facility's services helps illustrate a comprehensive approach to patient care and customer service. The AASM Accreditation Committee oversees the DME accreditation process. Site visitors are qualified individuals trained in DME accreditation as well as in sleep center accreditation.

AASM DME accreditation is available to free-standing suppliers as well as sleep facilities that provide DME equipment to their patients. It is not required that a facility be accredited through the AASM as a sleep disorders center to become accredited as a DME supplier. Because the AASM is not a deemed authority by CMS, the AASM accredits non-Medicare **DME suppliers** that supply any of the following types of equipment:

- Continuous Positive Airway Pressure (CPAP) and Auto Adjusting Continuous Positive Airway Pressure devices.
- Oxygen concentrators, reservoirs, high-pressure cylinders, liquid oxygen, oxygen accessories and supplies and oxygen conserving devices.
- Home Invasive Mechanical Ventilators.
- 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.
- Nebulizers.
- Suction Equipment.
- Insufflators and Exsufflators.
- Portable Oximeters.

AASM Durable Medical Equipment Accreditation Standards

A. Facility and Equipment

Standard

A-1 – Address (MANDATORY)

American Academy of Sleep Medicine (AASM) accredited Durable Medical Equipment (DME) suppliers must have a permanent, physical address recognized by the United States Postal Service. The DME supplier address may include a P.O. Box for mailing purposes only. The DME supplier must display all valid licenses, certificates of occupancy and permits to operate in an area accessible to visitors.

A-2 – DME Supplier Availability

The DME supplier must:

- a. Maintain a publicly listed telephone number. Exclusive use of a pager, mobile phone, or answering machine will not serve to meet this standard.
- b. Maintain a designated contact person accessible to the patient and/or caregiver(s) via telephone. For suppliers providing life-sustaining equipment (e.g. oxygen concentrators, reservoirs, high-pressure cylinders, oxygen accessories and supplies, oxygen conserving devices, and invasive home ventilators), the contact person must be available twenty-four hours a day, seven days a week.
- c. Maintain posted hours of operation.

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

A-3 – 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:

- a. Continuous Positive Airway Pressure (CPAP) and Auto Adjusting Continuous Positive Airway Pressure devices.
- b. Oxygen concentrators, reservoirs, high-pressure cylinders, liquid oxygen, oxygen accessories and supplies and oxygen conserving devices.
- c. Home Invasive Mechanical Ventilators.
- d. 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.
- e. Nebulizers.
- f. Suction Equipment.
- g. Insufflators and Exsufflators.
- h. 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.

Technical staff involved in the distribution and set-up of equipment must possess appropriate licensure and certification necessary to distribute DME equipment based on their individual state requirements.

A-4 – Materials for DME Equipment

The DME supplier must have the available manufacturer features, warranties and instructions for each DME equipment and/or item(s) that it provides. For equipment and/or item(s) dispensed which have unique serial numbers, there must be a written or electronic database maintained indicating the equipment and/or item(s). The patient name and/or medical record number must correspond to the equipment and/or item(s) dispensed.

B. Financial Management

Standard

B-1 – Financial Management Policies

The DME supplier must implement financial management practices that ensure accurate accounting and billing to insurance companies and patients. Financial records must be accurate, complete, current and reflect cash or accrual base accounting practices. Internal controls must be implemented and documented with policies addressing, at a minimum, each of the following:

- a. Balance sheets
- b. Income statements
- c. Cash controls including:
 - i. Bank reconciliations
 - ii. Statements of cash flow
- d. Payable controls including:
 - i. Authorization of payment
 - ii. Monthly reconciliation for cash or accrual base accounting
- e. Invoicing controls using currently published CPT and ICD-9 codes

B-2 – Patient Accounts

The DME supplier must maintain accounts that link equipment and/or item(s) to the patient and manage revenues and expenses on an ongoing basis, as they relate to patient services, including the following:

- a. Billing reconciliation of equipment, item(s) and/or service(s) using invoices, receipts and deposits maintained through an equipment/patient database.

C. Claims Submission Audit

Standard

C-1 – Patient Records Audit

A minimum of five patient DME records must be audited at least annually by the DME supplier. The audit must demonstrate:

- a. Accurately coded bills for equipment, item(s) and/or service(s) documented in the patient DME chart.
- b. Reasonable and medically necessary equipment, item(s) and/or service(s) have been provided to the patient.

C-2 – Billing Discrepancies Procedure

The DME supplier must have a procedure for identifying and correcting billing discrepancies. This procedure must include:

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

D. Practice Standards and Procedures

Standard

D-1 – Policy and Procedures Manual

The DME supplier must implement and maintain a policy and procedures manual that is easily accessible to all applicable staff members, in written or electronic format. The manual must:

1. Contain all policies, procedures and protocols specific to the DME supplier.
2. Include names and job descriptions for all DME supplier personnel.
3. Delineate education, training, responsibilities, certifications and licensures.
4. Document continuing education requirements related to the specialized equipment, item(s) and/or service(s) it provides to patients.
5. Include evidence of annual review, with periodic updates by the manager, director or owner, as warranted.
6. Support compliance with all State and Federal regulations, as it pertains to the business, including but not limited to, Stark Laws and the Health Insurance Portability and Accountability Act (HIPAA).
7. Maintain a charity policy for patients unable to afford equipment, item(s) and/or service(s). The DME supplier must provide evidence of adherence to and use of this policy.

D-2 – CPT/ICD-9 Codes Update

The DME supplier must have guidelines in place to ensure that the most current CPT/ICD-9 codes are utilized.

E. Human Resources Management

Standard

E-1 – Personnel Responsibilities

Technical staff (such as registered or certified polysomnographic technologists, registered or certified respiratory therapists and technicians who have completed an A-STEP accredited program or a CAAHEP accredited sleep technology training program, electroneurodiagnostic (END) program, or respiratory therapy add-on track for sleep technology) must be trained to deliver and set-up equipment, item(s) and/or service(s) and to train patients and/or caregiver(s).

- a. Where required by state law, these individuals must be licensed by their appropriate state or national governing board specific to their professional designation.
- b. All technical 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.
- c. The DME supplier must verify and maintain copies of current licenses, registrations and certifications for personnel who provide patient services. These documents must be verified upon employment and at least annually.

E-2 – Personnel Training

Training must be provided annually for each staff person who performs coding and billing of services provided by the DME supplier. Some suggested areas of training include:

- a. Coding requirements related to the services coded and billed.
- b. Claim development and submission processes.
- c. Documentation of services rendered.
- d. Billing standards and procedures, including review of rejected claims.
- e. Reason(s) for claim rejection.
- f. Legal sanctions for submitting deliberately false or reckless billings.

Documentation of training must be maintained by the DME supplier and be available upon request to accreditation organizations and government officials or their authorized agents. Training materials, attendance sheets and course outlines must be maintained in a file, written log or electronic database and must be available for review.

F. Consumer Services

Standard

F-1 – Receipt of Delivered Equipment

The DME supplier must:

- a. Provide information to the patient regarding expected delivery time for receipt of equipment, item(s) and/or service(s).
- b. Verify and document in the patient's DME chart the patient's receipt of all equipment, item(s) and/or service(s).

- c. Provide their telephone number to each patient at the time of delivery of the prescribed equipment and/or item(s).

F-2 – Options for Renting/Buying Equipment

The DME supplier must provide options for patients and/or caregiver(s) to rent or purchase equipment and/or item(s), when applicable.

F-3– Patient Complaints

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

G. Training/Instruction to Patient and/or Caregiver(s)

Standard

G-1 – Verification of Training

The DME supplier must, as applicable:

- a. Provide, or coordinate the provision of, appropriate information related to the set-up, features, routine use, troubleshooting and maintenance of all equipment and/or item(s) provided to the patient and/or caregiver(s).
- b. Coordinate, either in person or via remote electronic video communication system, the initial equipment set-up and provide adequate training and instructions for the use of equipment and/or item(s). Verification of set-up location (at the DME supplier location, in the patient’s home or via a video communication system) must be documented in the patient’s DME chart.
- c. Supply to the patient and/or caregiver(s) clear, written or pictorial, oral or electronic instructions related to the use, maintenance, infection control practices for, and potential hazards of, equipment and/or item(s) as appropriate. It is expected that translations of all these materials will be available, and interpreter services provided for non-English speaking patients, when applicable.

H. Performance Management

Standard

H-1 – Quality Assurance Program

The DME supplier must implement a quality assurance program that measures outcomes of consumer services, positive airway pressure (PAP) compliance, billing practices and adverse events.

The DME supplier must track all adverse events that are secondary to providing the patient with inadequate services or malfunctioning equipment (e.g. injuries, accidents, signs and symptoms of infection, hospitalization). The number of adverse events, event outcomes and resolutions must be maintained in a written log or electronic database.

The DME supplier must measure each of the following quality assurance parameters:

- a. Patient satisfaction and complaints about product(s) and/or service(s) rendered.
- b. Timeliness of response to patient's question(s), problem(s) and/or concern(s).
- c. Patient access times to receive ordered equipment, item(s) and/or service(s).
- d. Positive airway pressure (PAP) compliance expressed as a percentage and objectively measured for all patients who acquire a PAP device from the DME supplier.
- e. Frequency of billing and coding errors (e.g. number of insurance claims denied, errors resulting in claims denial).

These quality assurance indicators must be reported and reviewed at least once per quarter. For each quality assurance indicator, the DME supplier must specify:

- a. A goal percentage.
- b. An action plan if the goal percentage is reached in four consecutive quarters (i.e. raise the goal percentage or create a different quality assurance indicator to measure the parameter).
- c. An action plan if the goal percentage is not consistently reached in four consecutive quarters.

The DME supplier's manager, director or owner must sign and date the report. A copy of each signed report must be kept on file for the duration of the accreditation period.

I. Product Safety

Standard

I-1 – Equipment Safety Program

The DME supplier must have a policy, in written or electronic format, which promotes the safe use of equipment and/or item(s) and minimizes safety risks, infections and hazards both for its staff dispensing equipment and/or item(s) and for its patients receiving the equipment and/or item(s) for use.

I-2 – Equipment Failure, Repair and Maintenance Plan

The DME supplier must have, in written or electronic format, a policy for identifying, monitoring and reporting (where indicated) failure, repair and preventive maintenance of equipment and/or item(s) provided to the patient.

I-3 – Equipment Incident Investigation

The DME supplier must investigate any incident, injury or infection in which the DME supplier may have contributed to the event.

- a. The investigation must be initiated as soon as possible and within twenty-four hours after the DME supplier becomes aware of any incident, injury or infection.
- b. The investigation must include documentation of all necessary information, pertinent conclusions, and whether changes in the system(s) or processes are needed.
- c. The DME supplier must provide subsequent follow-up to the incident to prevent future occurrences.

I-4 – Emergency Plan

The DME supplier must have an emergency plan, in written or electronic format, which enables the DME supplier to respond to emergencies and disasters. The DME supplier must establish an arrangement with alternative DME supplier(s) in the event that the DME supplier cannot service its own customers as a result of an emergency or disaster. The emergency plan must delineate the following:

- a. Mechanisms and specific details for contacting emergency personnel.
- b. DME supplier personnel to be contacted in an emergency and their specific responsibilities.

I-5 – Product Verification (MANDATORY)

The DME supplier must verify, authenticate and document the following in the patient's DME chart prior to distributing, dispensing or delivering equipment, item(s) and/or service(s) to the patient:

- a. The products are not adulterated, counterfeit, suspected of being counterfeit and have not been obtained by fraud or deceit; and
- b. The products are not misbranded and are appropriately labeled for the intended distribution channels.

J. Information Management**Standard****J- 1 – Maintain Patient Records**

The DME supplier must maintain accurate, pertinent, accessible, confidential and secure patient records, in written or electronic format, in accordance with privacy and security standards of the Health Insurance Portability and Accountability Act (HIPAA) and other applicable state standards. These records must provide documentation of all patient interactions in the patient's DME chart.

J-2 – Fraud, Waste and Abuse Policies (MANDATORY)

The DME supplier must implement policies to prevent and control fraud, waste and abuse by using standards of conduct which ensure the organization's compliance with applicable Federal, State, local laws and regulations. These standards must be available for review in either written or electronic format.

K. Intake & Assessment**Standard****K-1 – Consultation with Ordering Healthcare Professional**

The DME supplier 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, item(s) and/or service(s). These interactions must be documented in the patient's DME chart. Any changes in the patient's medical equipment necessitate an updated prescription, which must be kept unaltered in the patient's DME chart. Any certificates of medical necessity must also be maintained in the patient's DME chart.

K-2 – Review Patient Records

The DME supplier must review the patient's DME medical record, as warranted, and incorporate and maintain any pertinent information related to the patient's condition(s) which may affect the provision of the DME equipment, item(s) and/or service(s).

L. Equipment Delivery & Set-Up**Standard****L-1 – Delivery and Set-up in a Timely Manner**

The DME supplier must provide the patient with all accredited respiratory and sleep-related equipment, item(s) and/or service(s) prescribed by an ordering healthcare professional in a timely manner.

- a. The DME supplier must verify that all equipment, item(s) and/or service(s) delivered to the patient are consistent with the ordering healthcare professional's request.
- b. The DME supplier must notify the ordering healthcare professional when the patient has been set-up with the ordered equipment, item(s) and/or service(s). This must be documented in the patient's DME chart.
- c. The DME supplier must notify the ordering healthcare professional when it will take longer than ten business days to provide the patient with equipment, item(s) and/or service(s).
- d. If the DME supplier cannot or will not provide the equipment, item(s) and/or service(s) prescribed for the patient, the DME supplier must notify the ordering healthcare professional within five business days of the original order.

L-2 - Loaner Equipment

The DME supplier must provide, or arrange for, loaner equipment and/or item(s) comparable to the original equipment and/or item(s) during any repair period. For each piece of equipment and/or item(s), the DME supplier must document in a written log book or electronic database:

- a. The serial number of the equipment and/or item(s).
- b. The date that the equipment and or item(s) were lent out.
- c. To whom the equipment and/or item(s) were lent.
- d. The date the equipment and/or item(s) were returned.

M. Follow-up

Standard

M-1 – Continued Equipment Management

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

M-2 – Equipment Recalls

The DME supplier must notify the patient of any manufacturer DME equipment and/or item(s) recalls within ninety days of manufacturer recall notification. The DME supplier must remove the recalled equipment and/or item(s), and replace it with comparable approved loaner equipment and/or item(s).

M-3 – Compliance with Positive Airway Pressure (PAP) Therapy

The DME supplier must offer follow-up to patients who are prescribed positive airway pressure (PAP) therapy to ensure compliance within twelve weeks of initiating therapy. .

Adequate compliance with therapy is defined as positive airway pressure (PAP) usage four hours or more per night on at least 70% of nights during a consecutive thirty-day period. Compliance must be measured objectively.

The DME supplier must create, maintain and archive a quarterly report which objectively measures positive airway pressure (PAP) percent compliance for all patients who acquire a PAP device from the DME supplier. This compliance report must serve as one of the measured parameters in the DME supplier's quality assurance program.

Positive airway pressure (PAP) therapy compliance assessment must measure treatment use and clinical response. This must be documented by any of the following modalities:

- a. Direct patient inquiry.
- b. Face-to-face clinical re-evaluation by the ordering healthcare professional.
- c. Questionnaires.
- d. Telephone inquiry to the ordering healthcare professional or the patient.

- e. An informatics system capable of obtaining positive airway pressure use.
- f. A metric of clinical response.

The patient's DME chart must contain documentation of the compliance assessment or written evidence of follow-up attempts made to obtain the positive airway pressure (PAP) therapy compliance assessment.

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

Standard

N-1 – Disclosure (MANDATORY)

The DME supplier must provide current information to the accrediting body for all individuals and joint venture companies holding an ownership or controlling interest (5% or more). The DME supplier must report to the accrediting body any agent relationship and managing employee interest in the DME supplier, and subcontractor relationships with another DME supplier.

Figure A.2 – AASM DME Accreditation Standards Comparison to CMS Supplier Standards

The American Academy of Sleep Medicine Durable Medical Equipment Accreditation Task Force (DATF) created the AASM Standards for Non-Medicare DME Supplier Accreditation with a constant eye to the CMS Medicare DMEPOS Supplier Standards. The task force sought to create a set of standards that could easily transition to accrediting a Medicare supplier should the opportunity for the AASM to gain deemed status arise. This comparison document illustrates how each AASM DME Standard mirrors the CMS Medicare DMEPOS Supplier Standards. The CMS Standards are listed in order with the applicable AASM standard below.

Organization	Standard
	Section I: Supplier Business Services Requirements
CMS	A-1: The supplier shall have one or more individuals who perform leadership functions, with the authority, responsibility, and accountability to direct the organization and its key activities and operations.
AASM	<p>E-1. Standard – Personnel Responsibilities</p> <p>Technical staff (such as registered or certified polysomnographic technologists, registered or certified respiratory therapists and technicians who have completed an A-STEP accredited program or a CAAHEP accredited sleep technology training program, electroneurodiagnostic (END) program, or respiratory therapy add-on track for sleep technology) must be trained to deliver and set-up equipment, item(s) and/or service(s) and to train patients and/or caregiver(s).</p> <ul style="list-style-type: none"> a. Where required by state law, these individuals must be licensed by their appropriate state or national governing board specific to their professional designation. b. All technical 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.

Organization	Standard
	<p>c. The DME supplier must verify and maintain copies of current licenses, registrations and certifications for personnel who provide patient services. These documents must be verified upon employment and at least annually.</p>
CMS	<p>A-2: The supplier shall govern its business so that it obtains and provides appropriate quality equipment, item(s) and service(s) to beneficiaries.</p>
AASM	<p>A-3. Standard – Appropriate Equipment</p> <p>The DME supplier must provide appropriate quality equipment to patients. For this accreditation, such equipment may include any of the items listed below:</p> <ul style="list-style-type: none"> a. Continuous Positive Airway Pressure (CPAP) and Auto Adjusting Continuous Positive Airway Pressure devices. b. Oxygen concentrators, reservoirs, high-pressure cylinders, oxygen accessories and supplies, and oxygen conserving devices. c. Home Invasive Mechanical Ventilators. d. 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. e. Intermittent Positive Pressure Breathing (IPPB) Devices. f. Nebulizers, Suction Equipment. g. Insufflators and Exsufflators.

Organization	Standard
	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.
CMS	A-3: The supplier shall have a physical location and display all licenses, certificates, and permits to operate. The licenses, certificates and permits must be displayed in an area accessible to customers and patients. The supplier shall provide copies, upon request, to government officials or their authorized agents.
AASM	A-1. Standard - Address American Academy of Sleep Medicine (AASM) accredited Durable Medical Equipment (DME) suppliers must have a permanent, physical address recognized by the United States Postal Service. The DME supplier address may include a P.O. Box for mailing purposes only. The DME supplier must display all valid licenses, certificates of occupancy and permits to operate in an area accessible to visitors.
CMS	A-4: The supplier shall provide only durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) and other items that meet applicable Food and Drug Administration (FDA) regulations and medical device effectiveness and safety standards. The supplier shall obtain from the manufacturer copies of the features, warranties, and instructions for each type of non-custom fabricated item.
AASM	See Standard A-3 above (CMS standard A-2) A-4. Standard - Materials for DME Equipment The DME supplier must have the available manufacturer features, warranties and instructions for each piece of DME equipment and/or item(s) that it provides. For equipment and/or item(s) dispensed which have unique serial numbers, there must be a written or electronic database

Organization	Standard
	maintained indicating the equipment and/or item(s). The patient name and medical record number must correspond to the equipment and/or item(s) dispensed.
CMS	A-5: The supplier shall comply with all Medicare statues, regulations (including the disclosure of ownership and control information requirements at 42 CFR §420.201 through §420.206), manuals, program instructions, and contractor policies and articles.
AASM	<p>D-1. Standard – Policy and Procedures Manual</p> <p>The DME supplier must implement and maintain a policy and procedures manual that is easily accessible to all applicable staff members, in written or electronic format. The manual must:</p> <ol style="list-style-type: none"> 1. Contain all policies, procedures and protocols specific to the DME supplier. 2. Include names and job descriptions for all DME supplier personnel. 3. Delineate education, training, responsibilities, certifications and licensures 4. Document continuing education requirements related to the specialized equipment, item(s) and/or service(s) it provides to patients. 5. Include evidence of annual review, with periodic updates by the manager, director or owner, as warranted. 6. Support compliance with all State and Federal regulations, as it pertains to the business, including but not limited to, Stark Laws and the Health Insurance Portability and Accountability Act (HIPAA). 7. Maintain a charity policy for patients unable to afford equipment, item(s) and/or service(s).

Organization	Standard
	<p>The DME supplier must provide evidence of adherence to and use of this policy.</p> <p>D-2. Standard – CPT/ICD-9 Codes Update</p> <p>The DME supplier must have guidelines in place to ensure that the most current CPT/ICD-9 codes are utilized.</p> <p>N-1. Standard – Disclosure</p> <p>The DME supplier must provide current information to the accrediting body for all individuals and joint venture companies holding an ownership or controlling interest (5% or more). The DME supplier must report to the accrediting body any agent relationship and managing employee interest in the DME supplier, and subcontractor relationships with another DME supplier.</p>
CMS	<p>A-6: The supplier shall implement business practices to prevent and control fraud, waste, and abuse by:</p> <ul style="list-style-type: none"> • Using procedures that articulate standards of conduct to ensure the organization’s compliance with applicable laws and regulations; and • Designating one or more individuals in leadership positions to address compliance issues.
AASM	<p>C-1. Standard – Patient Records Audit</p> <p>A minimum of five patient records must be audited at least annually by the DME supplier. The audit must demonstrate:</p> <ol style="list-style-type: none"> a. Accurately coded bills, representative of equipment, item(s) and/or service(s) documented in the patient DME chart. b. Reasonable and medically necessary equipment, item(s) and/or service(s) have been

Organization	Standard
	<p>provided to the patient.</p> <p>C-2. Standard – Billing Discrepancies Procedure</p> <p>The DME supplier must have a procedure for identifying and correcting billing discrepancies. This procedure must include:</p> <ol style="list-style-type: none"> 1. Designation of staff member(s) responsible. 2. The use of audits and/or other risk evaluation techniques to monitor billing activities. 3. Procedures to resolve and prevent recurrence of identified discrepancies. <p>See Standard D-1 above (CMS standard A-5)</p> <p>J-2. Standard – Fraud, Waste and Abuse Policies</p> <p>The DME supplier must implement policies to prevent and control fraud, waste and abuse by using standards of conduct which ensure the organization’s compliance with applicable Federal, State, local laws and regulations. These standards must be available for review in either written or electronic format.</p>
CMS	B-1: The supplier shall implement financial management practices that ensure accurate accounting and billing to beneficiaries and the Medicare program. Financial records shall be accurate, complete, current, and reflect cash or accrual base accounting practices.
AASM	<p>B-1. Standard – Financial Management Policies</p> <p>The DME supplier must implement financial management practices that ensure accurate accounting and billing to insurance companies and patients. Financial records must be accurate, complete, current and reflect cash or accrual base accounting practices. Internal controls must be implemented</p>

Organization	Standard
	<p>and documented with policies addressing, at a minimum, each of the following:</p> <ul style="list-style-type: none"> a. Balance sheets b. Income statements c. Cash controls including: <ul style="list-style-type: none"> i. Bank reconciliations ii. Statements of cash flow d. Payable controls including: <ul style="list-style-type: none"> i. Authorization of payment ii. Monthly reconciliation for cash or accrual base accounting e. Invoicing controls using currently published CPT and ICD-9 codes
CMS	<p>B-2: The supplier shall maintain accounts that link equipment and item(s) to the beneficiary and manage revenues and expenses on an ongoing basis, as they relate to beneficiary services, including the following:</p> <ul style="list-style-type: none"> • Reconciling charges to beneficiaries for equipment, supplies, and services with invoices, receipts, and deposits; • Planning to meet the needs of beneficiaries and maintain business operations by having an operating budget, as appropriate to the business's size and scope of services; and

Organization	Standard
	<ul style="list-style-type: none"> • Having a mechanism to track actual revenues and expenses.
AASM	<p>B-2. Standard – Patient Accounts</p> <p>The DME supplier must maintain accounts that link equipment and/or item(s) to the patient and manage revenues and expenses on an ongoing basis, as they relate to patient services, including the following:</p> <ol style="list-style-type: none"> a. Billing reconciliation for equipment, item(s) and/or service(s) with invoices, receipts and deposits through use of a patient database
CMS	<p>C-1: The supplier shall:</p> <ul style="list-style-type: none"> • Implement policies and issue job descriptions that specify personnel qualifications, training, certifications/licensures where applicable, experience, and continuing education requirements consistent with the specialized equipment, items, and services it provides to beneficiaries; • Provide copies of such policies, job descriptions and certifications/licensures (where applicable) upon request to accreditation organizations and government officials or their authorized agents; and • Verify and maintain copies of licenses, registrations, certifications, and competencies for personnel who provide beneficiary services.
AASM	<p>See Standard E-1 above (CMS standard A-1)</p> <p>See Standard D-1 above (CMS standard A-5)</p>

Organization	Standard
CMS	C-2: Technical personnel shall be competent to deliver and set-up equipment, item(s) and services and train beneficiaries and/or caregiver(s).
AASM	<p data-bbox="520 370 1037 402">E-2. Standard – Personnel Training</p> <p data-bbox="520 435 1898 540">Training must be provided annually for each staff person who performs coding and billing of services provided by the DME supplier. Training may be offered on several topics, including, but not limited to:</p> <ul style="list-style-type: none"> <li data-bbox="569 573 1499 605">a. Coding requirements related to the services coded and billed. <li data-bbox="569 643 1299 675">b. Claim development and submission processes. <li data-bbox="569 712 1167 745">c. Documentation of services rendered. <li data-bbox="569 782 1612 815">d. Billing standards and procedures, including review of rejected claims. <li data-bbox="569 852 1066 885">e. Reason(s) for claim rejection. <li data-bbox="569 922 1587 954">f. Legal sanctions for submitting deliberately false or reckless billings. <p data-bbox="520 992 1898 1133">Documentation of training must be maintained by the DME supplier and be available upon request to accreditation organizations and government officials or their authorized agents. Training materials, attendance sheets and course outlines must be maintained in a file, written log or electronic database and must be available for review.</p>
CMS	C-3: Professional personnel shall be licensed, certified, or registered and function within their scope of practice as required by the State standards under which the professional is licensed, certified or registered.

Organization	Standard
AASM	See Standard E-1 above (CMS standard A-1)
CMS	<p>D-1: When providing equipment, item(s), and service(s) to beneficiaries and/or caregiver(s), the supplier shall:</p> <ul style="list-style-type: none"> • Provide clear, written or pictorial, and oral instructions related to the use, maintenance, infection control practices for, and potential hazards of equipment and/or item(s) as appropriate; • Provide information regarding expected time frames for receipt of delivered items; • Verify that the equipment, item(s), and service(s) were received; • Document in the beneficiary’s record the make and model number or any other identifier of any non-custom equipment and/or item(s) provided; • Provide essential contact information for rental equipment and options for beneficiaries and/or caregiver(s) to rent or purchase equipment and/or item(s) when applicable; and • Provide information and telephone number(s) for customer service, regular business hours, after-hours access, equipment and/or item(s) repair, and emergency coverage.
AASM	<p>F-1. Standard – Instructions for Equipment</p> <p>The DME supplier must provide to the patient and/or caregiver(s) clear, written or pictorial, oral or electronic instructions related to the use, maintenance, infection control practices for, and potential hazards of equipment and/or item(s) as appropriate. It is expected that translations of all these materials will be available, and interpreter services provided, for non-English speaking patients, when applicable.</p>

Organization	Standard
CMS	D-2: If the supplier cannot or will not provide the equipment, item(s) or service(s) that are prescribed for a beneficiary, the supplier shall notify the prescribing physician (for purpose of these standards, we are using this term to include other practitioners who can prescribe DMEPOS under Medicare laws and regulations) or other health care member(s) promptly within 5 calendar days.
AASM	<p>L-1. Standard - Delivery and Set-up in a Timely Manner</p> <p>The DME supplier must provide the patient with all accredited respiratory and sleep-related equipment, item(s) and/or service(s) prescribed by an ordering healthcare professional in a timely manner.</p> <ul style="list-style-type: none"> a. The DME supplier must verify that all equipment, item(s) and/or service(s) delivered to the patient are consistent with the ordering healthcare professional's request. b. The DME supplier must notify the ordering healthcare professional when the patient has been set-up with the ordered equipment, item(s) and/or service(s). This must be documented in the patient's DME chart. c. The DME supplier must notify the ordering healthcare professional when it will take longer than ten business days to provide the patient with equipment, item(s) and/or service(s). d. If the DME supplier cannot or will not provide the equipment, item(s) and/or service(s) prescribed for the patient, the DME supplier must notify the ordering healthcare professional within five business days of the original order.
CMS	D-3: Within 5 calendar days of receiving a beneficiary's complaint, the supplier shall notify the beneficiary, using either oral, telephone, e-mail, fax, or letter format, that it has received the complaint and is investigating. Within 14 calendar days, the supplier shall provide written notification to the

Organization	Standard
	beneficiary of the results of its investigation. The supplier shall maintain documentation of all complaints received, copies of the investigations, and responses to beneficiaries.
AASM	<p>F-4. Standard –Patient Complaints</p> <ul style="list-style-type: none"> a. Within five calendar days of receiving a patient’s complaint, the DME supplier must notify the patient that it has received the complaint and has initiated an investigation of the incident. b. Within fourteen calendar days, the DME supplier must provide written notification to the patient of the result of the investigation and maintain such notification in the patient’s DME chart. c. The DME supplier must maintain documentation of all complaints received, findings from prior and current investigations and complaint resolutions. d. Based upon the results of each investigation, procedures must be developed to correct the problem identified in order to prevent future occurrences.
CMS	<p>E-1: The supplier shall implement a performance management plan that measures: outcomes of consumer services, billing practices, and adverse events. The data collection may target certain aspects of services that have a potential to cause harm or injury; occur frequently (creating a greater than expected number of adjustment(s), repair(s), or replacement(s)); or require significant instruction to assure safe use and benefit of the equipment and/or item(s).</p>
AASM	<p>H-1. Standard – Quality Assurance Program</p> <p>The DME supplier must implement a quality assurance program that measures outcomes of consumer services, billing practices and adverse events.</p> <p>The DME supplier must track all adverse events that are secondary to providing the patient with</p>

Organization	Standard
	<p>inadequate services or malfunctioning equipment (e.g. injuries, accidents, signs and symptoms of infection, hospitalization). The number of adverse events, event outcomes and resolutions must be maintained in a written log or electronic database.</p> <p>The DME supplier must measure each of the following quality assurance parameters:</p> <ul style="list-style-type: none"> a. Patient satisfaction and complaints about product(s) and/or service(s) rendered. b. Timeliness of response to patient’s question(s), problem(s) and/or concern(s). c. Patient access times to receive ordered equipment, item(s) and/or service(s). d. Frequency of billing and coding errors (e.g. number of insurance claims denied, errors resulting in claims denial). <p>These quality assurance indicators must be reported and reviewed at least once per quarter. For each quality assurance indicator, the DME supplier must specify:</p> <ul style="list-style-type: none"> a. A goal percentage. b. An action plan if the goal percentage is reached for four consecutive quarters (i.e. raise the goal percentage or create a different quality assurance indicator to measure the parameter). c. An action plan if the goal percentage is not consistently reached in four consecutive quarters. <p>The DME supplier’s manager, director or owner must sign and date the report. A copy of each signed report must be kept on file for the duration of the accreditation period.</p>
CMS	E-2: At a minimum, each supplier shall measure:

Organization	Standard
	<ul style="list-style-type: none"> • Beneficiary satisfaction with an complaints about product(s) and service(s); • Timeliness of response to beneficiary question(s), problem(s), and concern(s); • Impact of the supplier’s business practices on the adequacy of beneficiary access to equipment, item(s), service(s), and information; • Frequency of billing and coding errors (e.g. number of Medicare claims denied, errors the supplier finds in its own records after it has been notified of a claims denial); and • Adverse events to beneficiaries due to inadequate service(s) or malfunctioning equipment and/or item(s) (e.g., injuries, accidents, signs and symptoms of infection, hospitalizations). This may be identified through follow-up with the prescribing physician, other healthcare team member(s) or the beneficiary and/or caregiver(s).
AASM	See Standard H-1 above (CMS standard E-1)
CMS	E-3: The supplier shall seek input from employees, customers, and referral sources when assessing the quality of its operations and services.
AASM	See Standard H-1 above (CMS standard E-1)
CMS	<p>F-1: the supplier shall:</p> <ul style="list-style-type: none"> • Implement a program that promotes the safe use of equipment and item(s) and minimizes safety risks, infections, and hazards both for its staff and for beneficiaries. • Implement and maintain a plan for identifying, monitoring, and reporting (where indicated)

Organization	Standard
	<p>equipment and item(s) failure, repair, and preventive maintenance provided to beneficiaries;</p> <ul style="list-style-type: none"> • Investigate any incident, injury or infection in which DMEPOS may have contributed to the incident, injury or infection, when the supplier becomes aware. The investigation should be initiated within 24 hours after the supplier becomes aware of an incident, injury or infection resulting in a beneficiary’s hospitalization or death. For other occurrences, the supplier shall investigate within 72 hours after being made aware of the incident, injury or infection. The investigation includes all necessary information, pertinent conclusions about what happened, and whether changes in system(s) or processes are needed. The supplier should consider possible links between the equipment, item(s) and service(s) furnished and the adverse event; • Have a contingency plan that enables it to respond to emergencies and disasters or to have arrangements with alternative suppliers in the event that the supplier cannot service its own customers as the result of an emergency or disaster; and • Verify, authenticate, and document the following prior to distributing, dispensing, or delivering products to an end-user: <ul style="list-style-type: none"> a. The products are not adulterated, counterfeit, suspected of being counterfeit, and have not been obtained by fraud or deceit; b. The products are not misbranded and are appropriately labeled for their intended distribution channels.
AASM	<p>I-1 – Equipment Safety Program</p> <p>The DME supplier must have a policy that promotes the safe use of equipment and/or item(s) and minimizes safety risks, infections and hazards both for its staff dispensing equipment and/or item(s) and for its patients receiving the equipment and/or item(s) for use.</p>

Organization	Standard
	<p data-bbox="520 264 1314 297">I-2 – Equipment Failure, Repair and Maintenance Plan</p> <p data-bbox="520 329 1892 440">The DME supplier must have, in written or electronic format, a policy for identifying, monitoring and reporting (where indicated) failure, repair and preventive maintenance of equipment and/or item(s) provided to the patient.</p> <p data-bbox="520 467 1087 500">I-3 – Equipment Incident Investigation</p> <p data-bbox="520 532 1871 602">The DME supplier must investigate any incident, injury or infection in which the DME supplier may have contributed to the event.</p> <ul style="list-style-type: none"> <li data-bbox="573 634 1892 704">a. The investigation must be initiated as soon as possible and within twenty-four hours after the DME supplier becomes aware of any incident, injury or infection. <li data-bbox="573 737 1780 813">b. The investigation must include documentation of all necessary information, pertinent conclusions, and whether changes in the system(s) or processes are needed. <li data-bbox="573 846 1749 927">c. The DME supplier must provide subsequent follow-up to the incident to prevent its recurrence. <p data-bbox="520 971 831 1003">I-4 – Emergency Plan</p> <p data-bbox="520 1036 1875 1214">The DME supplier must have an emergency plan, in written or electronic format, which enables the DME supplier to respond to emergencies and disasters. The DME supplier must establish an arrangement with alternative DME supplier(s) in the event that the DME supplier cannot service its own customers as a result of an emergency or disaster. The emergency plan must delineate the following:</p> <ul style="list-style-type: none"> <li data-bbox="573 1247 1560 1279">a. Mechanisms and specific details for contacting emergency personnel. <li data-bbox="573 1312 1860 1344">b. DME supplier personnel to be contacted in an emergency and their specific responsibilities.

Organization	Standard
	<p>I-5 – Product Verification (MANDATORY)</p> <p>The DME supplier must verify, authenticate and document the following in the patient’s DME chart prior to distributing, dispensing or delivering equipment, item(s) and/or service(s) to the patient:</p> <ul style="list-style-type: none"> a. The products are not adulterated, counterfeit, suspected of being counterfeit and have not been obtained by fraud or deceit; and b. The products are not misbranded and are appropriately labeled for the intended distribution channels.
CMS	<p>G: The supplier shall maintain accurate, pertinent, accessible, confidential, and secure beneficiary records, in accordance with privacy and security standards of the Health Insurance Portability and Accountability Act (HIPAA) and other applicable State standards.</p>
AASM	<p>See Standard D-1 above (CMS standard C-1)</p> <p>J-1. Standard – Maintain Patient Records</p> <p>The DME supplier must maintain accurate, pertinent, accessible, confidential and secure patient records, in written or electronic format, in accordance with privacy and security standards of the Health Insurance Portability and Accountability Act (HIPAA) and other applicable state standards. These records must provide documentation of all patient interactions in the patient’s DME chart.</p>
	<p><i>Section II: Supplier Product-Specific Service Requirements</i></p>
CMS	<p>1: All DMEPOS must serve a medical purpose to be covered under the Medicare program and may require prescribing physician to collaborate and coordinate clinical services with other healthcare professionals (e.g., orthotists; prosthetists; occupational, physical, respiratory therapists; pedorthists;</p>

Organization	Standard
	etc.).
CMS	2: In addition to the supplier product-specific service requirements in this section, the DMEPOS supplier shall implement the requirements stated in Appendices A through C, as applicable to its business.
CMS	A-1: The supplier shall consult with the prescribing physician as needed to confirm the order and to recommend any necessary changes, refinements, or additional evaluations to the prescribed equipment, item(s), and/or service(s).
AASM	<p>K-1. Standard – Consultation with Ordering Healthcare Professional</p> <p>The DME supplier 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, item(s) and/or service(s). These interactions must be documented in the patient’s DME chart. Any changes in the patient’s medical equipment necessitate an updated prescription, which must be kept unaltered in the patient’s DME chart. Any certificates of medical necessity must also be maintained in the patient’s DME chart.</p>
CMS	<p>A-2: The supplier shall:</p> <ul style="list-style-type: none"> • Review the beneficiary’s record as appropriate and incorporate any pertinent information, related to beneficiary’s condition(s) which affect the provision of the DMEPOS and related services, or to the actual equipment, item(s) and service(s) provided, in collaboration with the prescribing physician; and • The DMEPOS prescriptions, any certificates of medical necessity (CMNs) and pertinent documentation from the beneficiary’s prescribing physician shall be kept unaltered in the

Organization	Standard
	beneficiary's record.
AASM	<p>K-2. Standard – Review Patient Records</p> <p>The DME supplier must review the patient's DME medical record, as warranted, and incorporate and maintain any pertinent information related to the patient's condition(s) which may affect the provision of the DME equipment, item(s) and/or service(s).</p>
CMS	<p>B-1: The supplier shall:</p> <ul style="list-style-type: none"> • Deliver and set-up, or coordinate set-up with another supplier, all equipment and item(s) in a timely manner as agreed upon by the beneficiary and/or caregiver, supplier and prescribing physician; • Provide all equipment and item(s) that are necessary to operate the equipment or item(s) and perform any further adjustments as applicable; • Provide, or arrange for, loaner equipment equivalent to the original equipment during any repair period except for orthotics and prosthetics; and • Assure that all equipment and item(s) delivered to the beneficiary is consistent with the prescribing physician's order and identified beneficiary needs, risks, and limitations of which the supplier is aware.
AASM	<p>See Standard L-1 above (CMS Standard D-2 Section I)</p> <p>F-2 – Receipt of Delivered Equipment</p> <p>The DME supplier must:</p>

Organization	Standard
	<p>a. Provide information to the patient regarding expected delivery time for receipt of equipment, item(s) and/or service(s).</p> <p>b. Verify and document in the patient's DME chart the patient's receipt of all equipment, item(s) and/or service(s).</p> <p>c. Provide their telephone number to each patient at the time of delivery of the prescribed equipment and/or item(s).</p> <p>F-3 – Options for Renting/Buying Equipment</p> <p>The DME supplier must provide options for patients and/or caregiver(s) to rent or purchase equipment and/or item(s), when applicable.</p>
CMS	<p>C-1: The supplier shall, as applicable:</p> <ul style="list-style-type: none"> • Provide or coordinate the provision of, appropriate information related to the set-up (including preparation of enteral/parenteral nutrients), features, routine use, troubleshooting, cleaning, infection control practices, and maintenance of all equipment and item(s) provided; • Provide relevant information and/or instructions about infection control issues related to the use of all equipment and item(s) provided; • For initial equipment and/or item(s) provided by mail order delivery: verify and document in the beneficiary's record that the beneficiary and/or caregiver(s) has received training and written instructions on the use of the equipment and item(s); and

Organization	Standard
	<ul style="list-style-type: none"> • Ensure that the beneficiary and/or caregiver(s) can use all equipment and item(s) provided safely and effectively in the settings of anticipated use.
AASM	<p>G-1. Standard – Verification of Training</p> <p>The DME supplier must, as applicable:</p> <ol style="list-style-type: none"> a. Provide, or coordinate the provision of, appropriate information related to the set-up, features, routine use, troubleshooting, cleaning, infection control practices and maintenance of all equipment and/or item(s) provided to the patient and/or caregiver(s). b. Coordinate, either in person or via remote electronic video communication system, the initial equipment set-up and provide adequate training and instructions for the use of equipment and/or item(s). Verification of set-up location (at the DME supplier location, in the patient's home or via a video communication system) must be documented in the patient's DME chart.
CMS	<p>C-2: Beneficiary and/or caregiver(s) training and instructions shall be commensurate with the risks, complexity, and manufacturer's instructions and/or specifications for the equipment and item(s). The supplier shall tailor training and instruction materials and approaches to the needs, abilities, learning preferences, and language of the beneficiary and/or caregiver(s).</p>
AASM	<p>F-1. Standard – Instructions for Equipment</p> <p>The DME supplier must provide to the patient and/or caregiver(s) clear, written or pictorial, oral or electronic instructions related to the use, maintenance, infection control practices for, and potential hazards of equipment and/or item(s) as appropriate. It is expected that translations of all these materials will be available, and interpreter services provided, for non-English speaking patients, when applicable.</p>

Organization	Standard
CMS	D: The supplier shall provide follow-up services to the beneficiary and/or caregiver(s), consistent with the type(s) of equipment, item(s) and service(s) provided, and recommendations from the prescribing physician or healthcare team member(s).
AASM	<p>M-1 – Continued Equipment Management</p> <p>The DME supplier must provide appropriate follow-up services to the patient and/or caregiver(s) consistent with the type(s) of equipment, item(s) and/or service(s) provided. Follow-up services must comply with the recommendations from the ordering healthcare professional.</p> <p>M-2 – Equipment Recalls</p> <p>The DME supplier must notify the patient of any manufacturer DME equipment and/or item(s) recalls. The DME supplier must remove the recalled equipment and/or item(s), and replace it with comparable approved loaner equipment and/or item(s).</p> <p>M-3 – Compliance with Positive Airway Pressure (PAP) Therapy</p> <p>The DME supplier must offer follow-up to patients who are prescribed positive airway pressure (PAP) therapy to ensure compliance within three months of initiating therapy. .</p> <p>Adequate compliance with therapy is defined as positive airway pressure (PAP) usage four hours or more per night on at least 70% of nights during a consecutive thirty-day period.</p> <p>Positive airway pressure (PAP) therapy compliance assessment must measure treatment use and clinical response. This must be documented by any of the following modalities:</p> <ul style="list-style-type: none"> a. Direct patient inquiry. b. Face-to-face clinical re-evaluation by the ordering healthcare professional.

Organization	Standard
	<ul style="list-style-type: none"> c. Questionnaires. d. Telephone inquiry to the ordering healthcare professional or the patient. e. An informatics system capable of obtaining positive airway pressure use. f. A metric of clinical response. <p>The patient's DME chart must contain documentation of the compliance assessment or written evidence of follow-up attempts made to obtain the positive airway pressure (PAP) therapy compliance assessment.</p>
	<i>Appendix A: Respiratory Equipment, Supplies, and Services</i>
CMS	1: Respiratory Services encompass the provision of home medical equipment and supplies (described below) that require technical and professional services.
CMS	2: The supplier shall provide respiratory services 24 hours a day, 7 days a week as needed by the beneficiary and/or caregiver(s).
AASM	<p>A-2. Standard – DME Supplier Availability</p> <p>The DME supplier must:</p> <ul style="list-style-type: none"> a. Maintain a publicly listed telephone number. Exclusive use of a pager, mobile phone, or answering machine will not serve to meet this standard. b. Maintain a designated contact person accessible to the patient and/or caregiver(s) via telephone. For suppliers providing life-sustaining equipment (e.g. oxygen concentrators, reservoirs, high-pressure cylinders, oxygen accessories and supplies, oxygen conserving devices, and invasive home ventilators), the contact person must be available twenty-four

Organization	Standard
	<p>hours a day, seven days a week.</p> <p>c. Maintain posted hours of operation.</p> <p>If the DME supplier chooses to distribute patient education materials and advertising, this information must display the DME supplier contact information.</p>
CMS	<p>3: Home medical equipment and supplies covered in this appendix include:</p> <ul style="list-style-type: none"> • Oxygen concentrators, reservoirs, high-pressure cylinders, oxygen accessories and supplies, and oxygen conserving devices; • Home Invasive Mechanical Ventilators; • Continuous Positive Airway Pressure (CPAP) Devices; • Respiratory Assist Devices (RAD); • Intermittent Positive Pressure Breathing (IPPB) Devices; and • Nebulizers.
CMS	<p>B-1: In addition to the requirements described in Section II: Supplier Product-Specific Service Requirements, the supplier shall comply with the current version of the <i>American Association for Respiratory Care Practice Guidelines</i> listed below:</p> <ul style="list-style-type: none"> • Oxygen Therapy in the Home or Extended Care Facility; • Long Term Invasive Mechanical Ventilation in the Home; and • IPPB

Organization	Standard
CMS	<p>C-1: In addition to the requirements described in Section II: Supplier Product-Specific Service Requirements, the supplier shall comply and provide training to the beneficiary and/or caregiver(s) consistent with the current version of the <i>American Association for Respiratory Care Practice Guidelines</i> listed below:</p> <ul style="list-style-type: none"> • Oxygen Therapy in the Home or Extended Care Facility; • Long Term Invasive Mechanical Ventilation in the Home; • IPPB; • Providing Patient and Caregiver Training; and • Suctioning of the Patient in the Home.

AASM Out of Center Sleep Testing Entity Accreditation

Since 1977, American Academy of Sleep Medicine (AASM) accreditation has been the gold standard by which the medical community and the public evaluate sleep medicine services. The evolution of portable diagnostic technology and recent policies related to out of center testing have shaped the diagnosis of patients with sleep apnea. In June 2010, the Board of Directors of the AASM approved the development of standards for accreditation of out of center sleep testing (OCST) entities and in February of 2011, the AASM began accrediting sleep facilities for Out of Center Sleep Testing for Adult Patients.

OCST entities offer sleep testing out of the context of the sleep center. Earning accreditation for OCST from the leader in sleep medicine enables sleep medicine entities to offer broader options to patients and for facilities to gain recognition as OCST entities who meet the highest standards for quality care. AASM OCST Accreditation is granted to sleep service entities that illustrate compliance with all of the AASM Standards for Out of Center Sleep Testing in Adult Patients. This process includes the completion of an accreditation application and supporting documentation, a site visit, approval by the AASM Board of Directors and reaccreditation.

OCST in Adult Patients Standards for Accreditation describe the required structural, professional and human resources, clinical and technical standards, and emergency and quality assurance methods required for accreditation by the AASM. The clinical evaluation of patients accepted for sleep testing conducted in the sleep service entity and OCST must comply with the current versions of AASM practice parameters, AASM clinical guidelines and AASM best practice guidelines pertaining to the diagnosis of obstructive sleep apnea syndrome in adults.

Following the OCST in Adult Patients Standards for Accreditation are four articles describing acceptable screening questionnaires that can be used by sleep specialists at test locations of the integrated model to determine the high pre-test probability of a patient. High pre-test probability is considered, along with a patient's co-morbid conditions, to determine the appropriateness of out of center sleep testing for that given patient. The articles follow the accreditation standards describe the following screening tools:

- OSA-50
- Berlin
- STOP Questionnaire
- MAP Index

Integrated model test locations will be required to use one of the above mentioned screening tools consistently when determining high pre-test probability. It is at the discretion of the sleep specialist to determine which questionnaire best fits the needs of the test location.

AASM Out of Center Sleep Testing in Adult Patients Accreditation Standards

A. General Standards

Standard

A-1 – Facility License (MANDATORY)

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

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

A-2 – Medical Code of Ethics (MANDATORY)

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

B. Personnel

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

Standard

B-1 – Medical Director (MANDATORY)

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

B-2 – Medical Director Qualifications (MANDATORY)

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

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

the American Board of Medical Specialties or a member board of the American Osteopathic Association.

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

B-3 – Medical Director Responsibilities (MANDATORY)

The medical director:

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

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

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

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

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

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

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

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

To meet this requirement, the individual must provide, in the application packet, a letter of acceptance to sit for the examination by the ABMS or AOA approved board.

Upon completion of the examination, the individual must provide a copy of the official notification from the ABMS or AOA board indicating final status.

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

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

All interpreting physicians must participate in at least 10 credits per year averaged over three years of *AMA PRA Category 1 Credit*[™] in sleep medicine. Compliance with CME requirements must be documented.

B-8 – Technical Personnel

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

B-9 – Scoring Personnel

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

B-10 – Technical Personnel Continuing Education

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

B-11 – OCST Technical Personnel Training

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

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

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

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

C. Patient Policies

Standard

C-1 – Patient Acceptance

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

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

C-2 – Practice Parameter Requirements

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

D. Facility and Equipment

Standard

D-1 – Phone Access

The program must have 24 hour telephone access to the personnel defined in standard B-10.

D-2 – Stationery

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

D-3 – OCST Equipment

The OCST equipment must meet the minimum definitions described in at least one of the CPT codes 95800, 95801 or 95806, or one of the HCPCS codes G0398, G0399 or G0400.

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

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

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

G0398 Home sleep study test (HST) with type II portable monitor, unattended; minimum of 7 channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory effort and oxygen saturation

G0399 Home sleep test (HST) with type III portable monitor, unattended; minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation

G0400 Home sleep test (HST) with type IV portable monitor; minimum of 3 channels

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

E. Policies and Procedures

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

Standard

E-1 – Policy and Procedures Manual

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

E-2 – Protocols

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

E-3 – Equipment Maintenance

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

E-4 – Equipment Maintenance Continued

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

F. Data Acquisition, Scoring and Reporting

Standard

F-1 – OCST Reports

OCST reports must include at minimum:

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

F-2 – OCST Recording Equipment

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

F-3 – RDI Scoring Equivalency

Sleep service entities performing OCST must use equipment that provides a measure of respiratory events per unit time (RDI). The Medical Director must determine that the device provides a measure that is equivalent to an apnea-hypopnea index (AHI) based on full polysomnography.

F-4 – Computer-assisted Scoring

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

F-5 – Review of Raw Data

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

G. Patient Evaluation and Care

Standard

G-1 – Patient Management (MANDATORY)

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

Options for treatment of OSA found on OCST may include:

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

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

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

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

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

G-3 - Documenting Patient Evaluation and Management

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

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

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

G-5 – Follow-up After PAP Titration or Therapy During OCST (MANDATORY)

Patients being treated with fixed CPAP on the basis of APAP titration or being treated with APAP must have clinical follow up within 30 days of initiation of PAP to determine treatment effectiveness and safety. This is especially important during this period of PAP

use. A reevaluation must be scheduled and, if necessary, a standard attended PAP titration must be performed if symptoms are not resolved or if the APAP treatment otherwise appears to lack effectiveness.

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

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

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

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

- a. direct patient inquiry;
- b. office encounter with sleep service entity technical or medical staff;
- c. office encounter with the referring physician;
- d. questionnaires;
- e. telephone inquiry to the referring physician or the patient; or
- f. an informatic system capable of obtaining positive airway pressure use and a metric of clinical response.

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

H. Patient Records

Standard

H-1 – Medical Records

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

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

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

H-2 – Documentation

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

I. Emergency Procedures**Standard****I-1 – Emergency Plan**

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

J. Quality Assurance**Standard****J-1 – Quality Assurance Program**

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

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

J-2 – Quality Assurance Reporting

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

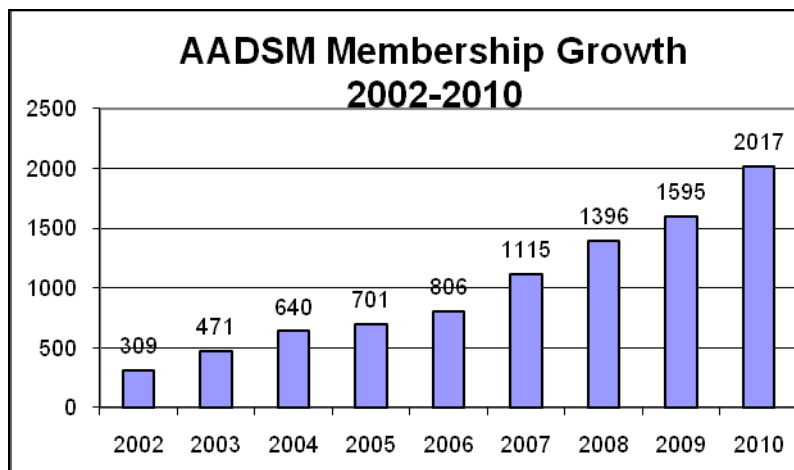
J-3 – Quality Improvement

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

American Academy of Dental Sleep Medicine Facility Accreditation and Dental Sleep Medicine Certification

The American Academy of Dental Sleep Medicine (AADSM) is the premier professional organization in dental sleep medicine. Since its founding in 1991, the AADSM has established and maintained appropriate treatment protocols for the use of oral appliance therapy and upper-airway surgery to treat sleep-related breathing disorders. Patients with mild to moderate OSA who do not respond to, are not compliant with, or who fail treatment attempts with CPAP are ideal candidates for Oral Appliance Therapy (OAT) provided by a licensed dentist. Oral Appliance Therapy involves the selection, fitting, and use of a custom fabricated oral appliance worn during sleep that maintains an opened, unobstructed airway in the throat. With over 2000 members, the AADSM is committed to safeguarding patient care and developing the role of dental sleep medicine professionals within the sleep medicine team. The chart below demonstrates the significant growth in membership since 2002. At the conclusion of the 2010 membership year, the AADSM retained a roster of 2017 member dentists, and has continued its strong growth of 552.8% since contracting management services with the AASM in 2002.

Figure A.3 – AADSM Membership Growth 2002-2010.



Delivery of Oral Appliance Therapy

In January 2011, the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) published new local coverage determinations (LCDs) addressing the delivery of oral appliance therapy.⁷ The LCDs emphasized the role of the dentist in the delivery of oral appliance therapy by clarifying that coverage for oral appliance therapy for the treatment of OSA would be provided if “the device is provided and billed for by a licensed dentist (DDS or DMD).” The LCDs also emphasized the role of the board certified sleep

⁷ National Government Services, Inc. Local Coverage Determination (LCD) for Oral Appliances for Obstructive SLEEP Apnea (L28601). Revised 01/03/2011. Available at: <https://www.cms.gov/medicare-coverage-database/>. Accessed April 20, 2011.

specialist and/or staff physicians at accredited sleep centers in the interpretation of the required sleep test used to diagnose OSA. The AADSM and AASM consider the publication of the new LCDs as a step forward in encouraging a partnership between the sleep specialist and the dentists specializing in dental sleep medicine.

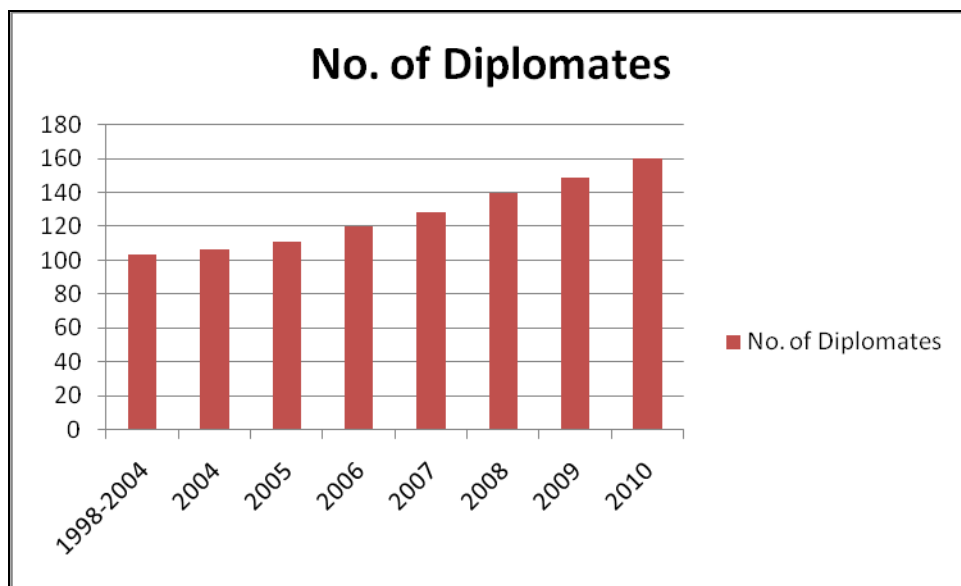
Dental Sleep Medicine Facility Accreditation

In June 2010, the AADSM Board of Directors approved moving forward with the development of an accreditation program for dental sleep medicine facilities which would set standards for the practice of dental sleep medicine. The Board appointed a task force charged with developing standards for dental sleep medicine facility accreditation. These standards were developed to promote excellence in the knowledge, experience and ability of dental sleep medicine facilities to manage ongoing care for patients with sleep-related breathing disorders. With the standards in place, a second task force developed the policies and business plan for the program. On March 1, 2011 the AADSM introduced the Dental Sleep Medicine (DSM) Facility Accreditation program and began accepting applications for accreditation. DSM Facility Accreditation is a voluntary process created to evaluate and recognize competency and delivery of optimal care to dental sleep medicine patients. Facilities that achieve accreditation illustrate to their patients, medical professionals and reimbursement decision-makers that they meet the high standards required to provide quality patient care. Additionally, standardization of the treatment for obstructive sleep apnea with oral appliances through the accreditation program will be an important step in the legitimization of the field. The proposed integrated delivery model requires a partnership with a dentist specializing in dental sleep medicine. This individual will be required to be the dental director of an AADSM accredited dental sleep medicine facility by 2014.

Dental Sleep Medicine Certification

Under the management of the AADSM, the American Board of Dental Sleep Medicine (ABDSM) is a self-designated independent certifying board for licensed dentists who treat sleep-related breathing disorders. The purpose of the ABDSM is to help set standards for the scope of dental sleep medicine and to assure professional dental and medical colleagues, patients, and the public of an acceptable level of education, training, and experience by those who become Diplomates of the ABDSM by examination. To date, there are 160 Diplomates of the ABDSM. Prior to the establishment of the ABDSM in 2004, and beginning in 1991, the certification exam was administered by the AADSM. The 103 Diplomates who were certified between 1991 and 2004 were grandfathered into the ABDSM in 2004. Since the transition of the exam to the ABDSM, an additional 57 dentists have become Diplomates of the ABDSM. The proposed integrated delivery model requires a partnership with a dentist specializing in dental sleep medicine. This individual will be required to be certified by the ABDSM by 2014.

Figure A.4 – Growth of Diplomates 1998-2010.



The *Standards for Accreditation of DSM Facilities* require dental directors to be either currently certified by the ABDSM or certified within five exam cycles at the time their application for accreditation is submitted. As a result, the number of Diplomates is expected to grow increasingly as DSM facilities pursue accreditation status through the AADSM.

AADSM Dental Sleep Medicine Facility Accreditation Standards

General Standards

Standard

A-1 – Address (MANDATORY)

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

A-2 – Facility License (MANDATORY)

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

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

A-3 – ADA Code of Ethics (MANDATORY)

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

B. Personnel

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

Standard

B-1 – Dental Director (MANDATORY)

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

B-2 – Dental Director Qualifications (MANDATORY)

The dental director must be either

1. A qualified dentist who is a Diplomate of the American Board of Dental Sleep Medicine (ABDSM)
OR
2. A qualified dentist who:
 - a. has completed a required 30 credits of continuing education within the past three years. A minimum of 20 credits must be in dental sleep medicine. The additional credits must be sleep medicine related, and
 - b. has delivered a minimum of twelve appliances within the previous 12 months.
 - c. To retain the accreditation, the dental director must pass the ABDSM examination in dental sleep medicine:
 1. within 5 examination cycles, or
 2. after January 1, 2016, the examination in dental sleep medicine must be passed within 2 examination cycles.
 The dental director must provide a copy of the official notification from the ABDSM attesting to successful completion of all requirements including but not limited to the board examination.

B-3 – Dental Director Responsibilities (MANDATORY)

The dental director:

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

B-4 – Dental Director Continuing Education (MANDATORY)

The dental director must participate in at least 10 credits per year averaged over three years of continuing education. A minimum of 5 credits per year must be ADA CERP recognized or AGD PACE approved credit in dental sleep medicine. The additional five credits may be sleep medicine related AMA PRA Category 1 CME. Compliance with CME requirements is required for all dental directors, regardless of whether they are certified by the ABDSM. Compliance with this standard must be documented.

Standards B-5 through B-7 address requirements for DSM clinical auxiliaries, which may include dental assistants, dental hygienists, nurses, and other auxiliary personnel as allowed under state law. Each must be licensed where required by state law. These standards do not differentiate between the various job descriptions

or titles that dental sleep medicine facilities may use for the employment of various clinical auxiliaries. CPR certification is required for all clinical staff members, regardless of their duties or titles. These requirements are in addition to any state or local requirements.

B-5 – Dental Sleep Medicine Clinical Auxiliaries

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

B-6 – Dental Sleep Medicine Clinical Auxiliaries Continuing Education

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

B-7 – Dental Sleep Medicine Clinical Auxiliaries Additional Certification

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

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

Standard

B-8 – Coding and Billing Personnel Training

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

- a. Coding requirements related to the services provided.
- b. Claim development and submission processes.
- c. Documentation of services rendered.
- d. Billing standards and procedures, including review of rejected claims.
- e. Reason(s) for claim rejection.
- f. Legal sanctions for submitting deliberately false or reckless billings.

Documentation of training must be maintained for each coding and billing staff member. Training materials, attendance sheets and course outlines must be maintained for training offered at the facility. Certificates or letters of completion should be maintained for courses attended outside the DSM facility.

C. Patient Acceptance and Records Policies

Standard

C-1 – Patient Acceptance

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

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

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

C-2 – Patient Records Maintenance

The DSM facility must maintain accurate, pertinent, accessible, confidential and secure patient records for all patients evaluated and/or treated there. Records must be maintained in written or electronic format, in accordance with privacy and security standards of the Health Insurance Portability and Accountability Act (HIPAA) and other applicable state standards. These records must provide documentation of all patient interactions including initial evaluation, diagnosis, treatment, testing, follow-up and miscellaneous encounters including phone calls and letters related to treatment.

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

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

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

C-4 – Oral Appliance Therapy

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

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

C-5 – Combination Oral Appliance – Positive Airway Pressure

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

management of the PAP component as well as appropriate documentation of the oral appliance therapy.

D. Facility

Standard

D-1 – Use of Space

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

D-2 – Dental Sleep Medicine Facility Availability

The DSM facility must:

- a. Maintain a publicly listed telephone number. Exclusive use of a pager, mobile phone, or answering machine will not serve to meet this standard.
- b. Maintain posted hours of operation.

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

D-3 – Treatment and Consultation Rooms – Physical Characteristics

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

D-4 - Satellite Clinical Locations

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

E. Oral Appliances

Standard

E-1 – Appropriate Oral Appliances (MANDATORY)

The DSM facility must provide appropriate, FDA approved, quality oral appliances (orthotics) to patients. Appliances are utilized to reposition the tongue, mandible and/or

other pharyngeal tissues in an effort to create and maintain a patient's airway during sleep. For this accreditation, such appliances may include any of the devices listed below:

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

E-2 – Materials for Oral Appliances

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

F. Policies and Procedures

Standard

F-1 – Policy and Procedures Manual

The DSM facility must implement and maintain a policy and procedures manual that is easily accessible to all applicable staff members, in written or electronic format. The manual must:

1. Contain all policies, procedures and protocols specific to the DSM facility.
2. Include names and job descriptions for all DSM facility personnel.
3. Delineate education, training, responsibilities, certifications and licensures.
4. Document continuing education requirements related to the specialized equipment it provides to patients.
5. Include evidence of annual review of the manual, with periodic updates by the dental director as warranted.
6. Support compliance with all State and Federal regulations, as it pertains to the business, including but not limited to, Stark Laws and the Health Insurance Portability and Accountability Act (HIPAA), and all Medicare requirements.

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

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

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

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

The DSM facility must implement policies to prevent and control fraud, waste and abuse by using standards of conduct which ensure the organization's compliance with applicable Federal, State, local laws and regulations. These standards must be available for review in either written or electronic format.

F-4 – HCPCS/ICD-9 Codes Update

The dental sleep medicine facility must have guidelines in place to ensure that the most current HCPCS/ICD-9 codes are utilized in billing the services provided.

G. Oral Appliance Safety Procedures**Standard****G-1 – Oral Appliance Safety Program**

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

G-2 – Adverse Event Investigation

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

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

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

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

H. Consumer Services**Standard****H-1 – Oversight (MANDATORY)**

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

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

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

H-2 – Patient Rights

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

H-3 – Plan of Care/Informed Consent

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

H-4 – Receipt of Oral Appliances

The DSM facility must:

- a. Provide information to the patient regarding expected delivery time for receipt of the prescribed oral appliance.
- b. Document that the appliance was personally checked by the treating dentist for structural integrity.
- c. Provide a written warranty for the appliance that delineates what support is included in the appliance fee and what services are likely to be needed at additional cost.
- d. Verify and document in the patient's chart the patient's receipt of the appliance.
- e. Provide daytime and after-hours contact information to each patient at the time of delivery of the prescribed appliance.

H-5 – Verification of Training

The DSM facility must, as applicable:

- a. Provide, or coordinate the provision of, appropriate information related to the set-up, features, routine use, troubleshooting and maintenance of the appliance provided to the patient.
- b. Supply to the patient and/or caregiver(s) clear, written or pictorial, oral or electronic instructions related to the use, maintenance, infection control practices for, and potential hazards of, the oral appliance as appropriate.

H-6– Patient Complaints

- a. Within five calendar days of receiving a patient's written complaint, the DSM facility must notify the patient that it has received the complaint and has initiated an investigation of the incident.
- b. Within fourteen calendar days, the DSM facility must provide written notification to the patient of the result of the investigation and maintain such notification in the patient's chart.
- c. The DSM facility must maintain documentation of all complaints received, findings from prior and current investigations and complaint resolutions.

- d. Based upon the results of each investigation, there must be evidence that procedures have been developed to correct the problem identified in order to prevent future occurrences.

I. Emergency Procedures

Standard

I-1 – Emergency Plan

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

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

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

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

I-2 – Emergency Equipment

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

J. Follow-up

J-1 – Follow-up Care

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

J-2 – Post Delivery Follow-up

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

J-3 – Short-term Follow-up

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

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

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

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

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

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

K. Claims Submission Audit

Standard

K-1 – Patient Records Audit

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

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

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

K-2 – Billing Discrepancies Procedure

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

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

L. Quality Assurance

Standard

L-1 – Quality Assurance Program and Reporting

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

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

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

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

Standard

M-1 – Disclosure (MANDATORY)

The DSM facility must provide current information to the accrediting body for all individuals and joint venture companies holding an ownership or controlling interest (5% or more). The DSM facility must report to the accrediting body any agent relationship and managing employee interest in the DSM facility, and subcontractor relationships with another DSM facility.

Appendix B: Measuring Outcomes

- Outcomes Used to Monitor the Success of the Integrated Delivery Model
- Positive Airway Pressure Therapy – Follow-up and Outcomes
- Oral Appliance Therapy – Follow-up and Outcomes
- Upper Airway Surgery – Follow-up and Outcomes

Outcomes Used to Monitor the Success of the Integrated Delivery Model

A recent draft assessment by the Agency for Healthcare Research and Quality⁸ concluded that severe obstructive sleep apnea (OSA) is a predictor of all-cause mortality with a hazard ratio of 1.5 to 3.0. Studies of the long-term clinical outcomes of therapy have not conclusively demonstrated decreased mortality due to methodological constraints, but observational cohort studies have reported evidence of an improvement in mortality with CPAP treatment.⁹ Patients who receive treatment from the integrated model test locations' board certified sleep physician (BCSP) or are referred for alternative treatment by BCSP will be tracked and assessed for outcomes improvement. In addition to tracking a number of co-morbid conditions and quality of life indicators for all patients diagnosed with OSA, we propose to assess positive airway pressure (PAP) therapy adherence, for those prescribed PAP, using Physician Consortium for Performance Improvement (PCPI) approved methodology. Subjective adherence to oral appliance therapy (OAT) will be tracked for patients who are prescribed OAT.

Positive Airway Pressure Adherence: In 2008 the Physician Consortium for Performance Improvement (PCPI) approved the Obstructive Sleep Apnea Physician Performance Measurement Set “designed for any clinician caring for patients aged 18 years and older diagnosed with obstructive sleep apnea.”¹⁰ The fourth measure in the PCPI measures set, assessment of adherence to PAP therapy, will be used by test locations to calculate their facility-wide PAP adherence rate.

Body Mass Index, Blood Pressure and Co-Morbid Conditions: Test locations will be required to track BMI, blood pressure, and self-reported co-morbid conditions for all patients diagnosed with OSA. Standardized language will be used for patient interviews to ensure consistent reporting of co-morbid conditions across the test locations. Severity of apnea has been associated with systemic hypertension, and there are several studies that suggest improvement of blood pressure with CPAP therapy.^{11,12} Whether these reductions in blood pressure translate to reduced risk of cardiovascular and cerebrovascular disease has yet to be demonstrated. Blood pressure is routinely measured during physician office visits and may provide a ready indicator of treatment efficacy, though an absence of change in blood pressure is not an indicator of treatment failure.

⁸ Methods Guide for Effectiveness and Comparative Effectiveness Reviews. AHRQ Publication No. 10(11)-EHC063-EF. Rockville, MD: Agency for Healthcare Research and Quality. March 2011. Chapters available at: www.effectivehealthcare.ahrq.gov.

⁹ Young T, Finn L, Peppard PE, Szklo-Coxe M, Austin D, Nieto FJ, et al. Sleep disordered breathing and mortality: eighteen-year follow-up of the Wisconsin sleep cohort. *Sleep*. 2008 Aug 1;31(8):1071-8..

¹⁰ Strollo P, Metersky M, Berry R, Becker P, Collop N, Davidson T, et al. American Academy of Sleep Medicine (AASM)/Physician Consortium for Performance Improvement (PCPI)/National Committee for Quality Assurance: Obstructive Sleep Apnea Physician Performance Measurement Set. Available at: <http://www.ama-assn.org/ama1/pub/upload/mm/370/obst-sleep-apnea.pdf>. Accessed April 20, 2011.

¹¹ Shamsuzzaman AS, Gersh BJ, Somers VK. Obstructive sleep apnea: implications for cardiac and vascular disease. *JAMA*. 2003 Oct 8;290(14):1906-14.

¹² Barbe F, Duran-Cantolla J, Capote F, de la Pena M, Chiner E, Masa JF, et al. Long-term effect of continuous positive airway pressure in hypertensive patients with sleep apnea. *Am J Respir Crit Care Med*. 2010 Apr 1;181(7):718-26.

Subjective measures of sleepiness and sleep quality: A dose-response relationship between number of hours of continuous positive airway pressure (CPAP) use and improvement in subjective measures has been documented.¹³ A subjective measurement of sleepiness, the Epworth Sleepiness Scale (ESS) will be measured for all patients diagnosed with OSA. An Epworth score of 11 or greater signifies excessive daytime sleepiness. Additional quality of life measures will be monitored for patients with OSA, including the 10 item Functional Outcomes of Sleep Quality (FOSQ-10) and the 12 item Short Form Health Survey (SF-12). The ESS, FOSQ-10 and SF-12 are validated, well-documented, and are easily obtained in the clinic environment. Copies of the articles outlining the use of these measures are included in this packet following this section.

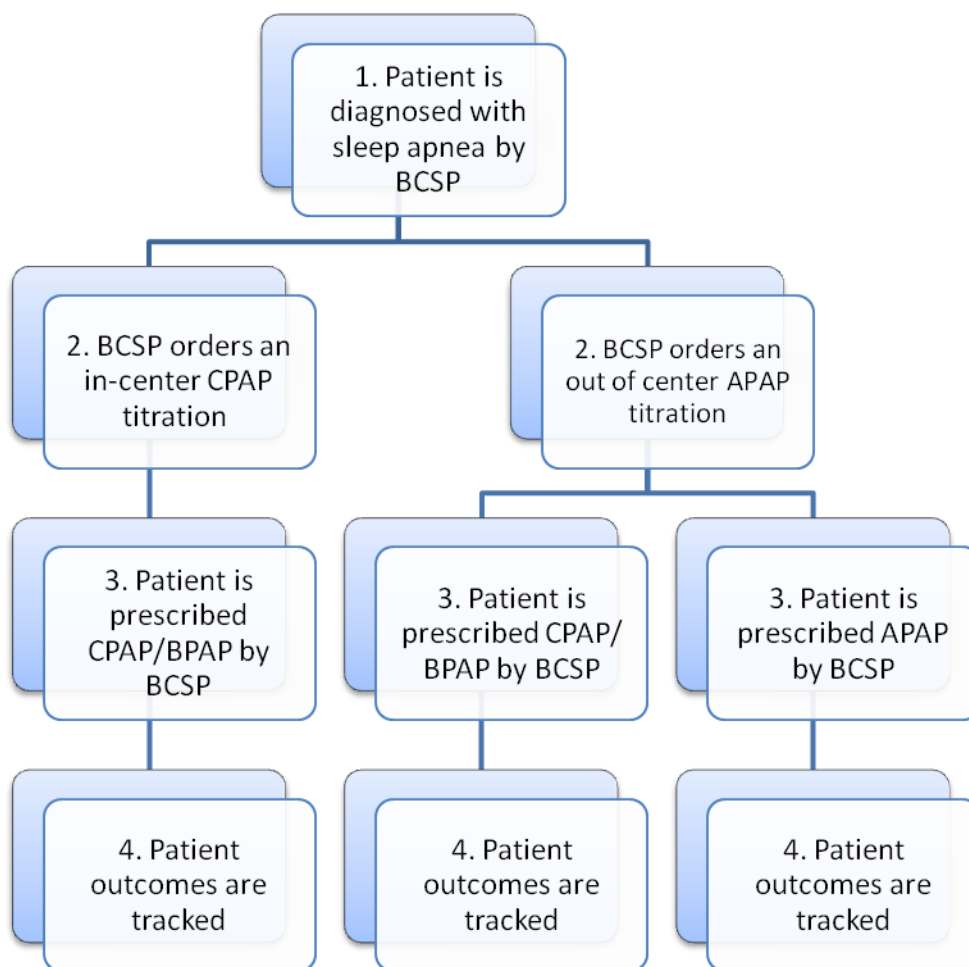
¹³ Weaver TE, Maislin G, Dinges DF, Bloxham T, George CF, Greenberg H, et al. Relationship between hours of CPAP use and achieving normal levels of sleepiness and daily functioning. *Sleep*. 2007 Jun 1;30(6):711-9.

Positive Airway Pressure Therapy – Follow-up and Outcomes

An assessment, intervention and outcomes tracking mechanism must be implemented by all test locations participating in the integrated delivery model accreditation. This mechanism assumes that the patient has already been tested and diagnosed with OSA by the test location. Testing for OSA will be performed according to the requirements of the center and out of center accreditation standards described in Appendix A.

The following is a flow chart describing the treatment pathway for a patient who is prescribed PAP therapy. Outcomes for patients prescribed OAT or referred for upper airway surgery will be tracked using mechanisms addressed later in this section.

Figure B.1



The following is a detailed description of the tracking mechanism all test locations will use for patients that are prescribed PAP therapy. The first three sections describe the information that will be collected over the course of the initial encounters with the patient. This information may be collected at any of the visits with the patient prior to initiation of

PAP therapy. The sections that follow describe the information collected at subsequent encounters after PAP therapy has been initiated.

Initial Encounters - Testing and Diagnosis: All patients diagnosed with OSA (ICD-9 codes 327.23 or 780.53) will be tracked by the test location. Patients who are not diagnosed with OSA will not be tracked in this mechanism.

Figure B.2 – This information will be obtained and tracked as the patient receives testing and a diagnosis.

Pt. ID	CPT Code(s) of Testing	Date of Testing	ICD-9 Dx Code	Date of Dx

Initial Encounters - Baseline Measurements of Outcomes: Baseline results of all outcomes measures will be tracked prior to initiation of PAP therapy including: a baseline Epworth Sleepiness Scale (ESS) score, baseline Functional Outcomes of Sleep Quality (FOSQ-10) score, and a Short Form (SF)-12 Health Survey score. The apnea-hypopnea index (AHI) for all patients diagnosed with OSA will be tracked. Additionally, for all patients started on PAP therapy, the initial PAP pressure will be tracked.

Figure B.3 – This information will be obtained as baseline measurements of outcomes.

Pt. ID	Baseline ESS	Baseline FOSQ-10	Baseline SF-12	AHI at initial testing	Initial PAP Pressure

Initial Encounters – Baseline Measurements of BMI, BP and Co-Morbidities: Baseline measurements of co-morbid conditions will be monitored at the patients' initial encounters. The patient's body mass index (BMI) and blood pressure (BP) will be recorded. Additionally, patients will be asked to self-report on four co-morbid conditions. Patients will attest to being diagnosed with diabetes, having had a stroke, having had a myocardial infarction, and having had heart failure.

Figure B.4 – This information will be obtained as baseline measurements of co-morbid conditions.

Pt. ID	Baseline BMI	Baseline BP	Baseline attestation of diabetes	Baseline attestation of stroke	Baseline attestation of myocardial infarction	Baseline attestation of heart failure

Subsequent Encounters (3 months, 6 months, 1 year, 2 years) Following Initiation of PAP Therapy: All patients prescribed PAP therapy by the BCSP will be seen three months, six months, one year and two years after initiation of PAP therapy to address questions, determine the patient's adherence to therapy and monitor improvement of outcomes. Patients may be seen more often after initial set-up for pressure adjustments and to address questions. For the purposes of this proposal, outcomes will not be measured at visits outside of the encounters described above. PCPI measure #4, adherence to positive airway pressure, will be used to track adherence at each subsequent encounter.

Outcomes, including sleepiness, sleep quality, BP, BMI and co-morbid conditions will be measured at each subsequent encounter.

Subsequent Encounters – Monitoring of PCPI Measure #4: Assessment of Adherence to Positive Airway Pressure: Using the PCPI measure set instructions, the test location will document measurement of patient adherence to PAP therapy. Adherence will be defined as use for four hours or greater per night. Centers will use PCPI methodology to calculate an overall percentage of adherence using appropriate exclusion criteria.

Figure B.5 – Flow Chart – to be used by test locations to determine if PCPI measure #4 is met, unmet or if valid exclusion criteria are met.

1. Patient chart documents assessment of adherence to positive airway pressure (PAP) therapy	<input type="radio"/> YES <input type="radio"/> NO
2. Patient has a valid patient reason for not having assessment (e.g., patient failed to bring in data card)	<input type="radio"/> YES <input type="radio"/> NO
3. Patient has a valid system reason for not using PAP (e.g., PAP not yet delivered, adherence not measured by machine)	<input type="radio"/> YES <input type="radio"/> NO
4. Patient adheres to PAP therapy 4 hours per night.	<input type="radio"/> YES <input type="radio"/> NO

Subsequent Encounters - PAP Adherence, Sleepiness and Sleep Quality Measures

Figure B.6 – This information will be obtained and tracked at each subsequent encounter 3 months, 6 months, 1 year and 2 years following initiation of PAP therapy.

Pt. ID	Date	CPT Code	Measure #4 Met, Unmet or Excluded	% PAP Adher. > 4 hrs./night	Total Hours PAP Use/ Night	ESS	FOSQ-10	SF-12

Subsequent Encounters - Body Mass Index, Blood Pressure and Co-Morbid

Conditions: At subsequent encounters, the test locations will track each patient's BMI and blood pressure. Additionally, patients will be asked to attest to the current condition of their co-morbidities. New diagnoses and incident development will be reported and tracked.

Figure B.7 – This information will be obtained and tracked at each subsequent encounter 3 months, 6 months, 1 year and 2 years following initiation of PAP therapy.

Pt. ID	Subsequent BMI	Subsequent BP	Subsequent attestation of diabetes	Subsequent attestation of stroke	Subsequent attestation of myocardial infarction	Subsequent attestation of heart failure

Facility Adherence: Using the reporting calculation outlined in PCPI measure #4, each test location will be able to determine a rate of PAP adherence for the duration of the integrated delivery model project. This rate of PAP adherence can be compared to the sleep field's benchmark adherence to determine the success of the integrated delivery model in improving adherence. Patients who: 1) discontinue treatment; 2) discontinue communication with the facility; 3) are referred for surgery; 4) are referred for oral appliance therapy; or 5) who relocate will not be included in the calculation of facility adherence. Widely divergent statistics for adherence have been reported, varying from 17 to 79%,¹⁴ with approximately 50% adherence reported in most studies using accepted methods of treatment delivery, education and follow-up.

Patients Lost During Follow-Up: Test locations are required to follow the above described process for tracking patients who are prescribed PAP therapy, including tracking PAP adherence and overall health outcomes for a two year period. However, in some cases patients may relocate, discontinue treatment, discontinue communication with the test location or may be referred for a different type of treatment.

Test locations must appropriately document patients lost during the two year follow-up period. If a patient does not receive follow-up for the full two-year period, the test location must categorize the reason for the lack of data. The reason can fall into one of the following categories:

- Relocation – patient relocates and continues follow-up and treatment at a different sleep center;
- Discontinued Treatment – patient discontinues treatment with PAP; and

¹⁴ Terri E. Weaver and Ronald R. Grunstein. Adherence to Continuous Positive Airway Pressure Therapy: the Challenge to Effective Treatment. Proc Am Thorac Soc. 2008 February 15; 5(2): 173-178.

- Discontinued Communication – patient does not respond to requests for follow-up and does not come into the test location for follow-up appointments with the sleep physician, location staff, or DME staff.

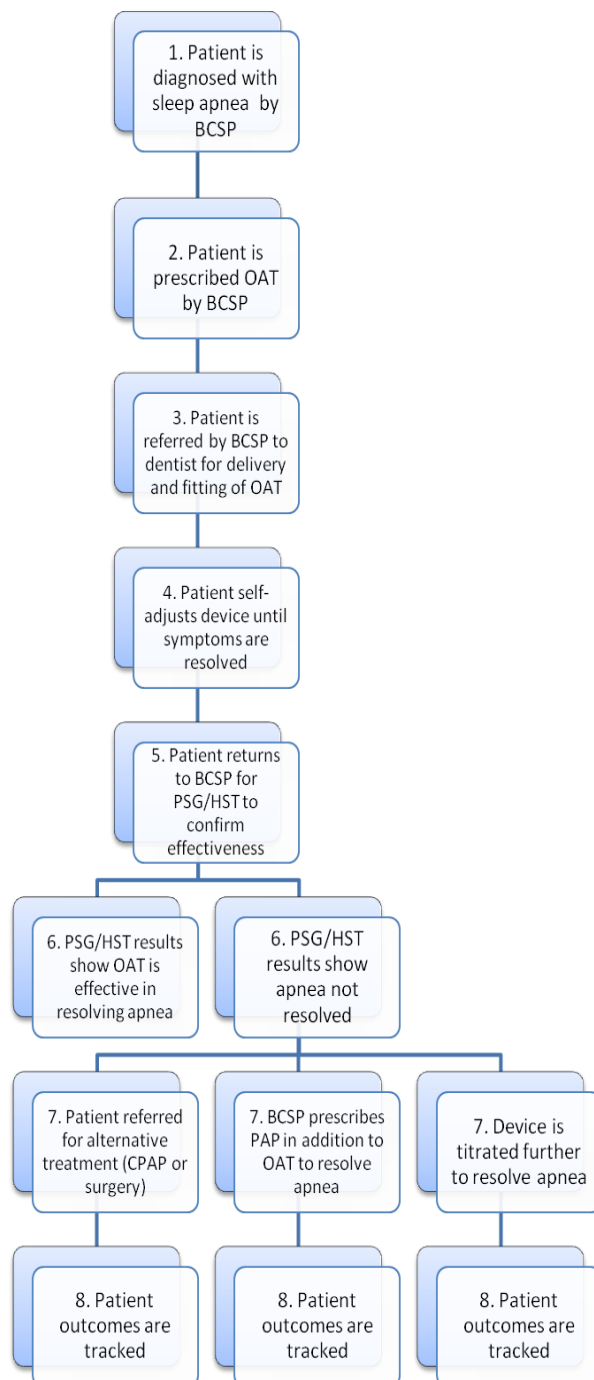
The number of patients that fall into the above categories will be tracked by each test location.

Patients who are referred for oral appliance therapy or surgery and do not also need PAP therapy will be tracked using a different mechanism described further in this section.

Oral Appliance Therapy – Follow-up and Outcomes

Patients who are diagnosed with OSA may be prescribed OAT by the test location sleep specialist and may be referred by the test location to an accredited dental sleep medicine facility for delivery and fitting of the device. The following is a flow chart describing the treatment pathway for a patient who is prescribed OAT.

Figure B.8



As outlined in the flow chart above, patients who are prescribed OAT must return to the board certified sleep physician (BCSP) for sleep testing (either in center or out of center) to confirm the effectiveness of the treatment. This testing will be performed two-six months after the delivery of the device once the patient has titrated the oral appliance until he/she is no longer experiencing symptoms or until the device has been titrated to the maximum amount. The patient will meet with the BCSP following the study to review the results.

The patient's apnea-hypopnea index (AHI) at the time of re-testing will be compared to the patient's baseline test AHI to determine if the OAT is effective in treating OSA. Patients whose sleep study results indicate that the OAT is not effective in treating OSA will either be referred for alternative treatment or referred for additional treatment. Treatments that can be prescribed as an alternative to or in addition to OAT include PAP therapy and upper airway surgery. Patients whose sleep study results indicate that the OAT is effective in resolving OSA will continue using OAT exclusively.

The following is a detailed description of the tracking mechanism all test locations will use for their patients that are prescribed OAT. Baseline measures of outcomes will be taken at the initial encounters with the patient.

Initial Encounters - Testing and Diagnosis: All patients diagnosed with OSA (ICD-9 codes 327.23 or 780.53) will be tracked. Patients who are not diagnosed with OSA will not be tracked in this mechanism. This information is identical to the information tracked for patients who are prescribed PAP therapy.

Figure B.9 – This information will be obtained and tracked as the patient receives testing and a diagnosis.

Pt. ID	CPT Code(s) of Testing	Date of Testing	ICD-9 Dx Code	Date of Dx

Initial Encounters - Baseline Measurements of Outcomes: Baseline results of all outcomes measures will be tracked prior to initiation of OAT including: a baseline Epworth Sleepiness Scale (ESS) score, baseline Functional Outcomes of Sleep Quality (FOSQ-10) score, and a Short Form (SF)-12 Health Survey score. The apnea-hypopnea index (AHI) for all patients diagnosed with OSA will be tracked. Additionally, for all patients started on OAT, the type of device prescribed will be tracked. This information is identical to the information tracked for patients who are prescribed PAP therapy except that for OAT patients, initial PAP pressure will not be tracked.

Figure B.10 – This information will be obtained as baseline measurements of outcomes.

Pt. ID	Baseline ESS	Baseline FOSQ-10	Baseline SF-12	AHI at initial testing	Type of Device Prescribed

Initial Encounters – Baseline Measurement of Body Mass Index, Blood Pressure and Co-morbid Conditions: Baseline measurements of co-morbid conditions will be monitored at the patients initial encounters. The patient’s body mass index (BMI) and blood pressure (BP) will be recorded. Patients will self-report on four co-morbid conditions by attesting to being diagnosed with diabetes, having had a stroke, having a myocardial infarction, and having had heart failure.

Figure B.11 – These baseline measurements of co-morbid conditions will be obtained at initial encounters.

Pt. ID	Baseline BMI	Baseline BP	Baseline attestation of diabetes	Baseline attestation of stroke	Baseline attestation of myocardial infarction	Baseline attestation of heart failure

Subsequent Encounters (return visit for sleep testing, 1 year, 2 years) Following Initiation of OAT: All patients prescribed OAT will return to the BCSP once for a follow-up sleep test and then twice in the subsequent two years for a follow-up appointment to assess symptoms and monitor outcomes. OAT adherence, sleepiness and sleep quality, and co-morbid conditions will be tracked. Adherence to OAT will be measured subjectively: patients prescribed oral appliance therapy will report to the sleep specialist whether or not they adhere to therapy. Patients prescribed both OAT and PAP therapy will be tracked for adherence to both treatments.

Subsequent Encounters - OAT Adherence, Sleepiness and Sleep Quality Measures

Figure B.12 – This information will be obtained and tracked at each subsequent encounter, including the patients’ return visit for testing, and visits 1 and 2 years following initiation of OAT.

Pt. ID	Date	CPT Code	Adhere to OAT (Y/N)	ESS	FOSQ-10	SF-12	AHI (at re-test)

Subsequent Encounters - Body Mass Index, Blood Pressure and Co-Morbid

Conditions: At subsequent encounters, the test locations will track each patient's BMI and blood pressure. Additionally, patients will be asked to attest to the current condition of their co-morbidities. New diagnoses and incident development will be reported and tracked.

Figure B.13 – This information will be obtained and tracked at each subsequent encounter, including patient's return visit for testing, and visits 1 and 2 years following initiation of OAT.

Pt. ID	Subsequent BMI	Subsequent BP	Subsequent attestation of diabetes	Subsequent attestation of stroke	Subsequent attestation of myocardial infarction	Subsequent attestation of heart failure

Facility Adherence: A rate of adherence for all OAT patients will be calculated for each test location. The number of patients who attest that they do adhere to OAT will be divided by the total number of patients prescribed OAT to determine the facility OAT adherence rate.

Patients Lost During Follow-Up: Test locations are required to follow the above described process for tracking patients who are prescribed OAT, including tracking OAT adherence and overall health outcomes for a two year period. However, in some cases patients may relocate, discontinue treatment, discontinue communication with the test location or may be referred for a different type of treatment.

Test locations must appropriately document patients lost during the two year follow-up period. If a patient does not receive follow-up for the full two-year period, the test location must categorize the reason for the lack of data. The reason can fall into one of the following categories:

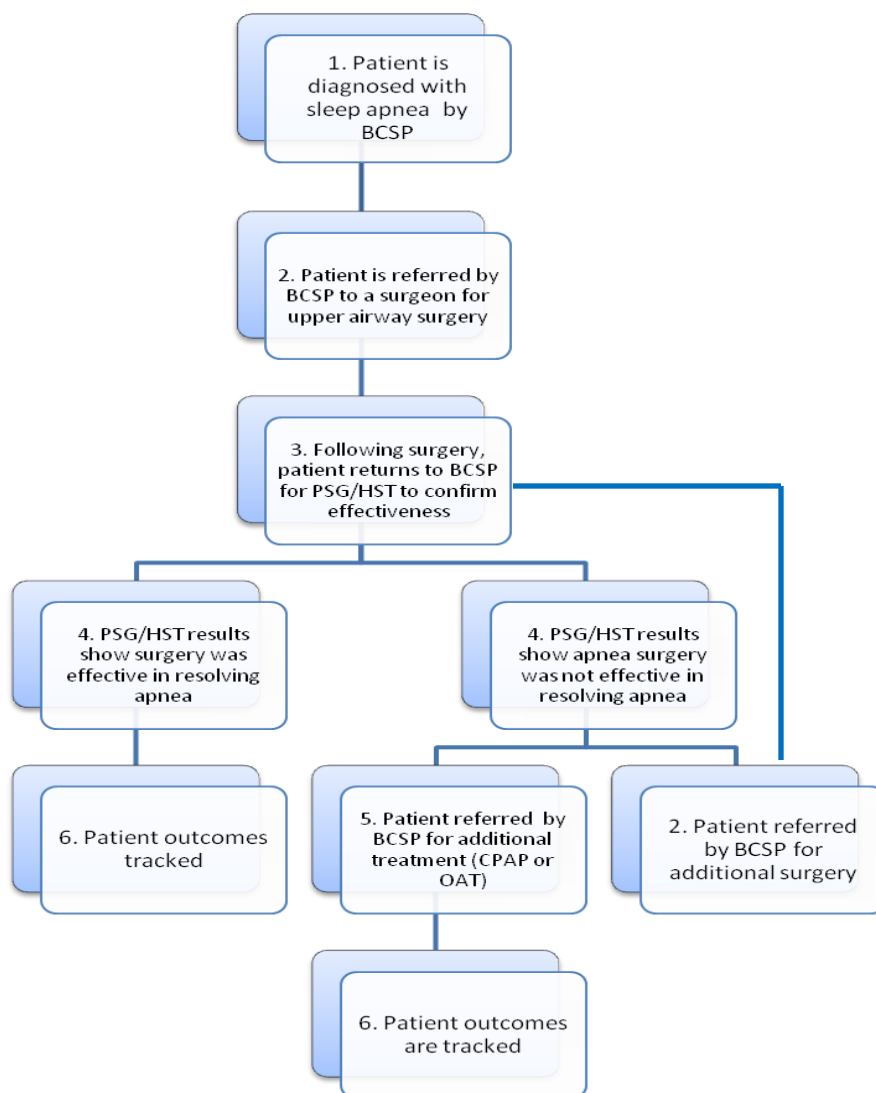
- Relocation – patient relocates and continues follow-up and treatment at a different sleep center;
- Discontinued Treatment – patient discontinues treatment with OAT; and
- Discontinued Communication – patient does not respond to requests for follow-up and does not come into the test location for follow-up appointments with the sleep physician.

The number of patients that fall into the above categories will be tracked by each test location.

Upper Airway Surgery – Follow-up and Outcomes

Patients who are diagnosed with OSA may be referred to a surgeon for upper airway surgery to resolve anatomical issues that have resulted in the patient's OSA. The following is a flow chart describing the steps a patient will go through when referred to a surgeon for upper airway surgery.

Figure B.14



Patients who are referred for upper airway surgery must return to the board certified sleep physician (BCSP) for sleep testing (either in center or out of center) to confirm the effectiveness of the treatment. This testing will be performed once the patient has recovered from the surgery and swelling caused by the surgery has subsided, approximately one and a half to three months following the surgery. The patient will meet with the BCSP to review the results of the study.

The patient's apnea-hypopnea index (AHI) at the time of re-testing will be compared to the patient's baseline test AHI to determine if the OAT is effective in treating OSA. Patients whose sleep study results indicate that the surgery has not been effective in treating OSA will be provided with additional treatment options. As indicated in the flow chart above, patients may require multiple or phased surgeries of the upper airway. In this case, the patient will return to the BCSP for testing following each surgery to determine the effectiveness and determine if additional surgeries are needed. The BCSP may also prescribe OAT or PAP therapy as an additional treatment for patients who have had upper airway surgery but continue to have OSA. Patients whose sleep study results indicate that the surgery was effective in resolving OSA will not need additional treatment.

The following is a detailed description of the tracking mechanism all test locations will use for patients that are referred for upper airway surgery. Baseline measures of outcomes will be taken at the initial visits with the patient.

Initial Encounters - Testing and Diagnosis: All patients diagnosed with OSA (ICD-9 codes 327.23 or 780.53) will be tracked. Patients who are not diagnosed with OSA will not be tracked in this mechanism. This information is identical to the information tracked for patients who are prescribed PAP therapy.

Figure B.15 – This information will be obtained and tracked as the patient receives testing and a diagnosis.

Pt. ID	CPT Code(s) of Testing	Date of Testing	ICD-9 Dx Code	Date of Dx

Initial Encounters - Baseline Measurements of Outcomes: Baseline results of all outcomes measures will be tracked prior to upper airway surgery including: a baseline Epworth Sleepiness Scale (ESS) score, baseline Functional Outcomes of Sleep Quality (FOSQ-10) score, and a Short Form (SF)-12 Health Survey score. The apnea-hypopnea index (AHI) for all patients diagnosed with OSA will be tracked. Additionally, for all patients referred for upper airway surgery, the type of surgery will be tracked. This information is identical to the information tracked for patients who are prescribed PAP therapy except that for patients referred for upper airway surgery, initial PAP pressure will not be tracked.

Figure B.16 – This information will be obtained as baseline measurements of outcomes.

Pt. ID	Baseline ESS	Baseline FOSQ-10	Baseline SF-12	AHI at initial testing	Type of surgery performed

Initial Encounters – Baseline Measurements of Body Mass Index, Blood Pressure and Co-Morbid Conditions: Baseline measurements of co-morbid conditions will be monitored at the patients initial encounters. The patient’s body mass index (BMI) and blood pressure (BP) will be recorded. Patients will self-report on four co-morbid conditions by attesting to being diagnosed with diabetes, having had a stroke, having a myocardial infarction, and having had heart failure.

Figure B.17 – This information will be obtained as baseline measurements of co-morbid conditions

Pt. ID	Baseline BMI	Baseline BP	Baseline attestation of diabetes	Baseline attestation of stroke	Baseline attestation of myocardial infarction	Baseline attestation of heart failure

Subsequent Encounters (return visit for sleep testing, 1 year, 2 years) Following Upper Airway Surgery: All patients referred for upper airway surgery will return to the sleep specialist once for a follow-up sleep test and then twice in the subsequent two years for a follow-up appointment to assess symptoms and monitor outcomes. Sleepiness and sleep quality, and co-morbid conditions will be tracked. Patients prescribed either OAT or PAP therapy in addition to upper airway surgery will be tracked for adherence to that treatment as well.

Sleepiness and Sleep Quality Measures

Figure B.18 – This information will be obtained and tracked at each subsequent encounter, including the patients’ return visit for testing, and visits 1 and 2 years following upper airway surgery.

Pt. ID	Date	CPT Code	ESS	FOSQ-10	SF-12	AHI (at re-test)

Subsequent Encounters - Body Mass Index, Blood Pressure and Co-Morbid Conditions: At subsequent encounters, the test locations will track each patient’s BMI and blood pressure. Additionally, patients will be asked to attest to the current condition of

their co-morbidities. New diagnoses and incident development will be reported and tracked.

Figure B.19 – This information will be obtained and tracked at each subsequent encounter including the patients' return visit for testing, and visits 1 and 2 years following upper airway surgery.

Pt. ID	Subsequent BMI	Subsequent BP	Subsequent attestation of diabetes	Subsequent attestation of stroke	Subsequent attestation of myocardial infarction	Subsequent attestation of heart failure

Patients Lost During Follow-Up: Test locations are required to follow the above described process for tracking patients who have been referred for upper airway surgery, including tracking overall health outcomes for a two year period. Tracking adherence is not a concern for upper airway surgery patients. However, the health outcomes data is important to track as a means of confirming the success or failure of the treatment. However, in some cases patients may relocate or discontinue communication with the test location.

Test locations must appropriately document patients lost during the two year follow-up period. If a patient who is referred for upper airway surgery does not receive follow-up for the full two-year period, the test location must categorize the reason for the lack of data. The reason can fall into one of the following categories:

- Relocation – patient relocates and continues follow-up at a different sleep center;
- Discontinued Communication – patient does not respond to requests for follow-up and does not come into the test location for follow-up appointments with the sleep physician.

The number of patients that fall into the above categories will be tracked by each test location.

Appendix C: Compliance Program

Background Information

The purpose of this document is to provide an overview of the components of an Integrated Delivery Model Compliance Program. The information contained in Roman numerals I through V will need to be customized by each test location to meet the needs of its individual Compliance Program. The references section (VI) provides the source documents the test location will use as reference materials in developing the specific sections of their Compliance Program.

While the following outline provides a comprehensive framework for integrated delivery model test locations to follow in the development of a Compliance Program, each program will need to develop policies and procedures related to the specific needs of that entity.

This is not a stand – alone document. How each of these components will be fulfilled needs to be determined and itemized by the test location in detail in their final Compliance Program.

I. Introduction

Benefits of a Compliance Program: To demonstrate our commitment to honest and responsible conduct, decrease the likelihood of unlawful and unethical behavior at an early stage, and to encourage employees to report potential problems to allow for appropriate internal inquiry and corrective action, each test location will establish a Compliance Program and perform regularly scheduled compliance audits.

Application of Compliance Program Guidance: The purpose of the Compliance Program is to provide uniform guidance for billing and accounting activities. This plan outlines collection compliance guidance for the each test location. The Compliance Program is a comprehensive strategy to ensure:

- a) That claims submitted to all payers, including private, government (Medicare and Medicaid), and other Federal agencies and individuals are consistently accurate.
- b) That accounting of collections is consistently accurate.
- c) That test location employees comply with the applicable laws, policies and regulations, and payer requirements relating to its participation in these programs.

II. Compliance Program Elements 1-7

Element 1: Written Policies and Procedures Outlining the Following:

- A. Standards of Conduct for Test Location Personnel.
- B. Potential Risk Areas.
- C. Claim Development and Submission Process.
- D. Health Insurance Portability and Accountability Act of 1996 (HIPAA).
- E. Credit Balances.

- F. Integrity of Data Systems Procedures.
- G. Retention of Records.
- H. Compliance as an Element of a Performance Plan.

Element 2: Designation of a Compliance Officer and a Compliance Committee. To ensure an effective compliance program, each test location will designate a compliance officer who has oversight authority over the test location.

Element 3: Conducting Effective Training and Education. Training and education will include initial compliance training for all new employees of the test location as well as annual compliance training for all personnel.

Element 4: Developing Effective Lines of Communication. The test locations will have access to their compliance officer. He/she will serve as the lead representative in preserving the ethical and legal stance of the organization.

Element 5: Enforcing Standards through Well-Publicized Disciplinary Guidelines. Disciplinary action will be applicable to all individuals within the test locations who fail to comply with their obligations. When there is information of potential violations or misconduct, the Compliance Officer has the responsibility of conducting an investigation. An internal investigation would include interviews and a review of medical record, billing, and other relevant documents. To assure protections from coerced disclosure of information gained through investigative interviews, the investigation may be referred to qualified legal counsel.

Element 6: Auditing and Monitoring. Periodic post-submission review of claims will be performed to ensure claims submitted for reimbursement accurately represent services provided, are supported by sufficient documentation, conform with applicable coverage criteria for reimbursement, revenue is recorded properly and the account is finalized appropriately. The Compliance Officer will assess the implementation and execution of the Compliance Program on an annual basis.

Element 7: Responding to Detected Offenses and Developing Corrective Action Initiatives. Test locations will respond to detected offenses by investigation. Corrective actions, including disciplinary actions, will be taken to resolve any violations.

III. Compliance Program Effectiveness

1. Code of Conduct. Test locations will require their employees to follow a code of conduct. Each covered individual is expected to abide by the following general principles:
 - A. Serve the public, and treat all persons employed by or associated with the facility with respect, concern, courtesy, and responsiveness.
 - B. Support equal treatment of all patients, employees and other persons associated with the facility, or obtaining or providing services to the facility, without regard to race, gender, color, age, religion, national origin, veterans' status, marital status, sexual orientation, or individual disabilities.

- C. Avoid actual or potential conflicts of interest including the appearance of a conflict of interest, except as allowed by this policy or other facility policies.
 - D. Promptly report to your supervisor any situation in which a covered individual reasonably feels that they may be or may become involved in a conflict of interest, whether or not such situation is specifically described in this policy.
 - E. Recognize that personal gains from employment or service to the facility are limited to respect, recognition, salary, and normal employee benefits.
 - F. Demonstrate the highest standards of personal integrity in all actions related to or affecting the business of the facility.
 - G. Not use your relationship with the facility to bestow any benefit on anyone related to the person by family, business, or social relationship.
 - H. Not disclose or use or allow others to use confidential information obtained as the result of your relationship with the facility for private gain or private purposes.
 - I. Not accept any fee, compensation, gift, payment of expense, or any other thing of monetary value except as authorized by policies of the facility.
 - J. Not engage in outside employment except as authorized by policies of the facility. No covered individual shall hold a public office or employment that is incompatible with their duties and obligations.
 - K. Not use facility time, property, equipment, supplies, or support services for private gain, or private purposes, except such limited use as authorized by policies of the facility.
2. Regular Review of Compliance Program Effectiveness. The test location Compliance Program is intended to be flexible and readily adaptable to changes in regulatory requirements and in the healthcare system as a whole. The program shall be reviewed annually and modified, as necessary.

IV. Self Reporting

If credible evidence of misconduct is discovered and, after reasonable inquiry, it is determined that this misconduct may have violated criminal, civil, or administrative law, the test location's legal office/counsel should be contacted promptly to determine self-reporting requirements.

V. Conclusion

The Compliance Program as presented in this document establishes a framework for effective billing and legal compliance by the test location. It does not set forth all of the test location's substantive programs and policies that are designed to achieve compliance.

References

1. OIG Compliance Program for Individual and Small Group Physician Practices October 2000
<http://www.oig.hhs.gov/authorities/docs/physician.pdf>

2. OIG Compliance Program Guidance for Third-Party Medical Billing Companies
December 1998 <http://oig.hhs.gov/fraud/docs/complianceguidance/thirdparty.pdf>
3. A Roadmap for New Physicians – Avoiding Medicare and Medicaid Fraud and Abuse
<http://oig.hhs.gov/fraud/PhysicianEducation/>
4. Fact Sheets for distribution to Integrated Sleep Management Program Compliance Officer, providers, billing and coding staff:
 - a. Incident – to billing
<http://www.cms.gov/MLNMattersArticles/downloads/SE0441.pdf>
 - b. Correct Use of Modifiers (Modifier Fact Sheets)
<http://www.wpsmedicare.com/j5macpartb/resources/modifiers/>
 - c. Guidelines for Teaching Physicians, Interns, and Residents
<http://www.cms.gov/MLNProducts/downloads/gdelinesteachgresfctsht.pdf>
 - d. Place of Service Chart posinfo@cms.hhs.gov
 - e. Evaluation and Management Services Guide
http://www.cms.gov/MLNProducts/downloads/eval_mgmt_serv_guide-ICN006764.pdf
 - f. The Medicare Learning Network National Articles (MLN)
<http://www.cms.gov/MLNMattersArticles>
 - g. Medicare Information for Advanced Practice Nurses and Physicians
[http://www.cms.gov/MLNProducts/downloads/Medicare Information for APNs and PAs Booklet ICN901623.pdf](http://www.cms.gov/MLNProducts/downloads/Medicare%20Information%20for%20APNs%20and%20PAs%20Booklet%20ICN901623.pdf)
 - h. The Medicare Appeals Process
<http://www.cms.gov/MLNProducts/downloads/MedicareAppealsProcess.pdf>
 - i. The Medicare Overpayment Collection Process
<http://www.cms.gov/MLNProducts/downloads/OverpaymentBrochure508-09.pdf>
 - j. Medicare Fraud and Abuse
http://www.cms.gov/MLNProducts/downloads/Fraud_and_Abuse.pdf
 - k. Positive Airway Pressure (PAP) Devices
http://www.cms.gov/MLNProducts/downloads/PAP_DocCvg_Factsheet_ICN905064.pdf
5. Specific Tools for Integrated Delivery Model Compliance Officer entitled:
 - a. Auditing a physician practice
 - b. Identification and repayment of overpayments
 - c. Determination of reasons for claims rejections
 - d. Verification of components of a Compliance Program – checklist
 - e. Governmental Requests for Medical Records Log

Appendix D: AASM Resources

- AASM Membership Information
- AASM Science and Research and Standards of Practice
- AASM Educational Courses and Products
- Sleep Medicine Training and Certification
- Journal *SLEEP* and the *Journal of Clinical Sleep Medicine*
- American Sleep Medicine Foundation
- Internet Technology and Staff Resources

AASM Membership

History

Founded in 1975, the American Academy of Sleep Medicine (AASM) was first formed as a sleep-center oriented organization named the Association of Sleep Disorders Centers (ASDC). The ASDC was founded with the purpose of establishing standards and diagnostic criteria for the field, developing an examination for sleep specialists, providing a forum for the exchange of information, and promoting the role of sleep medicine in clinical medicine. In 1984, the center-based ASDC established an organization named the Clinical Sleep Society (CSS) for individuals interested in the clinical aspects of sleep and sleep disorders, and in 1987, the ASDC and CSS reorganized to form the American Sleep Disorders Association (ASDA) with two branches of membership: individual membership and center membership. In 1999, the ASDA changed its name to the American Academy of Sleep Medicine and continues to be the leading professional organization promoting the subspecialty of sleep medicine.

Mission

The AASM is a professional membership organization dedicated to the advancement of sleep medicine and related research. The AASM's mission is to serve our members and improve the field of sleep health care by setting clinical standards, advocating for recognition, diagnosis and treatment of sleep disorders, educating professionals in sleep health care, and fostering the development and application of scientific knowledge.

Leadership and Committees

Led by a Board of Directors of four officers (President, President-Elect, Immediate Past-President and Secretary/Treasurer) and eight at-large directors, the AASM maintains a leadership of experts in the fields of sleep medicine and sleep research. The AASM Board of Directors meets quarterly to discuss ongoing matters of the organization, new initiatives, and strategic planning.

Members of the AASM may also volunteer to participate in several standing committees including the Academic Affairs Committee, the Accreditation Committee, the Education Committee, the Research Committee, the Sleep Technologist Issues Committee, the Standards of Practice Committee, and the Coding and Compliance Committee. All standing committees report directly to the Board of Directors. Committee members gain enriching professional experience, continuing the advancement of sleep medicine by evaluating policies and professional standards, developing educational materials and participating in a range of other essential tasks.

AASM Membership Structure and Benefits

AASM membership consists of two membership types: individual membership and center membership.

Individual Membership: Individual membership is available to health care professionals and researchers with an interest in sleep medicine and provides a variety of educational, professional support and networking benefits including:

There are currently seven categories of individual AASM membership: fellow membership, regular membership, student membership, emeritus members, affiliate membership, affiliate industry members, and corresponding membership for international members.

Center Membership: Center membership is available to facilities accredited as a sleep disorders center or laboratory through the AASM and provides a variety of promotional and practice management support benefits.

AASM Membership Statistics

At the conclusion of the 2010 membership-year, the AASM retained a roster of 8988 individual members and 1317 center members and has maintained a steady growth throughout its recent history as illustrated in figures 1.1 and 1.2.

Figure D.1—Individual Membership of the AASM (2000-2010)

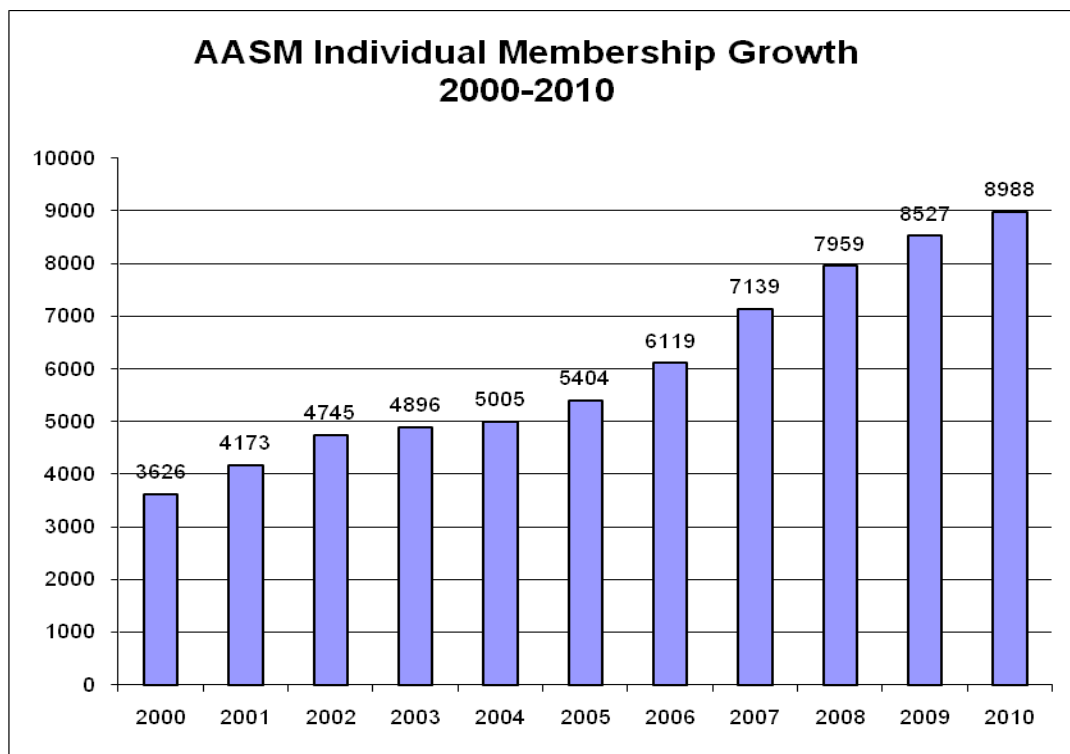


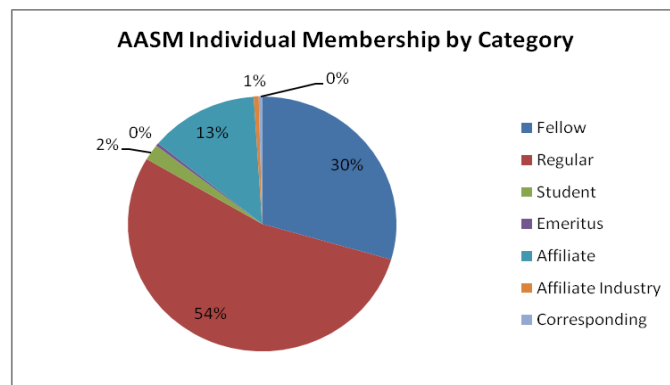
Figure D.2—Center Membership of the AASM (2000-2010)



Of these nearly 9000 individual members, 8260 (91.8%) reside in the United States or Canada. The breakdown of membership by categories is as follows:

Figure D.3—Individual Membership Categories of the AASM (October 1, 2010)

Category	# Members	% of Membership
Fellow	2651	29.5%
Regular	4853	54.0%
Student	181	2.0%
Emeritus	35	0.4%
Affiliate	1177	13.1%
Affiliate Industry	54	0.6%
Corresponding	37	0.4%



Science and Research / Practice Guidelines Development

Background

The AASM Science and Research Department serves as the organization's information-gathering and analysis unit. The department works on a variety of technically-oriented projects. The department's major function is to work with physician members to support the activities of the Standards of Practice Committee (SPC). The SPC is the internally-funded, medical-practice-evaluation activity of the AASM. In this capacity, the work of the Science and Research Department runs the gamut from highly technical work (compiling systematic reviews) to administrative support (facilitating the work of physician-volunteers). The Department is also a resource to the rest of the AASM by providing literature searching capabilities, obtaining requested literature from a variety of library resources, maintaining awareness of the latest scientific publications, and providing expertise and advice on a number of scientific and technical issues.

The SPC contributes to the AASM's mission for high standards of medical practice by evaluating medical procedures and practices, laboratory tests, and other technologies and by making recommendations on their appropriate clinical applications. The AASM develops its practice parameter documents using the principles of evidence-based medicine and has steadily increased the number of published practice parameters since 1994 (See Figure D.4). The SPC oversees the development of systematic reviews by content experts and then translates the evidence into actionable recommendations for the practice of sleep medicine.

AASM-Board-of-Directors-approved recommendations at the "standard-" or "guideline-" strength are AASM policy and must be followed by AASM-accredited sleep centers. This ensures that the highest quality of health care is practiced in accredited sleep centers. Although AASM practice parameters are written primarily for physicians for patient care, they are also useful to other entities in establishing reimbursement policies and research agendas.

The AASM also publishes two other types of practice guidance papers: Clinical Guidelines and Best Practice Guides. Clinical Guidelines are meant to summarize treatment strategies for complex disorders by combining information from a variety of practice parameters with consensus expert opinion for areas in which there is no high quality evidence. Best Practice Guides are developed for topics that are relatively narrow in scope for which there is little high quality evidence.

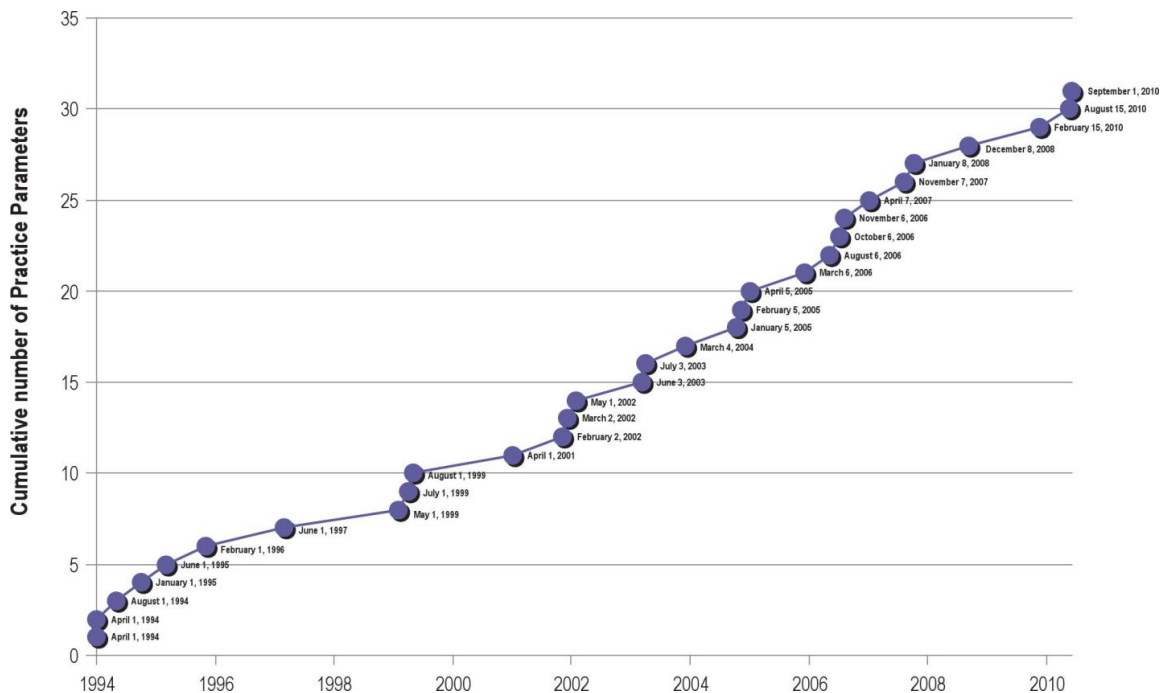


Figure D.4 – Publication schedule of practice parameters by year.¹⁵

Practice Guideline and Practice Parameter Development Processes

The AASM utilizes the most up-to-date methods to produce systematic reviews and clinical practice parameters (guidelines), for example see, Liberati (PRISMA statement),¹⁶ Cochrane Collaboration,¹⁷ AHRQ,¹⁸ IOM,^{19,20} and Rosenfeld and Shiffman.²¹ Teams are constructed from a combination of content experts and staff methodology experts to develop systematic reviews. When applicable, the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system²² is used for projects evaluating

¹⁵ Aurora RN, Morgenthaler TI. On the goodness of recommendations: the changing face of practice parameters. *Sleep*. 2010 Oct 1;33(10):1273-6.

¹⁶ Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gotzsche PC, Ioannidis JP, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *J Clin Epidemiol*. 2009 Oct;62(10):e1-34.

¹⁷ Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions*, Version 5.1.0 (updated March 2011). The Cochrane Collaboration 2011. Available from www.cochrane-handbook.org (accessed 14 April 2011).

¹⁸ Methods Guide for Effectiveness and Comparative Effectiveness Reviews. AHRQ Publication No. 10(11)-EHC063-EF. Rockville, MD: Agency for Healthcare Research and Quality. March 2011. Chapters available at: www.effectivehealthcare.ahrq.gov.

¹⁹ IOM (Institute of Medicine). 2011. *Finding What Works in Health Care: Standards for Systematic Reviews*. Washington, DC: The National Academies Press.

²⁰ IOM (Institute of Medicine). 2011. *Clinical Practice Guidelines We Can Trust*. Washington, DC: The National Academies Press.

²¹ Rosenfeld RM, Shiffman RN. Clinical practice guideline development manual: a quality-driven approach for translating evidence into action. *Otolaryngol Head Neck Surg*. 2009 Jun;140(6 Suppl 1):S1-43.

²² The GRADE Working Group. Grading quality of evidence and strength of recommendations. *BMJ* 2004; 328:1490-4.

treatments for which there is high quality literature in the form of randomized, controlled trials. Other grading schemes are used for diagnostic papers and papers for which there is not an abundance of high quality literature. The AASM is continually evaluating and improving its document development process to ensure the publication of high quality reviews.

Practice parameters are generated from systematic reviews by the Standards of Practice Committee. Figure D.5 shows the process of translating evidence summaries from systematic reviews to guideline statements using the GRADE method. Key ideas from GRADE that are being incorporated are: 1) the inclusion of an assessment of benefits and harms in conjunction with the overall body of evidence level in determining the final strength of the recommendation; and 2) increased transparency in the reporting process whereby the reasoning that went into determining the strength of recommendation is included.

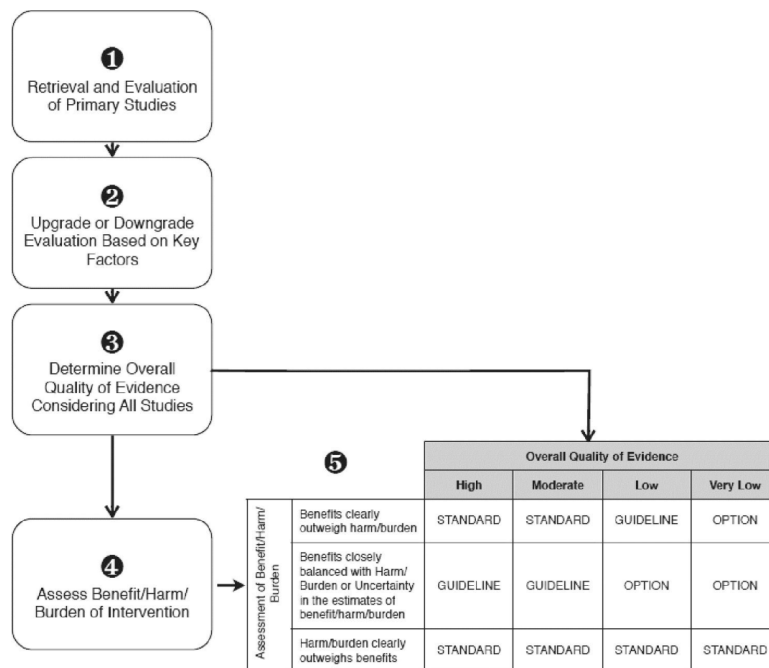


Figure D.5 – Process for converting evidence into recommendation levels.²³

Examples of Recent Papers

Over the past year, the AASM has published two best practice guides, two practice parameters, and two systematic reviews:

1. **Best Practice Guide for the Treatment of REM Sleep Behavior Disorder (RBD).**
Aurora RN, Zak RS, Maganti RK, Auerbach SH, Casey KR, Chowdhuri S, Karippot A,

²³ Aurora RN, Morgenthaler TI. On the goodness of recommendations: the changing face of practice parameters. *Sleep*. 2010 Oct 1;33(10):1273-6.

Ramar K, Kristo DA, Morgenthaler TI; Standards of Practice Committee; American Academy of Sleep Medicine. *J Clin Sleep Med* 2010; 6(1):85-95.

2. **Best Practice Guide for the Treatment of Nightmare Disorder in Adults.** Aurora RN, Zak RS, Auerbach SH, Casey KR, Chowdhuri S, Karippot A, Maganti RK, Ramar K, Kristo DA, Bista SR, Lamm CI, Morgenthaler TI; Standards of Practice Committee; American Academy of Sleep Medicine. *J Clin Sleep Med* 2010; 6(4):389-401.
3. **Practice Parameters for the Surgical Modifications of the Upper Airway for Obstructive Sleep Apnea in Adults.** Aurora RN, Casey KR, Kristo D, Auerbach S, Bista SR, Chowdhuri S, Karippot A, Lamm C, Ramar K, Zak R, Morgenthaler TI. *Sleep* 2010; 33(10):1408-13.
4. **Surgical Modifications of the Upper Airway for Obstructive Sleep Apnea in Adults: A Systematic Review and Meta-Analysis.** Caples SM, Rowley JA, Prinsell JR, Pallanch JF, Elamin MB, Katz SG, Harwick JD. *Sleep* 2010; 33(10):1396-407.
5. **Practice Parameters for the Respiratory Indications for Polysomnography in Children.** Aurora RN, Zak RS, Karippot A, Lamm CI, Morgenthaler TI, Auerbach SH; Bista SR, Casey KR, Chowdhuri S, Kristo DA, Ramar K. *Sleep*. 2011; 34(3): 379-88.
6. **Respiratory Indications for Polysomnography in Children: An Evidence-Based Review.** Wise MS, Nichols CD, Grigg-Damberger MM, Marcus CL, Witmans MB, Kirk VG, D'Andrea LA, Hoban TF. *Sleep* 2011; 34(3): 389A-398AR.

Papers in Development

Five projects are currently in development with an anticipated publication date in 2011 or 2012:

1. Non-respiratory Indications for Polysomnography in Children: An Evidence-Based Review and Practice Parameters
2. Indications for Polysomnography in Children with ADHD: Clinical Guidelines or Best Practice Guide
3. The Treatment of Central Sleep Apnea Syndromes in Adults: Practice Parameters with an Evidence-Based Literature Review and Meta-Analyses
4. Systematic Review and Meta-Analysis of the Treatment of Restless Legs Syndrome and Periodic Limb Movement Disorder. An Update for 2011
5. Obstructive Sleep Apnea Devices for Out-of-Center (OOC) Testing: Technology Evaluation

Impact Assessment

The AASM submits its guidelines to the National Guidelines Clearinghouse (NGC) for public access and conversion into guideline syntheses as overseen by the NGC. Figure D.6 shows the summary usage data provided by the NGC on the number of page views for each AASM document. The number of page views increased for every document except one (which had an unusually high page view usage in 2009) between 2009 and 2010.

Figure D.6 – The number of page views for each document increased between 2009 and 2010 for all but one document.

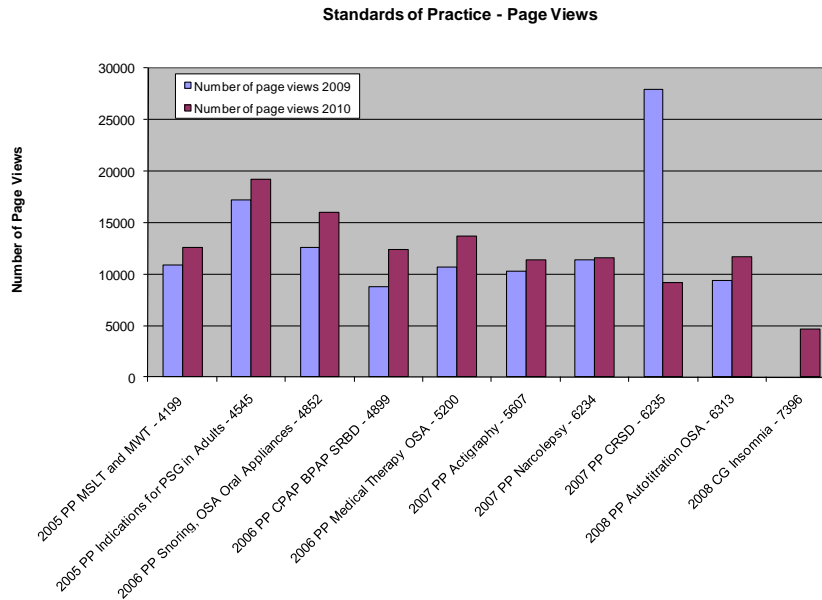
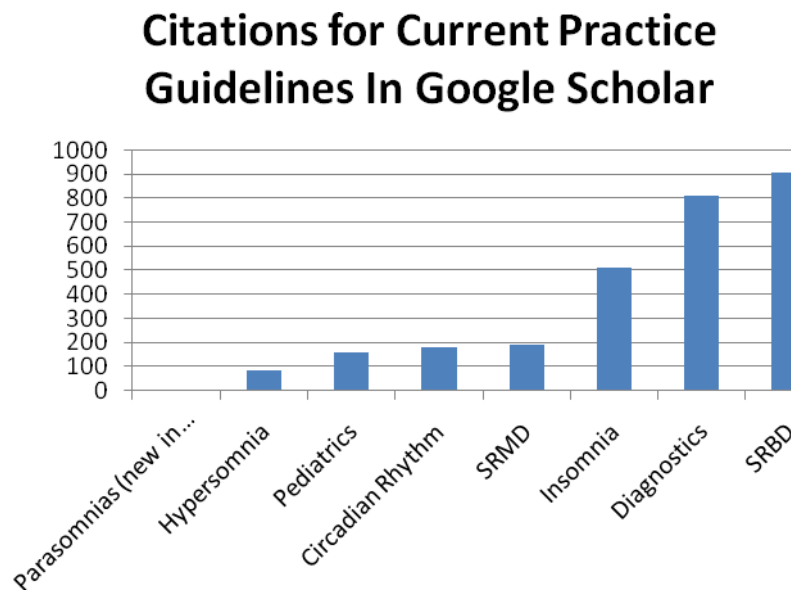


Figure D.7 – Number of citations for AASM documents in Google Scholar.



Educational Courses and Products

Courses

The AASM initially received accreditation from the Accreditation Council for Continuing Medical Education (ACCME) in November 1995. At that time, the AASM accredited two educational offerings – the National Sleep Medicine Course and the SLEEP meeting. Since then, the AASM has been reaccredited several times. Most recently, the AASM was reaccredited for a four-year term by the Accreditation Council for Continuing Medical Education in November 2009. The number of educational offerings by the AASM has grown substantially. The AASM has expanded the number of live courses it offers, as well as offering online learning opportunities as well. In 2010 and 2011 to date, over 2,300 individuals attended a live course offered by the AASM.

Figure D.8 – A review of the educational offerings from the AASM in 2010 and 2011 thus far:

Course	Dates	Location	Number of Faculty	Final Registration
Current Topics of Sleep Medicine	February 19-20, 2010	Phoenix, AZ	15	154
Business of Sleep Medicine	February 20-21, 2010	Phoenix, AZ	15	194
Coding and Compliance for Psychologists	March 19, 2010	Oak Brook, IL	2	28
Behavioral Sleep Medicine: An Introduction to the Psychology of Sleep Medicine	March 20-21, 2010	Oak Brook, IL	12	96
Intensive Scoring Workshop	August 12, 2010	Denver, CO	2	130
Board Review for Sleep Specialists	August 13-15, 2010	Denver, CO	15	160
Intensive Scoring Workshop	September 30, 2010	Reston, VA	2	257
Board Review for Sleep Specialists	October 1-3, 2010	Reston, VA	15	325
Interpreting Sleep Studies	October 22-24, 2010	AASM National Office	8	132
Pharmacology and Sleep	October 30-31, 2010	AASM National Office	8	55
Comprehensive Evaluation and Management Coding	November 1-2, 2010	AASM National Office	1	39

Workshops in Sleep Medicine: Portable Monitoring	November 6, 2010	AASM National Office	5	68
Workshops in Sleep Medicine: Sleep Apnea Examination	November 7, 2010	AASM National Office	5	27
Current Topics of Sleep Medicine	February 18-19, 2011	La Jolla, CA	15	123
Business of Sleep Medicine	February 20-21, 2011	La Jolla, CA	15	166
Intensive Scoring Workshop	March 17, 2011	Los Angeles, CA	2	174*
Board Review for Sleep Specialists	March 18-20, 2011	Los Angeles, CA	15	227
A-STEP Introductory Course	March 21-April 1, 2011	AASM National Office	3	8
Sleep Center Manager Boot Camp	April 4-7, 2011	AASM National Office	12	66
Scoring of Sleep Workshop	April 16, 2011	AASM National Office	1	71
Total				2326

** These individuals all attended the Board Review for Sleep Specialists course. This number is not included in the total below.*

Recent AASM course offerings have been expanded to appeal to a broader group of sleep center staff. In March 2011 the AASM offered its first two-week A-STEP Introductory Course. The AASM A-STEP course is an 80-hour comprehensive program for sleep trainees and technicians new to the field. The course was designed to prepare trainees for a career in sleep and to help them initiate the process of certification. The AASM Sleep Center Manager Boot Camp course, a three and a half day course first offered in April 2011, was targeted to sleep center management staff. The course included extensive education in development of policies and procedures, review of business practices and it addressed legal, coding and reimbursement issues. In addition to supporting qualified physicians in the sleep field providing quality care to sleep disorders patients, the AASM is also committed to educating sleep technologists and sleep center managers.

SLEEP Annual Meeting

The SLEEP annual meeting is a joint meeting of the AASM and the Sleep Research Society (SRS). Because this meeting combines both the clinical practice and the research aspect of sleep, the meeting is known for linking the bench to the bedside with a robust scientific

program involving basic, translational and clinical sleep research, and practical studies on the care of patients with sleep disorders. The first meeting was held in 1986; the SLEEP meeting is celebrating its 25th Anniversary in June 2011 in Minneapolis, Minnesota. The meeting has grown significantly in the past 25 years from 739 attendees and 32 exhibitors in 1986 to 5850 attendees and 121 exhibitors in 2010. Furthermore, the number of scientific abstracts submitted for the meeting has nearly quadrupled. At SLEEP 2011, more than 1000 abstracts will be presented, along with 85 scientific sessions.

Figure D.9 – An overview of the growth of the SLEEP meeting.

Year	City	Attendance	Exhibitors	Abstracts
1986	Columbus, Ohio	739	32	287
1988	San Diego, California	1030	40	402
1989	Washington, DC	1363	42	448
1990	Minneapolis, Minnesota	1342	47	410
1991	Toronto, Ontario	1576	48	469
1992	Phoenix, Arizona	1670	48	410
1993	Los Angeles, California	1737	54	412
1994	Boston, Massachusetts	2210	56	505
1995	Nashville, Tennessee	2612	68	546
1996	Washington, DC	2557	68	584
1997	San Francisco, California	2903	70	787
1998	New Orleans, Louisiana	3097	86	618
1999	Orlando, Florida	3113	92	582
2000	Las Vegas, Nevada	3821	89	703
2001	Chicago, Illinois	4062	98	797
2002	Seattle, Washington	4122	111	760
2003	Chicago, Illinois	4846	115	1144
2004	Philadelphia, Pennsylvania	5030	112	945
2005	Denver, Colorado	5467	127	1076
2006*	Salt Lake City, Utah	5379	144	1116
2007	Minneapolis, Minnesota	6041	150	1133
2008	Baltimore, Maryland	6503	159	1160
2009	Seattle, Washington	5637	121	1310
2010	San Antonio, Texas	5850	121	1146

* In 2006, the name was changed to the SLEEP meeting.

Webinars

In addition to live courses, the AASM began offering live webinars in 2007. From 2007-2010, the AASM presented several webinars on various topics from preparation for board certification to behavioral therapy techniques for sleep disorders to various health policy topics. During these one hour lectures, an expert presented a PowerPoint presentation and lecture to participants over the internet. 77 webinars were presented and over 2,000 individuals participated in these sessions.

Online Learning Center

The AASM received a lot of feedback from members that although the webinars were on excellent topics, busy schedules and practices often prevented them from participating in the live sessions. Based on this feedback, the AASM stopped offering webinars at the end of 2010 and launched its online learning center in January 2011. The online learning center modules are created from recordings of live courses held by the AASM. Each module includes a streaming video presentation, educational references and the opportunity to earn CME credit. Currently, there are 21 modules available in the online learning center.

Access to the modules can be obtained in three ways – 3-day access from the AASM online learning center, 30-day access from the AASM online learning center or by a CD-ROM mailed to the individual.

Products

The AASM produces the leading reference materials related to sleep medicine. Below is an outline of just a few of the products offered by the AASM:

SAFER

In 2003 the Accreditation Council for Graduate Medical Education approved changes to program and institutional standards that grew from the report of the Work Group on Duty Hours. In addition to limiting resident work hours, the Work Group charged sponsoring institutions with the responsibility of “creating an environment within their residency programs that promotes safe patient care and high-quality learning. They are expected to assume additional responsibilities, including educating residents in recognizing the signs of fatigue.”

The AASM recognized that no instrument existed to educate residents in recognizing the signs of fatigue, and convened a task force to create one. The task force included experts in medical education, sleep medicine and health policy. The product was called Sleep, Alertness and Fatigue Education in Residency (SAFER) and was launched in 2003. It was updated and revised in 2006 and again earlier this year.

SAFER is a 25 minute narrated video presentation. It provides an introduction to the science of sleep and information on the effects of sleep deprivation. SAFER focuses on the competing demands, work-related stresses and unique challenges that face medical residents. SAFER provides concrete, implementable suggestions for management of fatigue and sleepiness during residency. Management of fatigue is enhanced when there is an understanding of the influences of circadian and homeostatic processes. SAFER helps

residents apply knowledge of these processes in deciding when and how long to sleep, and what fatigue countermeasures are used. SAFER includes a post-test.

As a result of recent incidents involving fatigue management and air traffic controllers, the AASM has reached out to the National Transportation Safety Board and the Federal Aviation Administration to encourage their use of SAFER with air traffic controllers.

International Classification of Sleep Disorders, Second Edition

The International Classification of Sleep Disorders, Second Edition (ICSD-2) is the authoritative text for clinicians to access information about sleep disorders, criteria for diagnosis and other relevant information imperative for the treatment of their patients. This second edition provides the most current nosology of sleep medicine and is designed in a more user-friendly format. It is an invaluable resource for all clinicians. Disorders are grouped into eight categories:

- Insomnias
- Sleep Related Breathing Disorders
- Hypersomnias of Central Origin Not Due to a Circadian Rhythm Sleep Disorder, Sleep Related Breathing Disorder or Other Cause of Disturbed Nocturnal Sleep
- Circadian Rhythm Sleep Disorders
- Parasomnias
- Sleep Related Movement Disorders
- Isolated Symptoms, Apparent Normal Variants, and Unresolved Issues
- Other Sleep Disorders

Scoring Manual

The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications provides a comprehensive and definitive reference for the evaluation of polysomnograms. The *Manual* is the result of an extensive review of the literature, analysis and consensus by task forces comprised of renowned sleep experts. It provides standard montages, electrode placements and digitization parameters. Building on the classic manual by Rechtschaffen and Kales, the new manual provides rules not only for scoring sleep stages but also for scoring arousals, respiratory events during sleep, movements during sleep and cardiac events. This publication is an essential resource for technologists as they perform and score polysomnographic recordings as well as the physicians who interpret them.

Sleep Medicine Training and Certification

The AASM supports the standardized training and certifying of sleep medicine physicians through ACGME accredited sleep medicine training program and ABMS member board certification exams.

Fellowship Training in Sleep Medicine

Though sleep medicine training programs were previously accredited by the AASM, commencing in 2005, the Accreditation Council for Graduate Medical Education (ACGME) began accrediting sleep medicine fellowships. Individuals can enter a fellowship after completing a core residency in any of the seven sponsoring specialties: internal medicine, neurology, otolaryngology, pediatrics, family medicine, psychiatry, and anesthesiology. To date, there are 71 accredited sleep fellowships with slots for approximately 100 individuals. The AASM recognizes the importance of these fellowships and continues to work very closely with several organizations to ensure the growth of the field. The AASM continues to provide a forum for sleep medicine fellowship directors. Also, commencing in 2011, the AASM is facilitating a “match” with the National Resident Matching Program (NRMP) and Electronic Residency Application Service (ERAS®) for those entering a sleep medicine fellowship. The first group of fellows will be assigned to programs using the match in November 2011.

Sleep Specialist Certification

Beginning in 2007, five of the member boards of the American Board of Medical Specialties (ABMS) started offering a sleep medicine certification exam. The five ABMS boards offering sleep medicine certification include American Board of Internal Medicine, the American Board of Psychiatry and Neurology, the American Board of Pediatrics, the American Board of Otolaryngology and the American Board of Family Medicine. The American Board of Anesthesiology has recently signed on as the sixth member board. It is anticipated that an exam for sleep medicine specialists will be offered by the American Board of Anesthesiology in 2013. Individuals certified in sleep medicine prior to 2007 were certified under the American Board of Sleep Medicine (ABSM). Physicians certified by the ABSM have been encouraged to recertify in sleep medicine under the new ABMS board exams and those physicians holding ABSM certification in good standing were automatically accepted to sit for the exam during testing from 2007 to 2011. After the exam is offered in November of 2011, all individuals applying for the ABMS member board sleep medicine certification exam will be required to have completed an ACGME accredited sleep medicine fellowship.

Journal *SLEEP* and *Journal of Clinical Sleep Medicine*

SLEEP

In 1978, publication commenced for the first peer-reviewed scientific journal for the sleep field. *SLEEP* publishes original findings and analysis related to sleep disorders, medical dysfunctions during sleep, clinical investigations, therapeutic trials, physiologic events, anatomic structures, the pharmacology of sleep and other relevant topics. The first Editor-in-chief and was Dr. Christian Guilleminault with Dr. William Dement serving as a co-Editor. *SLEEP* is now published by the Associated Professional Sleep Societies, a joint partnership of the AASM and the Sleep Research Society (SRS).

Under Editor-in-chief Dr. David White, several enhancements were made to *SLEEP* and a number of changes occurred. In 2005, he instituted the use of Associate Editors to oversee the review of submitted manuscripts and Deputy Editors to help with decisions regarding policy and direction. Concurrently, the number of issues of *SLEEP* increased to 12 and the number of manuscripts submitted to the journal totaled more than 400.

Now in its 34th volume, *SLEEP* is recognized as the leading scientific journal in the field with an impact factor of 5.402, which places it in the top six percent of more than 6100 journals ranked in the Journal Citation Reports Science Edition. Under current Editor-in-chief Dr. David Dinges, the journal has grown considerably, with more than 550 original manuscripts submitted in 2010. In 2011, *SLEEP* transitioned to an online-only publication, with a print edition of each issue available for purchase on-demand. In addition, *SLEEP* is available on the Kindle device through Amazon.

Journal of Clinical Sleep Medicine

In 2005, the AASM commenced publication of a second peer-reviewed scientific publication, *Journal of Clinical Sleep Medicine (JCSM)*, which focuses on research and continuing education applicable to clinical sleep medicine practitioners.

JCSM publishes original manuscripts such as clinical trials as well as clinical reviews, clinical commentary and debate, medical economic/practice perspectives, case series and novel/interesting case reports. In addition, *JCSM* publishes proceedings from conferences, workshops and symposia sponsored by the AASM and other organizations related to improving the practice of sleep medicine.

Under the leadership of its first and current Editor-in-chief Dr. Stuart Quan, *JCSM* is published six times a year with plans to publish eight issues a year beginning in 2011. Also in 2011, *JCSM* will transition to an online only publication with a print edition of each issue available for purchase on-demand. In the 2010 volume year, 138 original manuscripts were submitted for publication. Additionally, in 2009 Thompson Reuters accepted *JCSM* for indexing in its Science Citation Index. As a result, *JCSM* is now indexed and the first impact factor will be in the 2011 Journal Citation Reports.

The American Sleep Medicine Foundation

The American Sleep Medicine Foundation (ASMF) was created by the American Academy of Sleep Medicine (AASM) in 1998, growing out of the AASM's commitment to advancing the fields of sleep research and sleep medicine. The seeds for the foundation were planted, however, when the AASM was formed more than 30 years ago. When the AASM was established in 1975, its founders agreed that the organization should combine a sleep-center focus with an emphasis on clinical practice and research.²⁴

Recognizing the insufficient level of funding that was available to sleep scientists, the AASM board of directors, led by Dr. Wolfgang Schmidt-Nowara, formed the ASMF to provide tangible support for the advancement of sleep research. Originally called the Sleep Medicine Education and Research Foundation (then known as SMERF), the goal of the ASMF was to support education as well as clinical and basic research. The ASMF awarded its first grants in 1998, and among the research supported by these inaugural grants were studies at the University of Pennsylvania and Stanford University that provided preliminary data for major studies subsequently funded by the National Institutes of Health.

The AASM has invested more than \$10.5 million in the ASMF since its inception. The AASM provides the funding for all of the foundation's administrative costs and has funded most of the ASMF grants. As part of this investment, the AASM contributed \$500,000 to the ASMF in 2007 for the establishment of an endowment to support future research efforts. The ASMF also received a donation of \$2 million from the American Board of Sleep Medicine for the creation of an endowment, separate from the AASM endowment, for future initiatives.

This investment has translated into more than 50 grants that have studied topics ranging from computational modeling of the human pharyngeal airway and genomics of the zebrafish hypocretin/narcolepsy pathway to a large-scale, multi-center study on portable monitoring in the diagnosis and management of obstructive sleep apnea. The results of these grants have been published in prestigious journals such as *SLEEP*,²⁵ *Journal of the American Medical Association*,²⁶ and the *American Journal of Critical Care and Respiratory Medicine*.²⁷

In addition, grants from the ASMF support the pipeline of new scientists to the sleep field. The AASM Physician Scientist Training Award, established in 2007 with a \$1.875 million investment from the AASM, awards one-year grants to support sleep research by physician trainees who have completed or who, by virtue of completing appropriate residency

²⁴ Shepard JW, Jr., Buysse DJ, Chesson AL, Jr., Dement WC, Goldberg R, Guilleminault C, et al. History of the development of sleep medicine in the United States. *J Clin Sleep Med*. 2005 Jan 15;1(1):61-82.

²⁵ Drummond SP, Brown GG, Salamat JS, Gillin JC. Increasing task difficulty facilitates the cerebral compensatory response to total sleep deprivation. *Sleep*. 2004 May 1;27(3):445-51.

²⁶ Arnedt JT, Owens J, Crouch M, Stahl J, Carskadon MA. Neurobehavioral performance of residents after heavy night call vs after alcohol ingestion. *JAMA*. 2005 Sep 7;294(9):1025-33.

²⁷ Malhotra A, Huang Y, Fogel RB, Pillar G, Edwards JK, Kikinis R, et al. The male predisposition to pharyngeal collapse: importance of airway length. *Am J Respir Crit Care Med*. 2002 Nov 15;166(10):1388-95.

training, are eligible for ACGME sleep medicine fellowships but do not have university faculty appointments.

In February 2011, the ASMF announced a new grant opportunity to support one-year projects that address sleep problems or sleep education needs in disadvantaged populations. The first Humanitarian Projects Award winners will be announced at the 2011 SLEEP meeting in Minneapolis. Total grants awarded to the 2011 grant recipients may total up to \$50,000 with single grants reaching up to \$17,000.

The commitment to research that led to the formation of the ASMF nearly a decade ago remains at the heart of the organization's mission and vision. The ASMF aims to provide research scientists with significant funding opportunities for sleep-related investigations targeting critical areas of study that lack a sufficient body of evidence. The research funded by these grants will have a lasting impact on sleep science and clinical practice leading to improvements in sleep health care outcomes.

Information Technology Staff and Resources

The AASM has a large in-house information technology staff, composed of experienced programmers and database managers, project managers, web content and social media editors, web designers, and network administrators.

This team is responsible for the development, design and maintenance of 16 websites related to the AASM and other sleep-related organizations. These dynamic websites include information for members on organization-related initiatives, internet-based applications, resources for members of the sleep medicine field, and educational programs. In addition, the internet technology staff has developed sophisticated Internet-based applications for the sleep medicine field, including the Interscorer Reliability Program, which allows sleep centers to assess scoring competence, and the Online Learning Center, which features on-demand educational courses and resources. Additionally, the information technology department transitioned *SLEEP*, the premiere journal for the sleep medicine field, to an online publication that closely mirrors the design and functionality of PubMed to ensure access and ease of use.

The AASM is active with social media applications and utilizes several platforms, including Facebook, LinkedIn and Twitter, for Internet-based communications. In addition, the AASM maintains a blog that provides related information about sleep and sleep disorders for the public as well as a patient-orientated website.