

Healthcare & Life Sciences

Vital Signs

Strategic Insights for Healthcare Executives

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This Week's Industry Focus: Patient Monitoring

Home Sleep Monitoring; You Snooze, You Lose!

Author: Mike Arani, Research Analyst

Reimbursement trends for “unattended sleep monitoring” for obstructive sleep apnea has been the hot topic of sleep medicine in recent years. The alarming sleep related breathing disorders statistics and their correlation with highly prevalent conditions such as, Diabetes, Cardiovascular Diseases and Obesity have driven the demand for a large increase in the number of sleep studies in the U.S.

Currently, the most common sleep diagnosis service entities are provided by sleep labs, hospital and non-hospital based sleep service providers. Depending upon the private payors’ regional reimbursement guidelines, some sleep service providers do perform unattended sleep monitoring in special cases and for cash patients. However, Medicare, to this date, considers unattended home sleep monitoring to be a non-covered benefit under the current CMS coverage criteria.

Sleep Disordered Breathing (SDB) and Sleep Apnea

During sleep, the brain consolidates the information gathered throughout the day, the kidneys cleanse the body, and a whole host of important physiological functions are performed. Once asleep, respiration becomes completely involuntary. Certain physiological and/or neurological elements could disrupt this vital part of the rejuvenation cycle, and be the cause of sleep disordered breathing (SDB). The most common type of SDB is sleep apnea. During sleep apnea episodes, breathing stops or becomes very shallow, with each episode typically lasting from ten seconds to two minutes in the most severe cases. Obstructive sleep apnea (OSA), the more prevalent type of sleep apnea, is also the most common type of sleep disordered breathing (SDB).

Pauses can occur 30 to 40 times or more per hour. During apnea episodes, the blood oxygen level decreases, causing the heart to work harder in order to get enough oxygen to the tissues. With the more subtle form of disordered breathing called Upper Airway Resistance Syndrome (UARS), blood oxygen levels do not necessarily decrease but the patient experiences an arousal much like they would during an event of apnea and daytime sleepiness results and is treated in a similar manner.

Sleep apnea is defined as an absence of breathing during sleep. Apnea is currently defined as the cessation of airflow for at least ten seconds and is characterized as either central, no respiratory effort, obstructive, continued respiratory effort, or mixed,

combination of central and obstructive components.

Apnea is associated with either a fall in oxyhemoglobin saturation or an arousal from sleep. Hypopneas are partial reductions in airflow associated with falls in oxygen saturation or arousals from sleep. The sleep apnea syndrome has been clinically defined as recurrent apnea or hypopnea associated with clinical impairment usually manifested as increased daytime sleepiness or altered cardiopulmonary function. In general, the average number of episodes of apnea and hypopnea per hour are reported as an index (AHI) or as a respiratory disturbance index (RDI).

Classically, an AHI of greater than five episodes per hour has been the definition of the presence of the sleep apnea syndrome. Patients with UARS often have AHI's below five episodes per hour but are still symptomatic. Other commonly used cutoff points are AHI of 10 or 15 episodes per hour or an overnight total of 30 apneic-hypopneic episodes.

The demand for sleep diagnostic services will continue to grow due to increased awareness of sleep disorders among the general public and healthcare professionals. SDB is prevalent in about ten percent of the adult population in the United States. This substantial market potential combined with the increased rate of obesity, diabetes, stroke and congestive heart failure, will ensure a continuous demand for sleep diagnostic services.

Up to seventy percent of patients who have suffered a stroke, sixty percent of congestive heart failure patients, thirty percent of hypertension patients, seventy percent of morbidly obese patients, and sixty percent of diabetic patients also suffer from SDB. Sleep apnea is diagnosed via polysomnography or PSG where patient's vital signs such as EEG, ECG, Respiratory effort, Pulse Oximetry, etc are monitored.

Sleep Service Providers

Sleep service providers are primarily the sleep labs where sleep studies and polysomnography (PSG) are performed. Overall, sleep monitoring is performed in hospital and non-hospital based sleep labs, physician practices, and homes.

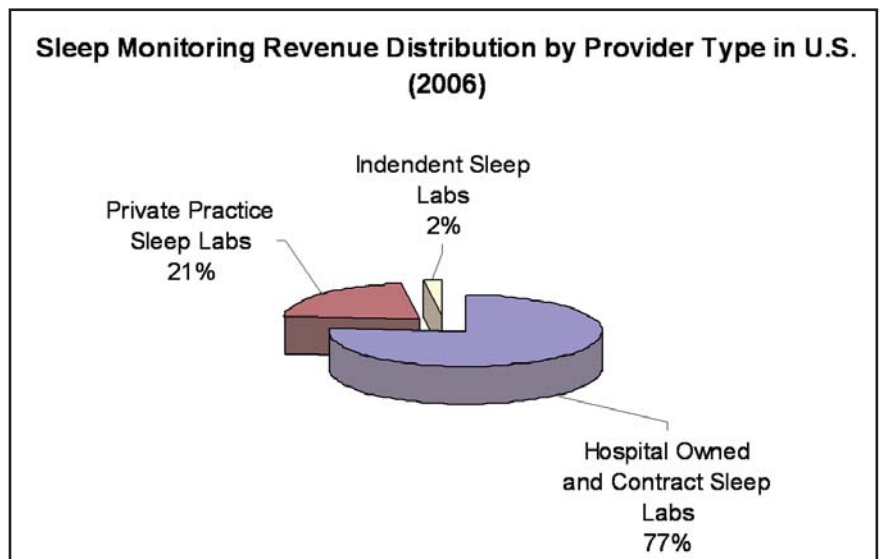
Due to the fact that only attended sleep studies are reimbursed by major payors, unattended home testing has not gained traction in the United States.

Sleep Labs are often segmented into three groups;

- Hospital Based (Hospital Owned or Contracted)
- Practice Based
- Independent Practice

Sleep Labs patients are referred by physicians when they suspect that their patients could suffer from sleep disorders. Physician referral is the first requirement in determining the sleep test's medical necessity.

Chart 1: Revenue distribution among the three groups of sleep service providers (U.S.) 2006.



Source: Frost & Sullivan

Figure 1: Sleep Labs referral sources by the physician specialty and sleep lab type (U.S.), 2006.

Referral Source by Specialty	Hospital-Based Sleep Labs (%)	Practiced Based Sleep Labs (%)	Independent Sleep Labs (%)
Pulmonologists	39	11	25
Family practitioners	29	37	48
Neurologists	10	4	1
Otolaryngologists	9	10	10
Cardiologists	7	4	3
Internal Medicine	5	33	11
Others	1	1	2

Source: Frost & Sullivan

Polysomnography (PSG)

Polysomnography or PSG consists of a simultaneous recording of multiple physiologic parameters related to sleep and wakefulness. The interaction of various organ systems during sleep and wakefulness is also evaluated. PSG is used to evaluate abnormalities of sleep or wakefulness, and other physiologic disorders that have an impact on, or are related to sleep or wakefulness.

By international standards, a polysomnography measures or monitors certain neurophysiology factors including EEG (electroencephalography), EOG (electrooculogram), EMG (electromyography), airflow, electrocardiography (ECG), pulse oximetry, respiratory effort, and snoring sound.

An attended study refers to a situation where a qualified technician is present with the ability to intervene if needed. Unattended studies are usually performed via ambulatory PSG systems. Ambulatory PSG is a full-channel sleep monitoring system that does not require a desktop or a laptop. The data gathered with an ambulatory PSG can be stored and retrieved when needed. A majority of the ambulatory devices available in the market have the capability to transmit data wirelessly.

Attended home sleep testing is not financially feasible because within a sleep lab setting the respiratory technician can attend to more than one patient at a time verses a single patient at an attended home testing.

Sleep Diagnostic Classification

The American Academy of Sleep Medicine (AASM) classifies four levels of complexity of recording technology used for the diagnosis of sleep related breathing disorders. The sleep-disorder studies are placed in a four-category classification system where they are ranked according to their intensity:

Level I: Standard PSG: Minimal requirements include recording of EEG, EOG, chin EMG, ECG, Airflow, Respiratory effort and oxygen saturation, Body position must be documented or objectively measured. Trained personnel must be in constant attendance and able to intervene. Leg movement recording (EMG or motion sensor) is desirable but optional.

Level II: Complex Home Monitoring: This type of mentoring is defined as any system designed for use in the home that records at least four channels of physiological data. Comprehensive, portable PSG is the same as level, except heart rate instead of ECG is acceptable and having trained personnel present to intervene is not required for all studies.

Level III: Modified, Portable Sleep Apnea Testing: Minimum requirements include recording of ventilation (at least two of the respiratory movement, or respiratory movement and airflow); ECG or heart rate; and oxygen saturation. Personnel are needed for preparation, but the ability to intervene is not required for all studies.

Level IV: Continuous (Single or Dual) Bioparameter Recording: Only one or two Physiological variables needed to be recorded. The ability to intervene is not required.

Other devices: Many new devices or new technologies, such as Lifeshirt, Watch Pat 100 and ARES, have become available that don't fit the "Type" system but often do monitor more than four channels of physiologic data.

Medicare's Position on Home Sleep Monitoring

In April 2005, Medicare again declared that unattended home sleep testing for the diagnosis of OSA was considered neither reasonable nor medically necessary. Until recently, Medicare has firmly believed that polysomnography (PSG) must be performed in a facility-based sleep study laboratory, not in the home or in a mobile facility, despite major marketing and lobbying efforts by the Sleep diagnostic and therapeutic device manufacturers. However, at a recent CMS meeting on September 12, 2007 the MedCAC committee members appear to have voted in favor of approving in unattended portable home testing for CMS beneficiaries. A final decision is expected by December 14, 2007.

The center for Medicare and Medicaid Services (CMS) declared in 2005 that;

"In order for Medicare to cover continuous positive airway pressure (CPAP) under our current NCD, Publication 100-03, Medicare National Coverage Determinations Manual, section 240.4, an individual must have obstructive sleep apnea (OSA) as demonstrated by polysomnography done in a facility-based sleep study laboratory. We received a request to expand the current NCD to allow other diagnostic tests to be used to diagnose OSA.

The evidence is not adequate to conclude that the use of unattended portable multi-channel sleep testing with a minimum of 7 monitored channels including EEG, EOG, EMG, ECG or heart rate, airflow, respiratory effort, and oxygen saturation (Type II Devices based on the 1994 ASDA classification) is reasonable and necessary in the diagnosis of OSA and these tests will remain non-covered for this purpose.

The evidence is not adequate to conclude that the use of unattended portable multi-channel sleep testing with a minimum of 4 monitored channels including ventilation or airflow, heart rate or ECG, and oxygen saturation (Type III Devices based on the 1994 ASDA classification system) is reasonable and necessary in the diagnosis of OSA and these tests will remain non-covered for this purpose" - The center for Medicare and Medicaid Services Website, 2005.

Current Home Sleep Monitoring Market

Unattended home sleep monitoring is offered in some U.S. regions depending on the major private payors' reimbursement guidelines. Cigna and Blue Cross Blue Shield, two major health insurance providers, do reimburse for unattended home sleep monitoring conditionally in certain regions.

Based on Cigna and Blue Cross Blue Shield guidelines, unattended portable recording for the assessment of OSA is an acceptable alternative to standard PSG in the following situations:

Patients with severe clinical symptoms that are indicative of a diagnosis of OSA and when initiation of treatment is urgent and standard PSG is not available

- For patients who are unable to be studied in the sleep laboratory
- For follow-up after the diagnosis has already been established by standard polysomnography and therapy initiated
- For follow-up studies when diagnosis has been established by standard PSG and therapy has been initiated, mainly to evaluate the response to therapy.

Medicare's opposition to reimbursement of unattended sleep tests is mainly due of the absence of a trained technologist who, when present, is able to correct or make equipment adjustments.

The most common malfunction that occurs in a sleep study is poor signal quality. Either because the sensor is not applied correctly or it loosens during the study. Therefore, for unattended home sleep monitoring the placement of the sensors must be much more reliable and stable.

Meanwhile, many patients prefer performing the study in their own bed and are willing to redo the study should this be necessary. Since the portable in-home monitor has fewer channels than in-lab systems, fewer complications can arise during the study. Some sleep service providers have been able to perfect the unattended test and reduce the redo rate due to poor signal quality, down to less than 5%. Also, most in-home providers agree to repeat the study at their cost when in the unlikely event a redo is required.

Successful Example of Home Sleep Monitoring - SleepQuest, Inc.

SleepQuest is one of the few organizations that have successfully implemented unattended home sleep monitoring for over the past ten years, despite the unfavorable reimbursement regulations. The key to SleepQuest's success lies in its comprehensive approach to Sleep Medicine. SleepQuest's in-home "Continuum of Care" approach encompasses screening, diagnosis, treatment and disease management. By reducing the complexity of the screening and diagnosis process, patients diagnosed with sleep apnea receive treatment under the supervision of renowned sleep medicine physicians.

Patients referred to SleepQuest by physicians, are sent home with a Type III sleep diagnostic device. The data gathered during the over-night home study is then scored and sent to the referring physician for the proper treatment prescription, at which point SleepQuest takes on the role of sleep care provider and disease management. This is done via helping the patient chose the right facial interface and flow generator and regular check-ups to ensure patient compliance.

The low-cost of operation and efficacy of "Continuum of Care" approach has allowed this disease management company to focus its resources more on the treatment of sleep apnea. Such approach has resulted in up to 93% treatment compliance rate, compared to the industry's less than 50% rate.

Dr. William C. Dement, a pioneering sleep researcher and the founder of the first sleep laboratory and American Academy of Sleep Medicine, serves as the Company's Chief Scientific Officer and recently presented on behalf of the Company at the CMS MedCAC meeting in Baltimore, MD on September 12, 2007. The committee members appear to have voted in favor of allowing home sleep testing for CMS beneficiaries and, as mentioned earlier, a final decision will be made by December 14, 2007.

Although, Medicare does not yet recognize unattended sleep studies as medically necessary and therefore doesn't reimburse for the procedure, SleepQuests' home sleep monitoring system does receive reimbursement from other major payors, such as Blue Cross of California, Pacificare, Kaiser, Health Net and a number of managed care organizations. The cost of an in-home

test is roughly one-third of an in-lab test so patients benefit from lower co-pays and insurance companies benefit from a lower cost per study.

In addition, the company is currently contracted with CMS, Blue Shield of California and United Health Care as well as others for the treatment devices for sleep apnea sufferers. At present, the company has amassed 142 million lives under contract in the United States in which they can either provide testing or treatment and in some cases both services. With the pending change in reimbursement, SleepQuest could add these companies to its list of in-home companies with whom it provides testing services.

What If Medicare Covers Unattended Home Sleep Monitoring

With the latest innovative ambulatory PSG systems, the accuracy of unattended home sleep monitoring have improved significantly, as indicated in numerous studies performed annually.

If Medicare decides to cover home sleep monitoring in the near future it may mostly be limited to physicians involved with established sleep labs. Medicare is expected to implement a similar requirement for unattended home sleep monitoring as Cigna and Blue Cross Blue Shield.

The approval of conditional unattended home sleep monitoring is not expected to increase the sleep service providers' market revenues by more than 30 percent. Obviously, the reimbursement amount would not be as high as procedures performed in sleep labs. On the other hand, the conditions that make the unattended sleep studies acceptable by Medicare, would limit the number of extra studies performed.

The increase in the number of patients diagnosed with sleep apnea is more significant than the increase in the revenues for the sleep service providers. First, the additional diagnosed patients will drive the sales of sleep apnea therapeutic markets, especially CPAP therapy. Second, considering the numerous side effects of sleep apnea, such as cardiovascular complications, timely detection and treatment of sleep apnea will prevent the high cost of treatment for conditions caused by sleep apnea.

Figure 2 reflects the projected sleep service providers' revenue forecasts with and without Medicare reimbursement for unattended home sleep monitoring.

Ultimately, if Medicare decides to reimburse for unattended sleep studies, this will most likely include level III tests. It is not expected that sleep tests done with level IV devices such as overnight oximetry, the SleepStrip and ApneaLink to be covered.

Figure 2: U.S. Sleep Service Provider Market Revenues Forecast with and without Medicare Reimbursement of unattended Home Sleep

Year	Without Reimbursement (\$ Million)	With Reimbursement in 2007 (\$ Million)
2006	2171	2171
2007	2560	2560
2008	3030	3939
2009	3588	4664
2010	3925	5102
2011	4435	5765
Compound Annual Growth Rate (2006-2011):	15.4%	21.5%

Source: Frost & Sullivan

Company Spotlight: Compumedics LTD.

With US headquarters in El Paso, TX, Compumedics offers a diverse product portfolio covering a wide range of sleep disorder monitoring and neuro-diagnostic solutions for clinical and research purposes.

Compumedics five business divisions include:

- Sleep
- NeuroScan
- NeuroMedical Supplies
- NeuroScience
- DWL

The Sleep division offers innovative computer based diagnostic technologies in the areas of Sleep, Neurology and Cardiology-Respiratory. Compumedics' Sleep Polysomnography (PSG) systems sub-division encompasses an impressive collection of sleep diagnostic solutions configured for Laboratory, Portable and Ambulatory applications.

Somte PSG

Currently awaiting FDA clearance, the Somte is a patient-worn ambulatory full-PSG system that can be utilized for both attended and unattended sleep studies. This self-contained pre-programmed device includes a pre-configured LCD and requires no PC or lap top connection and can record up to 2G data over 24 hours.

Company Milestones

2007: Compumedics is awarded the 2006 Frost and Sullivan European Sleep Diagnostics and Associated Data Management Systems Market Technology Leadership of the Year Award.

2005: Compumedics establishes Compumedics DWL for blood flow Doppler technology.

2004: Compumedics acquires German based DWL Elektronische Systeme GmbH, global leader in brain blood flow diagnostics.

2003: Compumedics received notification from the FDA that its Somté System have received 510(k) clearance.

2002: Compumedics and Dräger Medical Germany signed letter of intent for the supply and development of sleep diagnostic technology.

2001: Compumedics received notification from the FDA that its Siesta Systems have received 510(k) clearance.

2000: Compumedics received notification from the FDA that its E-Series EEG Systems have received 510(k) clearance.

Compumedics LTD

7850 Paseo del Norte,
El Paso, Texas 79912

Reimbursement & Regulatory News

Recent FDA Approval Announcements:

Date	Company	Product Name	Function	Designation
12-Jun	Eurand N.V. (Dayton, OH)	Zentase (TM)	Treatment of exocrine pancreatic insufficiency (EPI)	Filed new drug application (NDA)
12-Jun	CEL-SCI Corporation (Vienna, VA)	Multikine (R)	Used as a neoadjuvant therapy in patients with squamous cell carcinoma of the head and neck	Granted orphan-drug designation
12-Jun	GlaxoSmithKline (GSK) (Philadelphia, PA)	Oral hycamtin (R)	Treatment for relapsed small cell lung cancer (SCLC)	Priority review granted for new drug application (NDA)
13-Jun	Chroma Therapeutics Limited (Oxford, UK)	CHR-2797	Treatment of acute myeloid leukemia	Approved its investigational new drug (IND) application
13-Jun	Lupin Pharmaceuticals, Inc. (Baltimore, MD)	Trandolapril tablets	Treatment of hypertension	Granted final approval
15-Jun	Sanofi-aventis (Bridgewater, NJ)	Apidra (R)	Treatment of glycemia	Full approval

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<p>Healthcare & Life Sciences IT</p> <ul style="list-style-type: none"> • Electronic medical records • Data and storage management • Emerging wireless technologies 			
<ul style="list-style-type: none"> • Acute Care Information Systems • CPOE • Enterprise clinical information systems 		<ul style="list-style-type: none"> • Claims management through IT • RFID in Healthcare • RHIOs 	

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CONTACT US			
Monali Patel Director, Healthcare Research t) 650.475.4506 e) mpatel@frost.com	Ryan Goulding VP, Healthcare Consulting t) 650.475.4508 e) rgoulding@frost.com	Stephen Mohan VP, Healthcare Sales t) 210.348.1032 e) stephen.mohan@frost.com	Greg Caressi VP, Healthcare & Life Sciences t) 650.475.4555 e) gcaressi@frost.com