

**Motor Carrier Safety Advisory Committee (MCSAC) and Medical Review Board (MRB)
Task 11-05: Recommendations for Obstructive Sleep Apnea (OSA) Regulatory Guidance**

Discussion Notes from January 4-5, 2012 MCSAC/MRB Subcommittee Meeting

Task 11-05: FMCSA requested that the MCSAC and MRB jointly provide information, concepts, and ideas the Federal Motor Carrier Safety Administration (FMCSA) should consider in developing regulatory guidance for motor carriers, commercial vehicle drivers, and medical examiners on OSA and whether drivers with this condition should be medically certified to operate commercial motor vehicles (CMVs) in interstate commerce.

- *In addition, the Committees should recommend potential amendments to the current regulations to address this respiratory disorder.*
- *The ideas and concepts should take into account that the regulatory guidance may not be used to impose new requirements on drivers.*
- *The Committees should provide information about how to handle drivers with OSA in the short-term until the Agency can consider the MRB's recommendations for a long-term regulatory action.*
- *In preparing its letter report to the Agency, the Committee should, wherever possible, indicate whether the ideas or concepts identified are supported by peer reviewed studies.*

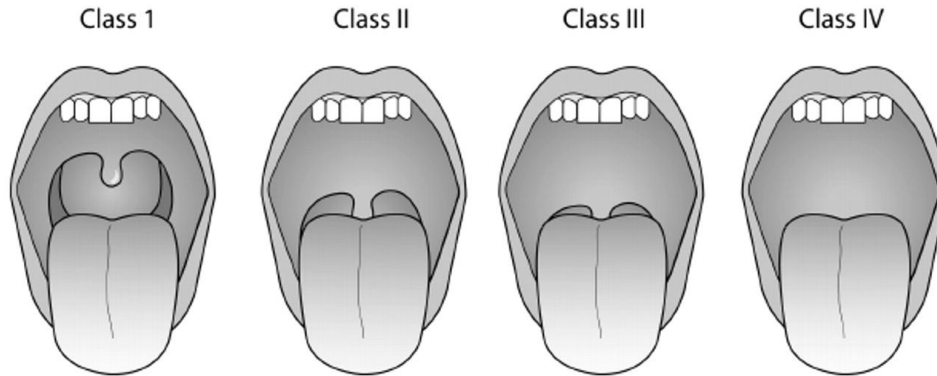
Key Questions for Addressing OSA and Driving

- I. Key Question #1: Are individuals with OSA at an increased risk for a motor vehicle crash when compared to comparable individuals who do not have OSA?**
- A. In 2007, the Manila Consulting Group conducted an evidence report, "Obstructive Sleep Apnea (OSA) and Commercial Motor Vehicle Driving."
1. This evidence report used statistical methods to rank studies that have been done and performed meta-analysis (i.e., pulled data done in different studies by different researchers so that they are comparable).
 2. The meta-analysis showed that results are statistically significant.
 - a. Analysis showed that the increased crash risk for drivers of motor vehicles who have OSA is 1.3-1.7 (where the crash risk for an ordinary person without OSA is 1.0).
 - b. The crash risk for drivers with OSA is approximately 3 times that of drivers without OSA.
 3. Note that studies have been on motor vehicle drivers with OSA, not exclusively CMV drivers.
 4. In comparison to other risks that FMCSA regulates associated with medical conditions, crash risk associated with OSA is significantly more.
 5. Increased crash risk associated with OSA can be comparable to driving while intoxicated (Blood Alcohol Concentration [BAC] = 0.05).
 6. Benefits to public safety: costs associated with crashes can likely be mitigated.
 7. Alertness is an essential component to commercial driving, and there is substantial evidence that shows that OSA affects alertness.
 8. The overall analysis (of multiple statistical studies) is overwhelming regarding moderate-severe OSA and increased crash risk.

II. Key Question #2: What disease-related factors are associated with an increased motor vehicle crash risk among individuals with OSA?

- A. Would Body Mass Index (BMI) plus something else help further predict which drivers should be screened for OSA testing?
- B. The most significant OSA risk factor to look for is metabolically central obesity.
 - 1. BMI is a powerful tool because it is a surrogate for central obesity. Men with high BMI tend to have their fat centrally distributed.
- C. To address the majority of CMV drivers (males), BMI is likely a sufficient OSA risk factor (i.e., will result in very few false positives).
- D. Potential other criteria: neck girth, uncontrolled/poorly controlled hypertension.
 - 1. The neck girth OSA risk criteria are not likely useful if the majority of drivers with BMI above 35 have neck girths above the relevant threshold.
 - a. But neck girth is a useful OSA risk criteria (supplemental to BMI) for women.
 - 2. Additionally, FMCSA already regulates hypertension by screening drivers for high blood pressure.
- E. Risk for OSA also increases with age, but obesity generally trumps age in terms of OSA risk criteria.
- F. If FMCSA directs medical examiners to take into account other OSA risk criteria factors (in addition to BMI) to determine whether OSA testing is appropriate for a driver, the examiner should have discretion to encourage (or require) OSA testing for a driver who has a BMI below the screening threshold and another risk factor.
 - 1. Additional OSA risk criteria include neck girth, jaw line, tonsil size, etc.
 - 2. These discretionary factors are important because requiring OSA testing only for drivers with a BMI of 35 or greater would miss many cases of OSA if BMI was the only criteria.
- G. Clinical guidance for medical examiners might include recommendation that examiners assess a driver's Mallampati Score.
 - a. Mallampati Score is a score system that is assessed by a visual examination of the back of the throat without a tongue depressor and without muscles contracted.
 - i. Idea is to look at the airway simulated as it appears during sleep as much as possible.
 - ii. Procedure:
 - (A) Ask patient to drop their jaw.
 - (B) Asking patient to lay back to assess the Mallampati Score would determine likelihood of positional sleep apnea.
 - b. Most OSA patients without the BMI risk factor are a class 3 or 4 on the Mallampati Score.
 - c. Sample images show what Classes 0-4 throat look like¹:

¹ Image is borrowed from Oxford Medicine Online,
<http://oalanobdc.oxfordmedicine.com/content/vol1/issue1/images/large/graphic015.jpeg> (last accessed Jan. 5, 2012).



- d. The lateral width of the airway is the most important factor in terms of the visual examination.
 - e. The Mallampati Score test is objective in that driver cannot manipulate result of the assessment.
- H. The studies show that a BMI of 33 is likely the BMI at which false positives and false negatives are minimized.
- 1. False positives would be requiring a driver who does not have moderate-to-severe OSA to undergo a sleep study.
 - 2. False negatives would be not requiring a driver who has moderate-to-severe OSA to undergo a sleep study.
 - 3. Approximately 75 percent of moderate-to-severe OSA cases would be captured with a cutoff of requiring a sleep study for drivers with a BMI of 33 or greater. Approximately 25 percent of drivers with moderate-to-severe OSA would be missed with this cutoff.
- I. See Recommendations 5 and 6 below.

III. Key Question #3: Given the findings of Key Question 2, are individuals with OSA unaware of the presence of the factors that appear to be associated with an increased motor vehicle crash risk?

- A. Most general drivers with OSA are unaware of that diagnosis. But when the patient is asked questions regarding symptoms, they generally resonate.
- 1. Most CMV drivers are probably unaware.
- B. Educating spouses can be beneficial because the bed partner usually recognizes whether or not the patient is exhibiting OSA symptoms.
- C. People are aware of their weight and hypertension generally, but do not put the information together to determine the likelihood they are suffering from OSA.
- D. Drivers suffering from OSA may not be able to objectively tell if they are generally fatigued if they are used to being fatigued.
- E. Drivers have likely heard of the OSA condition and may be aware of symptoms, but drivers do not understand the risks associated with OSA or the benefits of treatment.
- 1. If drivers are aware of crash risk factors associated with OSA, they will resist or avoid anything that may threaten their ability to make a living.
 - 2. Among unionized drivers, there is a high level of OSA awareness, but the view is typically that this is another issue that could take a driver off the road.

3. Driver education/awareness will be crucial in any FMCSA regulatory action on OSA (regulations or guidance).
- F. If drivers view examiners in an adversarial way, objective sleepiness questions will not be effective.
 1. Drivers will not likely provide objective answers if there is not a safety benefit net that would not threaten their job.
- G. Is there a way to remove barriers for the group of CMV drivers that suspect there is something wrong with them, but fear that coming forward might threaten their job?
 1. Drivers should be educated that they will not be taken off the road if they receive treatment for OSA.
 - a. Educate drivers regarding any driving time that would be lost for testing and treatment.
 2. Drivers should be educated regarding the positive experiences and benefits of other drivers who have been treated for OSA.
 3. Educate drivers regarding cost of testing and treatment.
 - a. FMCSA should find out from the Centers for Medicare & Medicaid Services (CMS) what are likely to be the proposed sleep disorder benefit requirements for insurance companies offering plans to state health insurance clearinghouses, if any.

IV. Key Question #4: Are there screening/diagnostic tests available that will enable examiners to identify those individuals with OSA who are at an increased risk for a motor vehicle crash?

- A. Unattended home sleep study tests vs. Overnight laboratory sleep study tests.
 1. Unattended home sleep tests are significantly cheaper than in-house laboratory sleep study tests.
 2. However, unattended home tests might miss a moderate-to-severe OSA diagnosis more often than in-house laboratory testing (false negatives).
 3. False negatives are inherent in home-testing; the cost savings likely make up for the chance of false negatives.
 4. Therefore, FMCSA should permit unattended home sleep studies for purposes of OSA diagnosis.
 5. See Recommendation 7.
- B. Potential chain of custody issues with home testing.
 1. Assuring chain of custody involves making sure that the person providing test data is the person intended to be tested.
 2. Home sleep test units use a wristband that you cannot take off after it is installed in a clinic, which is then connected to wires to the machine.
 - a. If it's broken for any reason, the circuit would be broken and data would not be collected.
 3. Home sleep test kits that are mailed to a driver's home could contain a bracelet that must be installed by a pharmacy or other qualified clinician on a patient who provides identification to corroborate the chain of custody.
 4. See Recommendation 7.
- C. Split night studies should be allowed.

1. Split night studies are those in which diagnosis and CPAP titration are performed on the same night with in-lab polysomnography.
 - D. What if a driver with a BMI above the threshold (e.g., 35) returns an unattended home test that returns negative (apnea-hypopnea index [AHI] ≥ 20) for moderate-to-severe OSA?
 1. The likelihood of OSA in patients with BMIs greater than or equal to 35 is close to 80 percent.
 2. Therefore, if FMCSA requirements do not assure chain of custody, and the home sleep study returns negative (AHI ≥ 20), this circumstance should probably require an in-lab sleep study, if the driver has a BMI equal to or above 35.
 3. Alternatively, FMCSA could require repeat home testing with oral instruction assistance (for face mask fitting issues and otherwise appropriately use the machine).
 - a. Large home health care organizations could likely step up to provide proper instruction on use of home sleep testing.
 - E. How should a medical examiner proceed if a driver has previously taken a sleep test that returned negative (AHI ≥ 20) and returns to a medical examiner for recertification?
 1. The examiner should screen the driver for OSA again (reevaluate) and perform testing up to and including another sleep study.
 2. A medical examiner should not eliminate the possibility that a driver may have OSA because up to two years previously the individual tested negative for OSA in a sleep study.
 - F. Could a non-medical doctor (M.D.) medical examiner recommend a sleep study (e.g., for a driver with a BMI of 35) that a health insurance company would pay for?
 1. Any clinician familiar with OSA should be able to recommend a sleep study.
 2. Issue of whether or not the study would be reimbursable is a different issue.
 - a. Perhaps FMCSA guidance would require non-M.D. medical examiners to screen drivers (see Recommendations 5 and 6), and refer drivers who trigger the screening criteria to a M.D. for follow-up before the medical examiner would issue the certification.
 3. The value of codifying follow-up requirements is that it forces non-sleep specialist medical examiners to become educated.
- V. **Key Question #5: Which treatments have been shown to effectively reduce crash risk among individuals with OSA?**
- A. See Recommendations 8-12.
 - B. The preferred OSA treatment is Positive Airway Pressure (PAP) (as recommended in 2007 by joint medical task force).
 1. PAP includes Continuous Positive Airway Pressure (CPAP) and Auto-titration CPAP (APAP).
 2. Studies have shown that PAP reduces crash risk among drivers with moderate to severe OSA. Strength of evidence is *strong*.
 - C. Other OSA treatments include medications, weight loss, surgery, dental implants (oral appliances).

1. While these treatments may reduce crash risk among drivers with moderate to severe OSA, the available evidence is not as strong as for the benefits of PAP.
- D. An effective treatment is one which will predictably reduce some measurable criteria associated with OSA.
- E. FMCSA should conduct a meta-analysis on multiple studies that have been conducted relating to cost effectiveness of PAP and other OSA treatments.

VI. Key Question #6: What is the length of time required following initiation of an effective treatment for individuals with OSA to reach a degree of improvement that would permit safe driving?

- A. See Recommendations 8, 10, 11, and 12 in table below.

VII. Key Question #7: How soon, following cessation of treatment (i.e., as a consequence of non-compliance), will individuals with OSA demonstrate reduced driver safety?

- A. One night without PAP therapy has been shown to reduce driver performance. Randomized trial data has shown that non-use of PAP can decrease driving performance.
- B. Drivers with OSA should be educated that they can experience reduced driving performance after just one night without PAP therapy.
 1. Drivers should be encouraged to immediately seek assistance from treating clinician if their PAP device malfunctions in any way.

Recommendations for FMCSA OSA Requirements:

<p>Recommendation 1 - General</p>	<ul style="list-style-type: none"> • OSA diagnosis precludes unconditional certification. • A driver with OSA diagnosis can be certified if: <ul style="list-style-type: none"> • The driver has untreated OSA with $AHI \leq 20$ (i.e., mild-to-moderate OSA) AND • The driver does not admit to experiencing sleepiness during the major wake period OR • OSA is being effectively treated. <p>A driver with an OSA diagnosis may be recertified annually, based on demonstrating compliance with therapy.</p> <ul style="list-style-type: none"> • Minimally acceptable compliance with PAP means at least 4 hours/day of use 70 percent of days. <ul style="list-style-type: none"> ▪ Drivers should be encouraged that more hours of PAP use is preferable. ▪ Optimal treatment efficacy occurs with 7 hours or more of daily use during sleep. • <i>The intent behind the AHI threshold is to prioritize those drivers with OSA that need immediate treatment.</i> <ul style="list-style-type: none"> ○ <i>Drivers with mild OSA (AHI levels as low as 5) may benefit from OSA treatment, and should be encouraged to explore treatment options.</i> ○ <i>Drivers with an AHI between 5 and 20 should be encouraged to seek treatment, if they have a history involving a fatigue-related crash or a single vehicle crash, or if they report sleepiness while operating a motor vehicle.</i> • <i>Why set the AHI threshold at 20?</i> <ul style="list-style-type: none"> ○ <i>Crash risk in the moderate-to-severe OSA range is statistically higher than for drivers with mild OSA.</i> ○ <i>From a practical perspective, setting the AHI limit at 15 or above, makes it more difficult to</i>
-----------------------------------	--

Task 11-05 Subcommittee Discussion Notes
January 4-5, 2012

	<p><i>get a patient under treatment to that AHI level. Although AHI of 15 is likely a safer threshold, there is not data to show this.</i></p>
<p>Recommendation 2 – Drivers with any of the following should be disqualified immediately or denied certification:</p>	<ul style="list-style-type: none"> • Report excessive sleepiness during the major wake period while driving, OR • Experienced a crash associated with falling asleep, OR • Experienced a single-vehicle crash, OR • Have been found non-compliant in treatment per Recommendation 1. <p>Notes:</p> <ul style="list-style-type: none"> • <i>With a single vehicle crash, there should be a presumption the driver experienced fatigue at the wheel.</i>
<p>Recommendation 3 – Drivers with any of the following may be granted conditional certification per Recommendation 4:</p>	<ul style="list-style-type: none"> • Have AHI > 20 until compliant with PAP, OR • Have undergone surgery and are pending post-op findings per Recommendations 10-12, OR • Have a BMI > 35 kg/m² (pending sleep study). <p>Notes:</p> <ul style="list-style-type: none"> • <i>BMI cutoff of 33 is supported by studies (MRB).</i> • <i>BMI cutoff should be objectively related to crash risk (Conway).</i>
<p>Recommendation 4 – Conditional certification</p>	<ul style="list-style-type: none"> • Driver with BMI > 35 kg/m² may be certified for 60 days pending sleep study and treatment (if diagnosed with OSA). • Within 60 days, if a driver being treated with OSA is compliant with treatment (per Recommendations 8-12), the driver may receive additional 90 day conditional certification. • After 90 days, if the driver is still compliant with treatment, the driver may be certified for no more than 1 year. Future certification dependent on continued compliance. • Refer to Recommendation 1 for definition of minimal compliance.
<p>Recommendation 5- Referral for diagnosis and stratification of severity</p>	<p>A driver must be referred for a sleep study if:</p> <ul style="list-style-type: none"> • BMI > 35 kg/m², OR • The driver is judged at risk for OSA based on: <ul style="list-style-type: none"> ▪ The driver's answers to a validated questionnaire (e.g., Berlin), OR ▪ A clinical evaluation (considering risk factors and symptoms in Recommendation 6), OR ▪ Some other validated screening tool. • Validated screening tool must be certified as meeting certain criteria established by FMCSA.
<p>Recommendation 6 – Identification of individuals with undiagnosed OSA</p>	<ul style="list-style-type: none"> • Medical examiners should screen all drivers for OSA. • Symptoms: loud snoring, witnessed apneas, daytime sleepiness. • Risk factors: <ol style="list-style-type: none"> a. Advancing age b. BMI \geq 28 kg/m² c. Small or recessed jaw d. Neck size \geq 17" male, 15.5" female e. Small airway (Mallampati Scale score of Class 3 or 4) f. Family history • Conditions associated with high risk: <ol style="list-style-type: none"> a. Hypertension (treated or untreated) b. Type 2 diabetes (treated or untreated) c. Hypothyroidism (untreated)
<p>Recommendation 7 – Method of diagnosis and severity</p>	<ul style="list-style-type: none"> • Preferred methods of diagnosis are either in-laboratory or at-home polysomnography, OR a FDA-approved limited channel ambulatory testing device which ensures chain of custody. <ul style="list-style-type: none"> ▪ Note that new technologies will likely emerge that will be able to screen for OSA. • Driver should be tested while on usual chronic medications. • <i>Note that the joint medical committee did not consider AHI levels from unattended studies, but only in-lab sleep studies, which detect the arousal component of hypopneas (not just saturation).</i> <ul style="list-style-type: none"> ○ <i>An in-home sleep study will underestimate AHI when compared to an in-lab sleep study.</i> ○ <i>An AHI detected on an in-home sleep study will be less than an in-lab study because the</i>

Task 11-05 Subcommittee Discussion Notes
January 4-5, 2012

	<p><i>in-home study likely does not consider total sleep time (e.g., if the patient remains awake because of arousal, no saturation data would be collected).</i></p> <ul style="list-style-type: none"> ○ <i>The degree of underestimation was higher for mild. You are more likely to mischaracterize a diagnosis for lower severity levels.</i> ○ <i>FMCSA OSA requirements should contain a note that an unattended sleep study may underestimate the severity of OSA. Therefore, the medical examiner should use clinical judgment when interpreting results of an unattended sleep study.</i> <ul style="list-style-type: none"> ▪ <i>If the clinician believes the level of apnea is greater than the level reported by the in-home study, the clinician should consider recommending an in-laboratory sleep study.</i> ○ <i>Some members note that medical examiners may have concerns with non-quantitative requirements.</i>
<p>Recommendation 8 – Treatment - PAP</p>	<ul style="list-style-type: none"> ● All individuals with OSA should be referred to a clinician with relevant expertise. ● PAP is the preferred OSA therapy. ● Adequate PAP pressure should be established through one of the following: <ul style="list-style-type: none"> ○ Titration study with polysomnography ○ Auto-titration system <p>A driver may be conditionally certified (per Recommendation 4) if successfully treated for 1 week AND</p> <ul style="list-style-type: none"> ● The driver can demonstrate at least minimal compliance (4 hrs/use 70% of nights) AND ● The driver does not report excessive sleepiness during major wake period.
<p>Recommendation 9 – Treatment alternatives</p>	<p>Compliance with dental appliances cannot be demonstrated so these technologies are not acceptable alternatives. Surgical treatment is acceptable.</p>
<p>Recommendation 10 – Bariatric surgery</p>	<p>After bariatric surgery, a driver may be certified if:</p> <ul style="list-style-type: none"> ● Compliant with PAP, OR 6 months have passed since surgery (for weight loss), AND ● Cleared by treating physician, AND ● $AHI \leq 20$, AND ● No reported excessive sleepiness during major wake period. <p>Annual recertification</p> <ul style="list-style-type: none"> ● $AHI \leq 20$ AND ● No reported excessive sleepiness during major wake period.
<p>Recommendation 11 – Oropharyngeal surgery, Facial bone surgery</p>	<p>After oropharyngeal or facial bone surgery, a driver may be certified if:</p> <ul style="list-style-type: none"> ● 1 month has passed since surgery, AND ● Cleared by treating physician, AND ● $AHI \leq 20$, AND ● No reported excessive sleepiness during major wake period. <p>Annual recertification</p> <ul style="list-style-type: none"> ● If clinically indicated, repeat sleep study.
<p>Recommendation 12 – Tracheostomy</p>	<p>After tracheostomy, a driver may be certified if:</p> <ul style="list-style-type: none"> ● 1 month has passed since surgery, AND ● Cleared by treating physician, AND ● $AHI \leq 20$, AND ● No reported excessive sleepiness during major wake period. <p>Annual recertification</p> <ul style="list-style-type: none"> ● If clinically indicated, repeat sleep study.

Likely Frequently Asked Questions from Drivers or Carriers Relating to Potential FMCSA OSA Requirements

- I. Will there be a clear benchmark of when a driver must be treated for sleep apnea like there is for hypertension? For example, treatment is only mandatory for a driver with an AHI of X or greater. It is reported that the experience with doctors, particularly those not boarded in sleep medicine, have differing views of when treatment is required.
 - o *See Recommendation 1.*

- II. If sleep apnea becomes a part of the DOT physical, will this be only the preliminary evaluation of whether a sleep study is needed or will the DOT physician be required to make the full sleep evaluation and pass on the driver? Should not the DOT doctor only be required to be able to evaluate whether a driver needs a sleep study and then be able to rely upon a physician boarded in sleep medicine for actual diagnosis. It is reported that approximately 50-60 percent of drivers need to be screened for sleep apnea and about 25 percent of the overall driver population have sleep apnea. If you require all DOT physicians to be qualified and comfortable in diagnosing and treating sleep disorders, will this severely limit the availability of DOT physicians and significantly increase the cost of all exams when only 25 percent of the drivers have a sleep disorder?
 - o *DOT medical examiner is making the determination of whether the driver needs to be referred for a sleep study. The medical examiner does not need a sleep disorder specialization.*
 - o *After a sleep study, the medical examiner will have the objective sleep data.*
 - o *For purposes of compliance, CPAP data is also objective.*
 - o *See Recommendations 2 and 3.*

- III. If during a DOT physical a driver is diagnosed with needing a sleep study, will the driver be placed out of service until a sleep study is performed? If so, will certain protocol be required for a sleep study to qualify as a valid study? Will split night studies be allowed?
 - o *See Recommendations 2-4.*
 - o *See Key Question #4 discussion.*

- IV. If a driver goes through a sleep study and is negative for sleep apnea, how long will the negative finding be valid for that driver (i.e., when will a follow up test be required?)
 - o *See Key Question #4 discussion.*

- V. If a driver is positive for sleep apnea and goes through a second or follow up study (either for a second opinion or after a driver loses weight) that reduces the driver's AHI level, will the sleep apnea diagnosis be removed from the DOT physical or what may a DOT physician rely upon to determine further PAP therapy is not needed?

- *If a second opinion sleep study shows AHI less than 20, the medical examiner should use his/her judgment whether or not to certify the driver, based on the results of the two sleep studies and any co-morbidities (Medicare criteria list for covering CPAP).*
 - *If one of the studies was an in-lab sleep study and the other was an unattended sleep study, the in-lab study should be given more weight.*
- VI. There needs to be a clear standard for compliance that a sleep physician would be able to defend if OSA treatment compliance became an issue in accident litigation. Standards for frequency compliance data retrieval, length of compliance period, etc. would be helpful. If a driver, particularly an over the road (OTR) driver, is out on the road and has a PAP malfunction or a mask or tube that breaks, will the driver be allowed to operate for a period of time until replacement equipment is available or be out of service?
- *Driver should resolve PAP equipment failure issues to maintain minimal compliance (at least 4 hours/day of use 70 percent of days).*
 - *If PAP equipment fails, driver should be encouraged to seek replacement equipment as soon as possible.*
 - *See minimally acceptably compliance in Recommendation 1.*
- VII. Unlike some disease for which the mere taking of medication provides immediate treatment, adaptation to a PAP device can often take a 15-45 day period of time. Will drivers who are participants in a monitored compliance program be allowed to drive during this initial treatment period? If not, 25 percent of the drivers being put out of work for 30 day periods will have a significant cost and impact on driver availability in the industry.
- *Yes. See Recommendation 4.*
- VIII. There are alternative treatments to sleep apnea that cannot be monitored for compliance, such as oral devices and surgery. In some ways if these are allowed, it is like having HOS regulations with no method of verifying compliance a full 10 hour break?
- *See Recommendations 8-12.*
- IX. Many companies have made substantial investments in sleep apnea programs. Will specific programs be able to be certified as compliant?
- *Companies would look to any requirements that come out of a FMCSA rulemaking relating to OSA to determine whether their programs are compliant with Agency requirements (self certification).*
 - *Right now, carriers with OSA programs are establishing internal requirements they think are appropriate. With FMCSA OSA requirements, carriers would know exactly what they need to do.*