American Academy of Otolaryngology—Head and Neck Surgery
Working for the Best Ear, Nose, and Throat Care
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January 2, 2007

Steve Phurrough, MD
Director of Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: National Coverage Determination for Obstructive Sleep Apnea

Dear Dr. Phurrough:

The following is a request to reassess the National Coverage Determination (NCD) for diagnosis and treatment of obstructive sleep apnea (OSA) to include home sleep testing as an alternative to polysomnography (PSG) by physicians licensed to practice medicine.

OSA is a prevalent, morbid, and mortal condition, and it is a progressive illness that adversely affects the health and well being of those afflicted. It causes daytime sleepiness, increased motor vehicle and job related accidents, and detracts from "feeling well" and "functioning well" at home and at work. The most important organic co-morbidities, including diabetes, heart failure, obesity, and hypertension, are expensive to treat. OSA is a substantial contributing factor to these conditions, and if diagnosed and treated, it will help control the illness, improve the patient's health and well being, and reduce expense to the US healthcare system. The full list of co-morbidities for sleep disordered breathing (SDB) is listed in Table I on the CD-ROM provided.

Diagnosis of SDB is restricted by requirement for in-lab polysomnography, an expensive test that is not widely available.

Home sleep testing is a validated alternative and an important step in improving recognition and control of OSA. Alternate and even less expensive paradigms for diagnosis and treatment are currently being explored. Home sleep testing is an important first step in promoting and working toward these alternatives. Additionally, the current reimbursement paradigm of high reimbursement for PSG and low reimbursement for treatment is not only a waste of precious resources, but also discourages more appropriate focus on rapid diagnosis and effective treatment for OSA.

The prevalence of SDB is well studied and documented. The prevalence increases with age and weight. OSA is generally defined as an apnea/hypopnea index (AHI) of > 5 events per hour during sleep. Using this definition applied to federal workers in Wisconsin, the prevalence was reported as 24% for males and 9% for females. Using a more restrictive AHI of ≥ 15, the prevalence was reported as 4% for adult males and 2% for adult females. (Young, 1993, pp. 1230-1235)

Several studies document the prevalence increases with age and certainly support a prevalence of 10% or more for Medicare patients, ages 65 and older (Young, 2004, pp. 2013-2016).

The economic burden of untreated OSA is substantial. A recent estimate of motor vehicle accidents related to sleep apnea shows that more than 800,000 drivers were involved in OSAS-related motor-vehicle collisions in the year 2000, costing $15.9 billion and 1,400 lives (Sassani, et al., 2004, pp. 453-458). A recent review of the economic costs of sleep disorders in Australia shows that the total financial cost of OSA is 0.8% of the Australian gross domestic product. The cost of suffering is 1.4% of the total burden of disease in Australia (Hillman, Murphy & Pezzullo, 2006, pp. 299-305). Given the

prevalence of SDB and the economic health and personal consequences, it is incumbent upon CMS to lead the way to improve diagnostic and treatment paradigms. The full articles regarding this issue are included in Appendix 1.

New paradigms for diagnosis and treatment are being explored. With over 50 years experience diagnosing and treating SDB, clinical suspicion is highly accurate. As CPAP is virtually not tolerated by anyone without sleep apnea, its use measured by compliance is an accurate confirmation of the illness. Investigators are now looking at treating patients suspect for SDB with CPAP. Patients who comply are diagnosed and put on treatment. Those who do not comply require a sleep test and further consideration. Three peer reviewed scientific publications support this approach. Each of these studies has taken a group of patients with history and physician examination suspect for OSA and randomized them into 2 groups. One group underwent PSG and then CPAP therapy. The second group bypassed the PSG and went directly onto CPAP therapy. The measured outcome was compliance and was identical for both paradigms. These 3 studies demonstrate that formal attended laboratory based PSG does not improve outcome over unattended home sleep study. Full articles on these studies can be found in appendix 2.

Current resources are inadequate to meet the demand for polysomnography, resulting in a long wait for patients to access care. This study, (Huskins, Craig A., 2005, pp. 500-505), aimed to evaluate the role of arbitrary-pressure continuous positive airway pressure (CPAP) as a method to reduce delays in commencing treatment. The study was of an open, randomized, parallel design. Ninety-one subjects with obstructive sleep apnea syndrome were randomized to either arbitrary-pressure CPAP based on body mass index

before treatment polysomnography or to CPAP at settings determined by polysomnography. Both interventions resulted in similar improvements in clinical outcomes as determined by Epworth Sleepiness Score, Short Form-36 Quality of Life questionnaire, objective compliance, and subjective attitudes to treatment. There was higher sleep efficiency at treatment polysomnography in the group commenced at arbitrary pressure (81.8 +/- 10.1% [mean +/- SD] compared with 72.2 +/- 18.0%, p = 0.01). Subjects unable to tolerate CPAP were identified by the use of arbitrary pressure, leading to a reduction in the proportion of "wasted" treatment polysomnograms (studies performed in subjects not persisting with treatment) relative to commencing therapy after treatment polysomnography (3 of 39 compared with 12 of 35, p = 0.01). This approach to initiating treatment with CPAP appears feasible when there are long waiting lists for polysomnography.

This study (Whitelaw,Brand & Felmons, 2005), prospectively randomized individuals with a history suggestive of symptomatic obstructive sleep apnea into 2 groups. One group was tested by level IV sleep studies, specifically oximetry. The second group was tested by conventional level I sleep testing, specifically PSG. Based on the history, the physical examination and the level I or level IV sleep test, 288 patients were treated for 4 weeks with auto-adjusting continuous positive airway pressure. Success was defined as an increase greater than 1.0 in Sleep Apnea Quality of Life Index. The correct prediction rate was 0.61 with polysomnography and 0.64 with home monitoring (not significant). The study concluded that the ability of physicians to predict the outcome of continuous positive airway treatment in individual patients is not significantly better with polysomnography than with home oximeter-based monitoring.

Treatment of obstructive sleep apnea syndrome (OSA) is often delayed because polysomnography (PSG), the recommended standard diagnostic test, is not readily available. (Senn,Brack, Russi & Bloch, 2006, pp. 67-75), evaluated whether the diagnosis of sleep apnea could be inferred from the response to a treatment trial with nasal continuous positive airway pressure (CPAP). The study consisted of 76 sleepy snorers who were consecutively referred for sleep apnea evaluation. CPAP treatment trial over 2 weeks was done as an initial diagnostic test and compared with polysomnography. The main outcome was diagnostic accuracy of the CPAP trial. The trial result was positive if the patient had used CPAP for > 2 h per night and wished to continue therapy, which suggested sleep apnea. The trial was evaluated in terms of predicting an obstructive apnea/hypopnea index (AHI) > 10/h during PSG performed for validation, and in terms of identifying sleep apnea patients treated successfully over > 4 months. Forty-four of 76 patients (58%) had sleep apnea as confirmed by an AHI > 10/h. The CPAP trial predicted sleep apnea with a sensitivity of 80%, a specificity of 97%, and positive and negative predictive values of 97% and 78%, respectively. In 35 of 76 sleep apnea patients (46%) with positive CPAP trial results, PSG could have been avoided. These patients were prescribed long-term CPAP therapy. After 4 months, 33 of 35 patients (94%) still used CPAP, and their symptoms remained improved. These patients were identified by the CPAP trial with positive and negative predictive values of 92% and 100%, respectively. In a selected population, a CPAP trial may help to diagnose OSA, to identify patients who benefit from CPAP, and to reduce the need for PSG.

The whole discussion seems to come to the question of whether home sleep testing is a valid alternative to PSG. PSG has never been established as a gold standard

in the diagnosis of SDB, and in fact, the current practice of split night studies has never been validated against the historical practice of full night PSG. CMS uses the measure of the AHI or respiratory distress index (RDI) as the criteria for diagnosis and therefore treatment. Home sleep testing and PSG use the exact same equipment to measure respiration. The other PSG measures, most notably sleep stages which are measured by EEG, are not used for the diagnosis of garden variety OSA. Therefore, the added channels of the PSG make no contribution to the diagnosis or treatment. SDB is grossly under diagnosed in large part due to a limited number of sleep diagnostic facilities. This request reaffirms the validity and importance of home sleep testing.

Comparing PSG to home sleep studies:

- Patients sleep in a lab rather than testing in their own home and bed.
- Many PSGs employ split night studies so 2-4 hours are devoted to diagnosis and 2-4 hours are devoted to setting a CPAP titration pressure, inadequate time periods for both studies, and neither validated against the historical standard of 1-2 nights PSG and the 1 night CPAP titration.
- PSG uses the same respiratory detectors, oximeter, chest and abdomen sensors and position sensors, as do multichannel home sleep tests.
- PSG provides EEG information regarding arousals yet this information has high interpreter variability and ultimately diagnoses are made first by the respiratory information, second by the patient's history and physical examination, and third by the oximetry recordings.

So in fact, EEG and arousals make little difference. Sleep stages, time and efficiency are useful information, but not necessary to make a diagnosis. CPAP pressures are determined by a single night 2-4 hours manual titration and a CPAP pressure calculated to last the patient for the upcoming years with no regard to night-to-night variability or pressure requirement changes overtime.

Home sleep tests:

- Use the same respiratory equipment and analysis as do PSG.
- Use the same oximetry equipment and analysis as do PSG.
- Use the same chest and abdominal equipment as do PSG.
- Use the same position sensors as do PSG.
- Report the same AHI except uses a denominator of total time in bed, rather than total time asleep, which for these with SDB seems not to be an issue.

Therefore, the outputs from PSG and home sleep tests are not very different. In addition, home sleep tests have several advantages over PSG:

- They are performed in the patient's own home, bed and privacy. The wires, leads etc., are less numerous and the patient's sleep is more comfortable and therefore indicative of their normal sleep.
- Home sleep tests are substantially less expensive; 25 to 30% the cost of PSG.
- Home sleep diagnostic dispensing and titration is easier than PSG lab setups and therefore can be performed by a greater number of practitioners, including all pulmonologists, cardiologists, anesthesiologists, and head and neck surgeons.

The entire controversy comes down to single issue: if in fact PSG is the most accurate sleep diagnostic paradigm (this issue is easily argued to the converse), are home sleep tests sufficiently accurate to be used for routine sleep apnea/SDB cases? It appears that the primary focus of discussion pro PSG is the efficacy of PSG vs. home sleep testing. There are numerous validation studies of home sleep testing versus PSG. A representative selection are listed and summarized below in chronological order of publication [1991-2006{a-s}]. Their full articles are included in Appendix 3.

List of Reviewed Articles on Home Sleep Testing Versus PSG Testing:

"Measurement of Sleep-related Breathing Disturbances in Epidemiologic Studies. Assessment of the Validity and Reproducibility of a Portable Monitoring Device",

S Redline et al. (Providence, RI) Chest 1991; 100:1281-1286. A group of 20 patients underwent simultaneous PSG and portable monitoring (PM) by EdenTec. 5 patients had different day PSG and PM. There was no difference in results so 25 patients are analyzed together. RDI is the only endpoint reported. Mean RDI for PSG is 37 and for PM is 36. Correlation is r = 0.96. The authors conclude: "These findings suggest that measurement of the RDI with in-house monitoring provides a valid and highly reproducible index for assessment of sleep-related respiratory disturbances for use in epidemiologic studies of general populations."

"Validation of a Portable Sleep Apnea Monitoring Device" GC Man et al. (Alberta, Canada) Chest 1995; 108:388-393**.** One-hundred and four patients underwent simultaneous PSG and home sleep testing by a PolyG unit. The coefficient of correlation

for this apnea index was r = 0.94 and for apnea/hypopnea index was r = 0.97 using an AHI of 15 the sensitivity was 86% and the specificity was 95% and the overall accuracy was 92%. The authors conclude: "The PolyG monitoring device is useful in identifying patients without significant sleep apnea."

"Comparison of Polysomnography with ResCare AutoSet in the Diagnosis of the Sleep Apnoea/Hypopnoea Syndrome", PA Bradley et al. (Edinburgh, UK) Thorax 1995; 50:1201-1203. Thirty-one patients tested simultaneously with PSG and home sleep testing with Rescare AutoSet. There was good correlation with r = 0.85. The AutoSet gave a sensitivity of 100%, specificity of 92%. The authors conclude: "The AutoSet is clinically useful for diagnosing the sleep apnoea/hypopnea syndrome."

"A Laboratory Validation Study of the Diagnostic Mode of the AutoSet™ System for Sleep-Related Respiratory Disorders", B Fleury et al. (Paris, France) Sleep 1996; 19:502-505**.** The study looked at 44 patients (10 women) who underwent simultaneous PSG and home sleep testing with ResMed AutoSet. Apnea correlated with r = 0.98, For an AI of 20/hour the AutoSet was 100% sensitive and 88% specific. The authors indicate: "That the AutoSet system, in its diagnostic mode, is a useful tool for identifying patients with significant OSA apnea syndrome. The system is less useful in patients with mild to moderate sleep disordered breathing.

"Comparison of a Limited Computerized Diagnostic System (ResCare AutoSet™) with Polysomnography in the diagnosis of obstructive sleep apnoea syndrome", JL Kiely et

al. (Dublin, Ireland) Eur Respir *J* 1996; 9:2360-2364**.** Thirty-six patients (27 males and 9 females) with OSA underwent simultaneous home sleep testing with ResCare AutoSet and Oxford SAC™ PSG. Correlation was high with r = 0.92. Based on an AHI of 15 the positive predictive value for AutoSet was 86%. The authors conclude: "That the AutoSet system is a sensitive and easy to use system, which facilitates screening for obstructive sleep apnoea with a reasonable degree of accuracy."

"Comparison of ResMed AutoSet (version 3.03) with Polysomnography in the Diagnosis of the Sleep Apnoea/Hypopnoea Syndrome", M Gugger (Berne, Switzerland) Eur Respir J 1997; 10:587-591. Sixty-seven patients underwent simultaneous PSG and home sleep testing with ResMed AutoSet. Correlated with r = 0.95. At 20 events/hour, the sensitivity was 97% and a specificity of 77%.

"Simultaneous Laboratory-Based Comparison of ResMed Autoset with Polysomnography in the Diagnosis of Sleep Apnoea/Hypopnoea Syndrome", P Mayer et al. (Paris, France) Eur Respir J 2000;16:123-127. Ninety-five patients underwent simultaneous PSG and home sleep testing with AutoSet. Correlation between AHI was good with r = 0.87. For an AHI $\geq$ 15 the AutoSet had a sensitivity of 92% and a specificity of 79%.

"Comparison of a Portable Respiratory-only Polygram with Simultaneous Polysomnography", G Alymow et al. (Essen, Germany) Poster 659 – International Sleep Meeting – Sydney Australia *Circa* 1999 (poster not available). Seventy-nine patients

were tested simultaneously with PSG and Embletta, Flaga. AHI correlated with r = 0.9. At an AHI of15 events/hour, the sensitivity was 97% and the specificity 93%.

"Evaluation of a Portable Respiratory Recording Device for Detecting Apnoeas and Hypopnoeas in Subjects from a General Population", E Ballester et al. (Barcelona, Spain) Eur Respir J 2000; 16:123-127. In this study, 116 patients underwent simultaneous PSG and home sleep testing with Sibel Home-300. At an AHI of >10, the sensitivity was 95% and the specificity was 92%. For an AHI of 30 the sensitivity was 100% and the specificity was 97%. The authors conclude: "These data suggest that the portable respiratory recording device is an effective device to identify apnoeas and hypopnoeas in a general population and is therefore a suitable device to use in epidemiological studies."

"The Validation of a Portable 3-channel Recording System (Oxyflow, Edentec) for the diagnosis of the Sleep Apnea Syndrome", GA Jimenez et al. (Cantabria, Santander) Arch Bronconeumol 2000;36:7-12 (article not available). This study tested 62 patients by simultaneous PSG and a home sleep test by EdenTec. Analysis of correlation was assessed using receiver operating characteristic curves (ROC). "The index of respiratory disturbance per hour of analysis with desaturation events > 4% was the parameter with the largest area under the ROC curve (0.90 for AHI $\geq$ 10; 0.94 for AHI $\geq$ 15 and 0.96 for AHI $\geq$ 30)."

"Clinical Validation of the Bedbugg™ in Detection of Obstructive Sleep Apnea", D Claman et al. (San Francisco, CA) USA *Otolaryngol Head Neck Surg* 2001; 125:227-

230**.** In this study, 42 patients underwent simultaneous PSG and home sleep test Bedbugg™, aka NovaSom. The correlations for the AHI was r = 0.96. At an AHI of >15 sensitivity was 86%. Specificity for AHI <15 was 95%. The authors conclude: "The Bedbugg™ device provides an accurate assessment of the apnea-hypopnea index."

"Comparison of the NovaSom QSG™, a new sleep apnea home-diagnostic system, and polysomnography", JA Reichert et al. (Redwood City, CA) USA *Sleep Medicine* 2003; 4: 213-218. In this study, 51 SDB patients underwent one night of simultaneous PSG and NovaSom, a.k.a. Bedbugg, and three nights of home sleep testing. With an AHI ≥15 for the in-lab studies, the sensitivity was 95%. For the home study the sensitivity was 91% and the specificity was 83%. This low specificity is based on 4 cases. If the AHI cutoff were 18 the specificity and positive predictive values would have been 100%. In any case an astute clinician, based on sleep test, history and physical examination would have made a proper diagnosis. The intra class correlation for the three nights was 0.88. In addition to positive correlation with simultaneous PSG, this study shows the correlation with traditional PSG to asynchronous home sleep testing – quite frankly validating both testing paradigms. Two other technologies have reported similar AHI's, but by employing different monitors.

"Evaluation of a Portable Device Based on Peripheral Arterial Tone for Unattended Home Sleep Studies", A Bar et al. (Haifa, Israel) *Chest* 2003; 123:695-703**.** The WatchPAT 100 is a portable home sleep test machine based on peripheral arterial tone. 102 subjects underwent simultaneous PSG and WP100 testing. Correlation for AHI < 10

was r = 0.82 and for AHI < 20 r = 0.87. The authors conclude: "The WP100 may offer an accurate, robust, and reliable ambulatory method for the detection of OSAS, with minimal patient discomfort.

"Validation of an Autoscoring Algorithm to Detect Obstructive Sleep Apnea",

MA Coyle et al. (California, Texas, Illinois), presented at the APPSS 2003 Chicago International Conference in June 2003**.** Another validated unattended home sleep diagnostic unit is the Life Shirt™ by Vivo metrics. This unit uses respiratory inductance plethysmography, assessing changes in lung volume. The patient wears a vest with the inductance electrodes and EKG electrodes plus a finger oximeter. 10 male patients underwent in-house PSG on one night at home, and the LifeShirt on another. The mean AHI's were 28 +/-21 and 27 +/-21 respectively. By regression analysis the r = 0.97. At an AHI = 5 sensitivity and specificity were 100%. At an AHI = 15, sensitivity was 86% and specificity 100%.

"Evaluation of a portable device for diagnosing the sleep apnoea/hypopnoea syndrome", K Dingli et al. (UK). Eur Respir J. 2003 Feb;21(2):253-9. Waiting times for hospital-based monitoring of the obstructive sleep apnoea/hypopnoea syndrome (OSAHS) are rising. This study tested whether Embletta, a new portable device, may accurately diagnose OSAHS at home. A synchronous comparison to PSG was performed in 40 patients and a comparison of home Embletta studies with in-laboratory polysomnography was performed in 61 patients. In the synchronous study, the mean difference (polysomnography-Embletta) in apnoeas+hypopnoeas (A+H) x h(-1) in

bed was 2 h(-1). In comparison to the apnoea/hypopnoea index (AHI) x h(-1) slept, the Embletta (A+H) x h(-1) in bed differed by 8 x h(-1). These data were used to construct diagnostic categories in symptomatic patients from their Embletta results: "OSAHS" (> or = 20 (A+H) x h(-1) in bed), "possible OSAHS" (10-20 (A+H) x h(-1) in bed) or "not OSAHS" (<10 (A+H) x h(-1) in bed). In the home study, the mean difference in (A+H) x h(-1) in bed was 3 x h(-1). In comparison to the polysomnographic AHI x h(-1) slept, the Embletta (A+H) x h(-1) in bed differed by 6 +/- 14 x h(-1). Using the above classification, all nine patients categorized as not OSAHS had AHI < 15 x h(-1) slept on polysomnography and all 23 with OSAHS on Embletta had an AHI > or = 15 on polysomnography, but 18 patients fell into the possible OSAHS category potentially requiring further investigation and 11 home studies failed. Most patients were satisfactorily classified by home Embletta studies but 29 out of 61 required further investigation. The study suggested a 42% saving in diagnostic costs over polysomnography if this approach were adopted.

"Using a Wrist Worn Device Based on Peripheral Arterial Tonometry to Diagnose Obstructive Sleep Apnea: In-Laboratory and Ambulatory Validation", SD Pittman et al. (Boston, MA, US and Vancouver, BC, Canada) *Sleep* 27.5 (2004):923-933. Thirty participants completed 2 overnight diagnostic studies with the WatchPAT 100 test device: 1 night in-laboratory with concurrent PSG and 1 night in the home with only WatchPAT. For the in-lab comparison, there was high concordance between RDI.C and PAT RDI (ICC = 0.88, mean difference 2.5 [18.9] events per hour); RDI.M and PAT ODI (ICC = 0.95, mean difference 1.4 [12.9] events per hour; and sleep time (ICC =

0.70, mean difference 7.0 [93.1] minutes) between the test device and PSG. For the HOME-LAB comparison, there was good concordance between RDI.C and PAT RDI (ICC = 0.72, mean difference 1.4 [30.1] events per hour) and RDI.M and PAT ODI (ICC = 0.80, mean difference 1.6 [26.4] events per hour) for the test device and PSG. Home studies were performed with no technical failures. The authors concluded: "In a population of patients suspected of having obstructive sleep apnea, the WatchPAT can quantify an ODI that compares very well with Medicare criteria for defining respiratory events and an RDI that compares favorably with Chicago criteria for defining respiratory events. The device can be used with a low failure rate for single use in the lab and home for self-administered testing."

"Assessment of a Wrist-Worn Device in the Detection of Obstructive Sleep Apnea", NT Ayas et al. (Massachusetts) Sleep Medicine 4 (2003): 435-442. Thirty adult subjects with and without suspected OSA simultaneously had a standard in-laboratory polysomnogram (PSG) and wore the WatchPAT100 during a full-night recording. PSG sleep and respiratory events were scored according to standard criteria. WatchPAT data were analyzed with an automated computerized algorithm which calculated the frequency of respiratory events per hour of actigraphy measured sleep using a combination of peripheral arterial tonometry (PAT) signal attenuation, desaturation on pulse oximetry, and changes in heart rate. This yielded a PAT apnea hypopnea index (AHI). Mean age was 47.0 ^ 14.8 years, mean body mass index 31.0 ^ 7.6 kg/m2, mean PSG AHI 23 ^ 23.9 events per hour, and mean PAT AHI 23 ^ 15.9 events per hour. There was a significant correlation between PAT AHI and AHI by PSG (r ¼ 0:87, P, 0:001). To

assess sensitivity and specificity of WatchPAT, we constructed receiver operator characteristic curves using a variety of AHI threshold values (10, 15, 20, and 30 events per hour). Optimal combinations of sensitivity and specificity for the various thresholds were 82.6/71.4, 93.3/73.3, 90.9/84.2, and 83.3/91.7, respectively. The WatchPAT is a device that can detect OSA with reasonable accuracy. Thus, the WatchPAT may be a useful method to diagnose OSA.

"Validation a Portable Monitoring Device for Sleep Apnea Diagnosis in a Population Based Cohort Using Synchronized Home Polysomnography", D Zou et al. (Sweden) SLEEP 29.3 (2006): 367-374. The objective of this study was to assess the accuracy of a portable monitoring device based on peripheral arterial tonometry to diagnose obstructive sleep apnea (OSA) and to propose a new standard for limited-channel device validation using synchronized polysomnography (PSG) home recordings and a population-based cohort. 98 subjects (55 men) consecutively recruited from the Skaraborg Hypertension and Diabetes Project underwent single-night, unattended PSG and WatchPAT 100 (WP_100). The WP_100 records peripheral arterial tone, heart rate, oxygen saturation and actigraphy for automatic analysis of respiratory disturbance index (RDI), apnea-hypopnea index (AHI), oxygen desaturation index (ODI), and sleep-wake state. The accuracy of WP_100 in RDI, AHI, ODI, and sleep-wake detection was assessed by comparison with data from simultaneous PSG recordings. The mean PSG-AHI in this population was 25.5 ± 22.9 events per hour. The WP_100 RDI, AHI, and ODI correlated closely (0.88, 0.90, and 0.92; $p < .0001$, respectively) with the corresponding indexes obtained by PSG. The areas under the curve for the receiver-operator characteristic

curves for WP_100 AHI and RDI were 0.93 and 0.90 for the PSG-AHI and RDI thresholds 10 and 20 ($p < .0001$, respectively). The agreement of the sleep-wake assessment based on 30-second bins between the 2 systems was 82 ± 7%. The WP_100 was reasonably accurate for unattended home diagnosis of OSA in a population sample not preselected for OSA symptoms. The current design, including simultaneous home PSG recordings in population-based cohorts, is proposed as a reasonable validation standard for assessment of simplified recording tools for OSA diagnosis.

"Validation of microMESAM as Screening Device for Sleep Disordered Breathing", Y Wang et al. (Germany) Pneumologie 57 (2003): 734-740. Polysomnography (PSG) is considered the gold standard in the diagnosis of sleep disordered breathing (SDB). Because of costs and labor-intensity it is, however, performed last in graded diagnostic protocols that often involve respiratory pressure measurements via nasal canula as an alternative sensitive method for SDB detection. MicroMESAM, a newly developed screening device based on this method, allows automated analysis of apnoeas, hypopnoeas and snoring. To validate the device, we first compared signal quality of MicroMESAM flow-time curves with those generated by a pneumotachograph. Then, in 50 patients suspected of having obstructive sleep apnoea, we compared MicroMESAM-generated automated analysis with manually scored results of simultaneously collected PSG data. MicroMESAM-generated flow-time curves correspond with pneumotachograph-generated curves in 95% of respiratory events, resulting in less 4 +/- 2% difference in respective area under the curves. MicroMESAM and PSG generated numbers of apnoeas ($r = 0.99$) and hypopnoea ($r = 0.81$), as well as AHI ($r = 0.98$)

correlated highly, displaying mean differences in AHI of 3.8, and in 1.96 sigma interval of + 11.1 to - 3.5/h. Sensitivities and specificities for SDB were 97.3%, respective 46% at SDB-defining AHI of 5, and 100%, respective 87.5%, at SDB-defining AHI of 10. MicroMESAM-generated flow-time curves correspond well with pneumotachograph generated curves, producing automated AHIs that are highly sensitive in detecting SDB. MicroMESAM, therefore, is suitable as a screening device for SDB.

In summary, **19** studies including **1,173** patients involving **10** different home sleep tests and involving **11** different countries demonstrate excellent correlation between PMHST and PSG. There are no reports of poor correlations, error in diagnosis or adverse outcomes as a result of PMHST.

Further strengthening the urgency for improved capability to diagnose SDB is the recognition that SDB can result in an early and untimely death. A study published in the Journal of Internal Medicine in 1991 brought this to the world's attention, reporting that nighttime cardiovascular death was more common among those who snored than for those who did not: "Habitual snoring was found to be a risk factor for morning death ($P<0.01$)." The European Respiratory Journal in 2005 reported the hazard of mortality in sleep apnea increases with apnea severity as indexed by the respiratory disturbance index (RDI). The New England Journal of Medicine in 2005 also reported: "People with obstructive sleep apnea have a peak in sudden death from cardiac causes during the sleeping hours, which contrasts strikingly with the nadir of sudden death from cardiac causes during this period in people without obstructive sleep apnea and in the general population."

The bottom line is:

- Sleep testing is easily and accurately performed by numerous home sleep test paradigms.
- Home sleep testing reduces cost.
- Home sleep testing improves access.
- Home sleep testing is reimbursed by private sector "Fee For Service Insurers."
- Multichannel home sleep testing is currently approved by CMS carriers in areas where in-lab PSG is not available. Home sleep testing is used by other health programs such as the VA Healthcare System and by Kaiser Permanente.
- Home sleep testing should be approved as a valid SDB test paradigm.

An example of the inconsistency of the current PSG/SDB policy is to consider the diagnosis and treatment of hypertension, another prevalent, morbid mortal illness. If the current sleep paradigm were employed for this illness, all patients suspected of hypertension (HTN) would be diagnosed only by cardiologists exclusively in 24 hour in-house laboratories where blood pressure would be continuously monitored for 24-hours. The cardiologist would then prescribe treatment. Primary care physicians would no longer be involved in the diagnosis or the treatment. Certainly an interesting model, probably not beneficial to the patient and certainly, as with SDB, would leave the vast majority of HTN patients undiagnosed.

We request that CMS reconsider the existing National Coverage Determination policy regarding home sleep testing for OSA. We have presented this proposal to both the American College of Cardiology (ACC) and the American Society of

Anesthesiologists (ASA). The ACC currently has this proposal under review for comment. The ASA, in a reply letter to the AAO-HNS, noted that "both pediatric and adult patients with OSA – even if asymptomatic – present special challenges in anesthetic care that must be systematically addressed to minimize the risk of perioperative morbidity or mortality. Pre-procedure diagnosis of OSA and assessment of its severity aid in planning preoperative, intraoperative and postoperative anesthetic management." The ASA also indicated that it is their member's experience that timely availability of sleep studies is inadequate in many areas, and that a valid and reliable test for OSA that is more readily available will improve their ability to safely care for such patients. While the ASA's Task Force on Perioperative Management of Patients with Obstructive Sleep Apnea did not review or assess the evidence on the sensitivity, specificity or reliability of home sleep studies, they believe that if found to be a valid diagnostic tool, a coverage policy that supports access to this methodology is in the best interest of the patients they serve.

If you have any questions about this request, please contact Mrs. Linda Ayers, MHCM, Director of Health Policy at (703) 684-4286 or layers@entnet.org.

Sincerely,

David R. Nielsen MD

David R. Nielsen, MD, FACS
Executive Vice President and CEO

Table I. Prevalence of SDB Co-Morbidities

Category	Condition	Prevalence
General	Male	24%
	Female	9%
Obesity	Male	90%
	Female	50%
Cardiac	Hypertension	All: 35% Uncontrolled: 80%
	Congestive heart failure	50%
	Coronary artery disease	30%
	Arrhythmias	50%
Respiratory	Pulmonary hypertension	20%
	Asthma	15%
Neurologic	Stroke	67%
	Headache	General: 49% In the morning: 74%
Metabolic	Insulin resistance	
	Metabolic syndrome	
Gastrointestinal	Gastroesophageal reflux disease	15%
Genitourinary	Erectile dysfunction	100% (only significant for severe SDB)
	Nocturia, enuresis	48%
Motor Vehicle Accident		7 times normal
Excessive Daytime Sleepiness		10%