



MEDICAL REVIEW BOARD

C/O: Federal Motor Carrier Safety Administration
1200 New Jersey Avenue, SE
Washington, DC 20590

August 23, 2016

T.F. Scott Darling, III
Administrator
Federal Motor Carrier Safety Administration
1200 New Jersey Avenue, SE
Washington, DC 20590

Dear Administrator Darling:

On August 22-23, 2016, the Medical Review Board (MRB) met in public meetings to deliberate on *Medical Review Board Task 16-1* regarding public comments from medical professionals and associations on the Federal Motor Carrier Safety Administration's (FMCSA's) and Federal Railroad Administration's (FRA's) Advanced Notice of Proposed Rulemaking (ANPRM) on obstructive sleep apnea. FMCSA tasked the MRB with reviewing and analyzing all ANPRM comments from medical professionals and associations and identify factors the Agency should consider regarding making a decision about the next step in the OSA rulemaking. FMCSA also requested that the MRB review the previous 2012 report on OSA from the MRB and Motor Carrier Safety Advisory Committee (MCSAC).

The attached report includes all of the MRB's recommendations related to MRB Task 16-1. In addition, and related to the Agency's implementation of a future OSA rulemaking, the MRB recommends that FMCSA initiate an educational initiative to ensure that all relevant stakeholders are adequately informed of OSA symptoms, health consequences, risk factors, diagnosis, and treatment costs and benefits. FMCSA should solicit the help of sleep experts and associations to refer Certified Medical Examiners (CMEs), drivers, and motor carriers to educational materials appropriately tailored to each group's needs.

On behalf of the MRB, I respectfully submit this report to FMCSA for its consideration.

Sincerely,

//signed//

Gina C. Pervall, MD, CIME
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.

I. General Recommendations Regarding OSA

- A. CMEs must screen drivers presenting for medical certification for OSA diagnostic testing in accordance with Recommendation III.B.
- B. CMEs cannot issue a medical card for more than 1 year to a driver with an established diagnosis of OSA, regardless of severity.
- C. A CME may certify a driver with an OSA diagnosis if the driver is being treated effectively (see **Recommendations V through IX**).
- D. For certification purposes, “effective treatment” or “treated effectively” is defined as the resolution of moderate to severe OSA to mild or better, as determined by a board-certified sleep specialist.

II. Immediate Disqualification

- A. Drivers should be disqualified immediately and referred for OSA diagnostic testing if any of the following conditions exist:
 - 1. Individuals who have admitted fatigue or sleepiness during the wake period.
 - 2. Individuals who have been involved in a sleep-related motor vehicle crash or accident or near crash.
- B. Drivers found non-compliant with treatment per **Recommendations V through IX** should be disqualified immediately until evaluated and treated effectively.
- C. The CME should have the discretion to disqualify any driver who appears to be at extremely high risk.
- D. Drivers disqualified for any of the above reasons must remain disqualified until evaluated and treated effectively.

III. Conditional Certification

- A. Conditional certification should include the following elements:
 - 1. A driver determined to be at risk for OSA based on BMI (with or without risk factors) may be certified for 90 days pending sleep study and treatment (if the driver is diagnosed with OSA).
 - 2. Within 90 days, if a driver being treated with OSA is compliant with treatment (per **Recommendations V through IX**), the driver may be certified for no more than 1 year. Drivers with a diagnosis of moderate to severe OSA should be re-certified based on documented effective treatment and compliance (see **Recommendations V through IX**).
- B. Referral to OSA Diagnostic Testing Based on Screening (i.e., identifying individuals with undiagnosed OSA)
 - 1. **MRB Recommendations:** Individuals with the following should be referred for diagnostic sleep evaluations:
 - a. Individuals with a BMI ≥ 40 mg/kg².
 - b. Individuals with a BMI ≥ 33 and < 40 mg/kg² in addition to and at least 3 or more of the following (For – 3; Against – 1):
 - i. Hypertension (treated or untreated);
 - ii. Type 2 diabetes (treated or untreated);
 - iii. History of stroke, coronary artery disease, or arrhythmias;
 - iv. Micrognathia or retrognathia;
 - v. Loud snoring;
 - vi. Witnessed apneas;
 - vii. Small airway (Mallampati Classification of Class 3 or 4 – **see photos of Mallampati Classification below**);
 - viii. Neck size > 17 inches (male), 15.5 inches (female);
 - ix. Hypothyroidism (untreated);
 - x. Age 42 and above; or

- xi. Male or post-menopausal female.
- c. Note: One MRB member (B. Morris) thought that there should be at least 4 of other risk factors in addition to $BMI \geq 33$ and $< 40 \text{ mg/kg}^2$ instead of 3.
- d. Frequency of OSA Diagnostic Testing:
 - i. MRB Recommendation: If a driver has had a sleep evaluation study in the past that returned a negative diagnosis for sleep apnea or a diagnosis of mild sleep apnea, indications that would warrant a recommendation for a new sleep study would be the appearance of one or more additional risk factors beyond those that required the original sleep study or a 10 percent increase in weight.
 - 1. Caveat: If age of 42 is the only additional risk factor that has changed, there should be a 3-year period between the prior sleep study and a newly recommended sleep study.
 - 2. B. Morris expressed concerns that not enough evidence exists regarding retesting. For this reason, he would recommend that requirement for retesting should be left at the discretion of the CME.
 - ii. Rationale: Some public comments expressed concern with the situation where a driver was sent for a sleep study due to risk factors in the CME guidelines, the study came back negative for sleep apnea, and the driver gets referred for another sleep study the next time he/she is examined because the same risk factors are still present. It could be an unnecessary cost imposed on these drivers.
- 2. Rationale: Based on public comments that other factors should be considered in addition to BMI, MRB recommends increasing the BMI threshold for recommending a sleep study based on BMI alone to 40, but add factors that in combination (e.g., having 3 or more) could trigger a sleep study recommendation, with a BMI between 33 and 39.
 - a. Self-reported sleepiness during major wake periods or history of a fatigue-related crash should also be standalone triggers that require a CME to require a sleep study.
 - b. However, the MRB removed the single-vehicle crash from the list of risk factors above because members expressed concern that CMEs would not have access to crash information except for instances of self-reporting or a referral from an employer.
 - c. Subjective sleepiness questionnaires would not be helpful because of unlikelihood of truthfulness.
 - d. Note, craniofacial abnormalities and Mallampati Classification may be difficult for some CMEs to assess.
 - e. The MRB replaced the “small or recessed jaw” risk factor with “micrognathia or retrognathia” because those terms are more clinical and objective.

IV. Method of Diagnosis and Severity

- A. Methods of diagnosis include in-laboratory polysomnography (which is preferred), as well as at-home sleep apnea testing that ensures chain of custody.
 - 1. In-laboratory polysomnography should be considered when the clinician suspects:
 - a. Another medical disorder occurring during sleep (e.g., a seizure disorder, restless leg syndrome, narcolepsy, central sleep apnea), and/or
 - b. The individual has significant co-morbidities (e.g., neuromuscular disorder or **COPD**).
 - 2. All sleep studies must be interpreted by a board-certified sleep specialist.
 - 3. New OSA screening technologies will likely emerge.
- B. The driver should be tested while on usual chronic medications.
- C. If the CME, in consultation with the sleep specialist, determines that the in-home sleep study is inadequate, then an in-laboratory test must be performed.

V. **Treatment: Positive Airway Pressure (PAP)**

- A. Based on the available medical literature, PAP therapy is the preferred OSA treatment.
- B. Adequate PAP pressure should be established through one of the following methods:
 - 1. Titration study with polysomnography.
 - 2. Auto-titration system.
- C. A driver may be certified initially for up to 1 year (per **Recommendation III**) if the following conditions are met:
 - 1. The driver must document PAP use for a time period no less than 30 consecutive days (minimum records requirement – initial certification), and
 - 2. The driver’s PAP use records must demonstrate at least 4 hours per night use on 70 percent of nights (minimum compliance standard), and
 - 3. The driver does not report excessive sleepiness during the major wake period.
- D. A driver may be re-certified for up to 1 year (per **Recommendation III**) if the following conditions are met:
 - 1. The driver must document PAP use for a time period no less than the number of days between the expiration of the driver’s previous medical card and the time at which they receive their medical exam (minimum records requirement – re-certification), and
 - 2. The driver’s PAP use records must demonstrate at least 4 hours per night use on 70 percent of nights (minimum compliance standard), and
 - 3. The driver does not report excessive sleepiness during the major wake period.
- E. If a driver fails to meet compliance standards, the CME may provide a 30-day certification to allow the driver to produce 30 days of consecutive PAP use data that meets the minimum compliance standard.

1. After the driver demonstrates compliance with 30 days of PAP use data, the CME may issue a 60-day certification to allow the driver to produce 60 days of consecutive PAP use data that meets the minimum compliance standard.
2. After the driver demonstrates compliance with 60 days of PAP use data, the CME may issue a 90-day certification to allow the driver to produce 90 days of consecutive PAP use data that meets the minimum compliance standard.
3. After the driver demonstrates compliance with 90 days of PAP use data, the CME may issue a 1-year certification.
4. If the driver cannot produce 30 days of consecutive PAP use data, the driver must be disqualified and cannot be re-certified until he/she are able to provide 30 days of compliant PAP use data.

VI. Treatment: Oral appliance

- A. MRB Recommendation: A driver with a diagnosis of moderate to severe OSA should try PAP therapy before oral appliance therapy, unless a board-certified sleep specialist has determined that an alternative therapy such as PAP is intolerable for a driver, in which case the driver should have the option to pursue oral appliance therapy to treat OSA.
 1. Rationale: Based on the available medical literature, drivers with a diagnosis of moderate to severe OSA are less likely to achieve resolution of moderate to severe OSA with an oral appliance than with PAP therapy.
 2. There is limited data regarding compliance and long-term efficacy of oral appliances.
- B. A driver may be certified or re-certified for up to 1 year (per **Recommendation III**) if the following conditions are met:
 1. A repeat sleep study shows resolution of moderate to severe OSA, and
 2. The driver has been cleared by the treating clinician, and
 3. **The driver must demonstrate objective compliance that is equivalent to the minimum records requirements and minimum compliance standard for PAP therapy, and**
 4. The driver does not report excessive sleepiness during the major wake period.

VII. Treatment: Bariatric surgery

- A. Post-op, first 6 months: A driver with an established diagnosis of moderate to severe OSA may be certified if he/she:
 1. Has been cleared by the treating clinician, and
 2. Is able to provide evidence of compliance with PAP **or oral device** OSA therapy (see **Recommendations V and VI**).
- B. Post-op, after 6 months: After 6 months have passed since surgery, a driver may be certified, provided that:
 1. A repeat sleep study shows that the driver no longer has a moderate to severe OSA diagnosis, and

2. The driver does not report excessive sleepiness during the major wake period.

C. Annual recertification

1. If clinically indicated, repeat the sleep study.

VIII. Treatment: Oropharyngeal surgery, Facial bone surgery

A. Post-op, less than 1 month: A driver with an established diagnosis of moderate to severe OSA may be certified if he/she:

1. Has been cleared by the treating clinician, and
2. Is able to provide evidence of compliance with PAP or oral device OSA therapy (see **Recommendations V and VI**).

B. Post-op, after 1 month: After 1 month has passed since surgery, a driver may be certified, provided that:

1. A repeat sleep study shows that the driver no longer has a moderate to severe OSA diagnosis, and
2. The driver does not report excessive sleepiness during the major wake period.

C. Annual recertification

1. If clinically indicated, repeat the sleep study.

IX. Treatment: Tracheostomy

A. Post-op, less than 1 month: A driver with an established diagnosis of moderate to severe OSA may be certified if he/she:

1. Has been cleared by the treating clinician, and
2. Is able to provide evidence of compliance with PAP or oral device OSA therapy (see **Recommendations V and VI**).

B. Post-op, after 1 month: After 1 month has passed since surgery, a driver may be certified, provided that:

1. A repeat sleep study shows that the driver no longer has a moderate to severe OSA diagnosis, and
2. The driver does not report excessive sleepiness during the major wake period.

C. Annual recertification

1. If clinically indicated, repeat the sleep study.