

MOTOR CARRIER SAFETY ADVISORY COMMITTEE

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C/O: Federal Motor Carrier Safety Administration

1200 New Jersey Avenue, SE

Room W64-232

Washington, DC 20590

February 21, 2012

The Honorable Anne S. Ferro

Administrator

Federal Motor Carrier Safety Administration

1200 New Jersey Avenue, SE

Washington, DC 20590

Dear Administrator Ferro:

The Motor Carrier Safety Advisory Committee (MCSAC) and the Medical Review Board (MRB) commenced work on Task 11-05 at the December 7, 2011, joint MCSAC-MRB meeting. The Federal Motor Carrier Safety Administration (FMCSA) tasked the Committee and the Board with jointly providing information, concepts, and ideas the Agency should consider in developing regulatory guidance for motor carriers, commercial motor vehicle (CMV) drivers, and medical examiners on obstructive sleep apnea (OSA) and whether drivers with this condition should be medically certified to operate CMVs in interstate commerce. FMCSA instructed the Committee and the Board to provide information about how to address drivers with OSA in the short-term until the Agency can consider recommendations for a long-term regulatory action. On December 16, the MCSAC and MRB jointly submitted recommendations for interim guidance relating to screening and evaluating drivers for OSA and subsequent determinations of a driver’s ability to operate a CMV safely.

At the December 2011 meeting, the MCSAC and the MRB created the OSA Subcommittee (subcommittee) and tasked it with making recommendations on revisions to the Agency’s regulations addressing qualifications of drivers to address OSA. The subcommittee met publicly on January 4-5, 2012, to discuss this task, and prepared recommendations for consideration by the MCSAC and MRB at the February 2012 joint MCSAC-MRB meeting. Enclosed are the Committee and Board joint recommendations for guidance for motor carriers, CMV drivers, and medical examiners on OSA and subsequent determinations of a driver’s ability to operate a CMV safely.[[1]](#footnote-1)

We respectfully submit this report to FMCSA for its consideration.

 Sincerely,

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| //signed//David R. ParkerChairman, Motor Carrier Safety Advisory Committee | //signed//Benjamin H. Hoffman, M.D., M.P.H.Chairman, Medical Review Board |

Enclosure

**Introduction**

The Motor Carrier Safety Advisory Committee (MCSAC) and the Medical Review Board (MRB) developed and discussed several key questions in considering Task 11-05 to provide information, concepts, and ideas the Federal Motor Carrier Safety Administration (FMCSA) should consider in developing regulatory guidance for motor carriers, commercial motor vehicle (CMV) drivers, and medical examiners on obstructive sleep apnea (OSA) and whether drivers with this condition should be medically certified to operate CMVs in interstate commerce. These questions are listed below.

* Are individuals with OSA at an increased risk for a motor vehicle crash when compared to comparable individuals who do not have OSA?
* What disease-related factors are associated with an increased motor vehicle crash risk among individuals with OSA?
* Are individuals with OSA unaware of the presence of the factors that appear to be associated with an increased motor vehicle crash risk?
* 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?
* Which treatments have been shown to effectively reduce crash risk among individuals with OSA?
* 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?
* How soon following cessation of treatment will individuals with OSA demonstrate reduced driver safety (i.e., as a consequence of non-compliance)?

Discussion of the above questions formed the basis of the joint MCSAC-MRB recommendations for consideration by FMCSA when developing regulatory guidance regarding OSA. The joint MCSAC-MRB recommendations are summarized below.

1. **General Recommendations Regarding OSA**
2. OSA diagnosis precludes unconditional certification.
3. A driver with an OSA diagnosis may be certified if the following conditions are met:
4. The driver has untreated OSA with an apnea-hypopnea index (AHI) of less than or equal to 20 (i.e., mild-to-moderate OSA), and
5. The driver does not admit to experiencing excess sleepiness during the major wake period, or
6. The driver’s OSA is being effectively treated.
7. Notes on AHI threshold:
8. The AHI threshold is used to prioritize drivers with OSA who need immediate treatment.
9. The AHI threshold is set at 20 because crash risk in the moderate-to-severe OSA range is statistically higher than for drivers with mild OSA.
10. Although an AHI of 15 is likely a safer threshold, there is no data to support this and such a threshold may be less practical in terms of enrolling patients for treatment.
11. Drivers with mild OSA (AHI levels as low as 5) may benefit from OSA treatment, and should be encouraged to explore treatment options.
12. 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 DOT-defined single vehicle crash,[[2]](#footnote-2) or if they report sleepiness while operating a motor vehicle.
13. A driver with an OSA diagnosis may be recertified annually, based on demonstrating compliance with treatment.
	1. Minimally acceptable compliance with Positive Airway Pressure (PAP) treatment consists of at least 4 hours per day of use on 70 percent of days.
	2. Drivers should be made aware that more hours of PAP use is preferable and that optimal treatment efficacy occurs with 7 or more hours of daily use during sleep.
14. **Immediate Disqualification or Certification Denial**
15. Drivers should be disqualified immediately or denied certification if any of the following conditions are met:
16. The driver admits to experiencing excessive sleepiness during the major wake period while driving, or
17. The driver experienced a crash associated with falling asleep, or
18. The driver has been found non-compliant with treatment per Recommendation I.D.
19. **Conditional Certification**
20. Drivers may be granted conditional certification if any of the following conditions are met:
21. The driver has an AHI of greater than 20 until compliant with PAP, or
22. The driver has undergone surgery and is pending post-op findings per Recommendations VI – VIII, or
23. The driver has a Body Mass Index (BMI) of greater than or equal to 35 kg/m2 pending a sleep study.
24. Notes on BMI threshold:
25. The MRB is in agreement that a BMI threshold of 33 is supported by studies.
26. MCSAC member Robert Petrancosta (Con-Way Freight) asserted that a BMI threshold should be objectively related to crash risk.
27. Conditional certification should include the following elements:
28. A driver with a BMI of greater than or equal to 35 kg/m2 may be certified for 60 days pending sleep study and treatment (if the driver is diagnosed with OSA).
29. Within 60 days, if a driver being treated with OSA is compliant with treatment (per Recommendations I.D. and V – IX), the driver may receive an additional 90-day conditional certification.
30. After 90 days, if the driver is still compliant with treatment, the driver may be certified for no more than 1 year. Future certification should be dependent on continued compliance.
31. OSA Screening (i.e., identifying individuals with undiagnosed OSA)
32. In addition to a BMI of 35 or above, the following information may help a clinician diagnose OSA:
33. Symptoms of OSA may include loud snoring, witnessed apneas, or sleepiness during the major wake period;
34. Risk factors of OSA may include the following factors. However, a single risk factor alone may not infer risk, and a combination of multiple factors should be examined.
	* 1. Factors associated with high risk*:*
* Small or recessed jaw
* Small airway (Mallampati Scale score of Class 3 or 4)
* Neck size > 17 inches (male), 15.5 inches (female)
* Hypertension (treated or untreated)
* Type 2 diabetes (treated or untreated)
* Hypothyroidism (untreated)
	+ 1. Other factors*:*
* BMI greater than or equal to 28 kg/m2
* Age 42 and above
* Family history
* Male or post-menopausal female
* Experienced a single-vehicle crash
1. **Method of Diagnosis and Severity**
2. Methods of diagnosis include in-laboratory polysomnography, at-home polysomnography, or an FDA-approved limited channel ambulatory testing device which ensures chain of custody.
3. In-laboratory polysomnography, which is more comprehensive, should be considered when the clinician suspects another sleep disorder in addition to sleep apnea.
4. New OSA screening technologies will likely emerge.
5. The driver should be tested while on usual chronic medications.
6. The MCSAC and MRB did not consider AHI levels from unattended (i.e., in-home) studies, only in-laboratory sleep studies that detect the arousal component of hypopneas, as well as saturation.
	1. An in-home sleep study may underestimate AHI when compared to an in-laboratory sleep study because the in-home study likely does not consider total sleep time.
	2. The medical examiner should use clinical judgment when interpreting the results of an unattended sleep study.
	3. 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.
7. **Treatment: Positive Airway Pressure (PAP)**
8. All individuals with OSA should be referred to a clinician with relevant expertise.
9. PAP is the preferred OSA therapy.
10. Adequate PAP pressure should be established through one of the following methods:
	1. Titration study with polysomnography
	2. Auto-titration system
11. A driver who has been disqualified may be conditionally certified (per Recommendation III) if the following conditions are met:
12. The driver is successfully treated for one week, and
13. The driver can demonstrate at least minimal compliance (i.e., 4 hours per use on 70 percent of nights), and
14. The driver does not report excessive sleepiness during the major wake period.
15. **Treatment: Bariatric surgery**
	* + 1. After bariatric surgery, a driver may be certified if the following conditions are met:
16. Six months have passed since the surgery (for weight loss), and
17. The driver has been compliant with PAP for six months, and
18. The driver has been cleared by the treating physician, and
19. The driver does not report excessive sleepiness during the major wake period.
	* + 1. After six months have passed since surgery, if the apnea appears to have resolved, a repeat sleep study should be considered to test for the presence of ongoing sleep apnea.
			2. Annual recertification
20. If clinically indicated, repeat the sleep study.
21. **Treatment: Oropharyngeal surgery, Facial bone surgery**
	* + 1. After oropharyngeal or facial bone surgery, a driver may be certified if the following conditions are met:
22. One month has passed since surgery, and
23. The driver has been cleared by the treating physician, and
24. The driver does not report excessive sleepiness during the major wake period.
	* + 1. After one month has passed since surgery, if the apnea appears to have resolved, a repeat sleep study should be considered to test for the presence of ongoing sleep apnea.
			2. Annual recertification
			3. If clinically indicated, repeat the sleep study.
25. **Treatment: Tracheostomy**
26. After a tracheostomy, a driver may be certified if the following conditions are met:
27. One month has passed since surgery, and
28. The driver has been cleared by the treating physician, and
29. The driver does not report excessive sleepiness during the major wake period.
30. After one month has passed since surgery, if the apnea appears to have resolved, a repeat sleep study should be considered to test for the presence of ongoing sleep apnea.
31. Annual recertification
32. If clinically indicated, repeat the sleep study.
33. **Treatment Alternatives**
34. There is limited data regarding compliance and long-term efficacy of dental appliances, and these technologies are not approved alternatives at this time.[[3]](#footnote-3)
35. Surgical treatment is acceptable (See Recommendations VI – VIII).
1. One MCSAC member (Todd Spencer of the Owner-Operator Independent Drivers Association) expressed several concerns about this task, including the following: (1) the benefits of regulating OSA will not justify the costs of screening and treatment; (2) there have been no studies regarding the effects of treating OSA in drivers of CMVs; and (3) the focus of this task on OSA alone is too narrow and should include all forms of sleep disorders. [↑](#footnote-ref-1)
2. Per 49 CFR 390.5, “accident” means (1) an occurrence involving a commercial motor vehicle operating on a highway in interstate or intrastate commerce which results in: (i) A fatality; (ii) Bodily injury to a person who, as a result of the injury, immediately receives medical treatment away from the scene of the accident; or (iii) One or more motor vehicles incurring disabling damage as a result of the accident, requiring the motor vehicle(s) to be transported away from the scene by a tow truck or other motor vehicle. [↑](#footnote-ref-2)
3. Based on public comments received at the February MCSAC meeting, one member (Danny Schnautz, Clark Freight Lines, Inc., Pasadena, TX) suggested that the efficacy of dental appliances may need to be reviewed. [↑](#footnote-ref-3)