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| FMCSA logoMOTOR CARRIER SAFETY ADVISORY COMMITTEE 1C/O: Federal Motor Carrier Safety Administration1200 New Jersey Avenue, SEWashington, DC 20590 | FMCSA logoMEDICAL REVIEW BOARD1C/O: Federal Motor Carrier Safety Administration1200 New Jersey Avenue, SEWashington, DC 20590 |

November 21, 2016

The Honorable T.F. Scott Darling, III

Administrator

Federal Motor Carrier Safety Administration

1200 New Jersey Avenue, SE

Washington, DC 20590

Dear Administrator Darling:

Enclosed for your consideration are the Medical Review Board (MRB) and the Motor Carrier Safety Advisory Committee (MCSAC) joint recommendations regarding public comments from medical professionals and associations on the Federal Motor Carrier Safety Administration’s (FMCSA) and Federal Railroad Administration’s (FRA) Advanced Notice of Proposed Rulemaking (ANPRM) on obstructive sleep apnea. In *Medical Review Board Task 16-1*, 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 MCSAC. On August 22-23, 2016, the MRB met in public meetings to deliberate on *Medical Review Board Task 16-1*, and developed draft recommendations.

On October 24, 2016, the MCSAC and MRB met jointly in public meetings to deliberate on the MRB’s draft OSA recommendations for *Medical Review Board Task 16-1*. During that meeting, the MCSAC recommended changes to the MRB’s Task 16-1 recommendations, which the MRB accepted. The attached report includes all of the joint MRB-MCSAC recommendations related to *Medical Review Board Task 16-1*.

We respectfully submit this report to FMCSA for its consideration.

Sincerely,

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| //signed// Gina C. Pervall, MD, CIME Chairman, Medical Review Board  | //signed//Col. Scott HernandezChairman, Motor Carrier Safety Advisory Committee |

Enclosure

**Introduction**

The Medical Review Board (MRB) and the Motor Carrier Safety Advisory Committee (MCSAC) developed and discussed several key questions and the 2012 joint MCSAC-MRB recommendations in considering the comments from medical professionals and associations on the March 2016 Federal Motor Carrier Safety Administration (FMCSA)-Federal Railroad Administration (FRA) Advanced Notice of Proposed Rulemaking (ANPRM), as the Agency requested in Task 16-1. The following list of questions address factors that FMCSA should consider in making a decision about the next stop in the obstructive sleep apnea (OSA) rulemaking.

* 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)?

In response to Task 16-1, discussion of the above questions, the March 2016 ANPRM comments from medical professionals and associations, the 2012 joint MCSAC-MRB recommendations, and most current medical standards and practice formed the basis of the following recommendations for consideration by FMCSA when determining the next step in an OSA rulemaking. The MRB and MCSAC joint recommendations are summarized below.

In addition, and related to the Agency’s action on a future OSA rulemaking, the MCSAC asks that FMCSA evaluate the impacts of these regulations on driver health and wellness and safety. Further, the MRB and MCSAC recommend 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.

1. **General Recommendations Regarding OSA**
2. Certified Medical Examiners (CMEs) must screen drivers presenting for medical certification for OSA diagnostic testing in accordance with Section III.B.
3. CMEs cannot issue a medical card for more than 1 year to a driver with an established diagnosis of OSA, regardless of severity.
4. A CME may certify a driver with an OSA diagnosis if the driver is being treated effectively (see Sections V through IX).
5. For certification purposes, “effective treatment” or “treated effectively” is defined as the resolution of moderate to severe OSA to mild OSA or better, as determined by a board-certified sleep specialist.
6. **Immediate Disqualification**
7. Drivers should be disqualified immediately and referred for OSA diagnostic testing if any of the following conditions exist:
	1. Individuals who report excessive sleepiness while driving.
	2. Individuals who experience a crash associated with falling asleep.
	3. Individuals who have been observed sleeping behind the wheel while operating the vehicle.
	4. Individuals found non-compliant with treatment per Sections V through IX.
8. The CME should have the discretion to disqualify any driver who appears to be at extremely high risk.
9. Drivers disqualified for any of the above reasons must remain disqualified until evaluated and treated effectively with compliance.
10. To requalify, drivers must show effective treatment and compliance. At minimum, they need compliance for 2 weeks with recertification for 90 days with continued compliance.
11. **Conditional Certification**
12. Conditional certification should include the following elements:
13. A driver determined to be at risk for OSA based on Body Mass Index (BMI) (with or without risk factors) may be certified for 90 days pending sleep study and treatment (if the driver is diagnosed with OSA).
14. Within 90 days, if a driver being treated with OSA is compliant with treatment (per Sections 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 Sections V through IX).
15. Referral to OSA Diagnostic Testing Based on Screening (i.e., Identifying Individuals With Undiagnosed OSA)
16. MRB-MCSAC Recommendation: Individuals with the following should be referred for diagnostic sleep evaluations:
	1. Individuals with a BMI ≥ 40 mg/kg2.
	2. Individuals with a BMI ≥ 33 and < 40 mg/kg2 in addition to and at least 3 or more of the following:
		1. Hypertension (treated or untreated);
		2. Type 2 diabetes (treated or untreated);
		3. History of stroke, coronary artery disease, or arrhythmias;
		4. Micrognathia or retrognathia;
		5. Loud snoring;
		6. Witnessed apneas;
		7. Small airway (Mallampati Classification of Class III or IV – see photos of Mallampati Classification below);
		8. Neck size > 17 inches (male), > 15.5 inches (female);
		9. Hypothyroidism (untreated);
		10. Age 42 and above; or
		11. Male or post-menopausal female.
	3. Note: One MRB member and several MCSAC members thought that there should be at least 4 other risk factors in addition to BMI ≥ 33 and < 40 mg/kg2 instead of 3. These members recommended reviewing the required number of risk factors in the future to determine if this number should be lowered.
	4. Sample images show what Mallampati Classification Classes I through IV throat look like[[1]](#footnote-1):



1. Rationale: Based on public comments that other factors should be considered in addition to BMI, the MRB and MCSAC recommend 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.
	1. 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.
	2. However, the MRB and MCSAC 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.
	3. Subjective sleepiness questionnaires would not be helpful because of unlikelihood of truthfulness.
	4. Note, craniofacial abnormalities and Mallampati Classification may be difficult for some CMEs to assess.
	5. The MRB and MCSAC replaced the “small or recessed jaw” risk factor with “micrognathia or retrognathia” because those terms are more clinical and objective.
2. Frequency of OSA Diagnostic Testing
	1. MRB-MCSAC 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 previous sleep study and a newly recommended sleep study.
		2. One MRB member (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.
	2. 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 impose an unnecessary cost on these drivers.
3. **Method of Diagnosis and Severity**
4. Methods of diagnosis include in-laboratory polysomnography (which is preferred), as well as at-home sleep apnea testing that ensures chain of custody.
5. In-laboratory polysomnography should be considered when the clinician suspects:
	1. Another medical disorder occurring during sleep (e.g., a seizure disorder, restless leg syndrome, narcolepsy, central sleep apnea), and/or
	2. The individual has significant co-morbidities (e.g., neuromuscular disorder or chronic obstructive pulmonary disease (COPD)).
6. All sleep studies must be interpreted by a board-certified sleep specialist.
7. New OSA screening technologies will likely emerge.
8. The driver should be tested while on usual chronic medications.
9. 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.
10. **Treatment: Positive Airway Pressure (PAP)**
11. Based on the available medical literature, PAP therapy is the preferred OSA treatment.
12. Adequate PAP pressure should be established through one of the following methods:
	1. Titration study with polysomnography.
	2. Auto-titration system.
13. A driver may be certified initially for up to 1 year (per Section III.A) 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) (Note: The CME has the discretion to extend the certification for no more than 30 days.), 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.
	4. While the driver is gathering PAP compliance data, he or she may continue to drive a CMV as long as he or she has a valid CME certificate and has not been disqualified.
14. A driver may be re-certified for up to 1 year (per Section III.A) if the following conditions are met:
15. 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
16. The driver’s PAP use records must demonstrate at least 4 hours per night use on 70 percent of nights (minimum compliance standard), and
17. The driver does not report excessive sleepiness during the major wake period.
18. 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 or she is able to provide 30 days of compliant PAP use data.
19. **Treatment: Oral appliance**
	1. MRB-MCSAC 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.
	2. A driver may be certified or re-certified for up to 1 year (per Section III.A) 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 does not report excessive sleepiness during the major wake period.
20. **Treatment: Bariatric surgery**
	* + 1. Post-operative, 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 Sections V and VI).
			2. Post-operative, 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.
			3. Annual recertification
21. If clinically indicated, repeat the sleep study.
22. **Treatment: Oropharyngeal surgery, Facial bone surgery**
	* + 1. Post-operative, 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 Sections V and VI).
			2. Post-operative, 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.
			3. Annual recertification
			4. If clinically indicated, repeat the sleep study.
23. **Treatment: Tracheostomy**
24. Post-operative, 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 Sections V and VI).
25. Post-operative, after 1 month: After 1 month has passed since surgery, a driver may be certified, provided that:
26. A repeat sleep study shows that the driver no longer has a moderate to severe OSA diagnosis, and
27. The driver does not report excessive sleepiness during the major wake period.

C. Annual recertification

1. If clinically indicated, repeat the sleep study.
1. Image is borrowed from Sleep Journal, <http://www.journalsleep.org/Articles/290707.pdf> (last accessed Nov. 14, 2016). [↑](#footnote-ref-1)