

FMCSA Bulletin to Medical Examiners and Training Organizations Regarding Obstructive Sleep Apnea

The purpose of this bulletin is to remind healthcare professionals on FMCSA's National Registry of Certified Medical Examiners (the National Registry) of the current physical qualifications standard and advisory criteria concerning the respiratory system, specifically how the requirements apply to drivers that may have obstructive sleep apnea (OSA).

Current Physical Qualifications Standard for Respiratory Conditions

FMCSA's physical qualifications standards prohibit individuals from receiving a medical examiner's certificate to operate commercial motor vehicles in interstate commerce if they have an "established medical history or clinical diagnosis of a respiratory dysfunction likely to interfere with his or her ability to control and drive a commercial motor vehicle safely." (49 CFR 391.41(b)(5)). OSA is considered a respiratory dysfunction when there is a determination that it is likely to interfere with the driver's ability to operate safely because of the severity of the case.

OSA is a respiratory disorder characterized by a reduction or cessation of breathing during sleep coupled with symptoms such as excessive daytime sleepiness. Given this, OSA may culminate in unpredictable and sudden incapacitation (e.g., falling asleep at the wheel), thus contributing to the potential for crashes, injuries, and fatalities.

During sleep, OSA blocks the airway and prevents the individual from breathing up to dozens of times per hour, awakening the sleeper. This means that the time in bed does not equal time slept – in fact, eight hours of sleep with OSA can be less refreshing than four hours of ordinary, uninterrupted sleep, posing serious cognitive and neuropsychological risks. Moreover, someone without enough restorative sleep is often unaware of impairments to a range of cognitive abilities such as vigilance, reaction time, attention span, memory, learning, problem-solving, decision making, and multi-tasking. OSA can also lead to mood swings and difficulty controlling inappropriate feelings. In driving simulations, OSA patients were more likely to unintentionally swerve and strike objects – a serious and dangerous outcome for the transportation industry.

OSA raises health and safety concerns beyond those of other sleep disorders. Near-term increases in fatigue and cognitive dysfunction can result. Also, there are long-term adverse health effects such as dramatically increased risk for hypertension, heart disease, stroke, diabetes, and obesity.

FMCSA's Advisory Criteria from 2000

In 2000, FMCSA issued advisory criteria providing interpretive guidance to medical examiners concerning its physical qualifications standards. These advisory criteria are recommendations from FMCSA to assist medical examiners in applying the minimum physical qualification standards. The advisory criteria have been published with the Federal Motor Carrier Safety Regulations as part of the medical examination report form in 49 CFR 391.43 (Physical Qualification of Drivers; Medical Examination; Certificate, 65 FR 59363 (October 5, 2000)).

The advisory criterion for § 391.41(b)(5), which has been unchanged since 2000, provides the following guidance for medical examiners in making the determination whether a driver satisfies the respiratory standard:

Since a driver must be alert at all times, any change in his or her mental state is in direct conflict with highway safety. Even the slightest impairment in respiratory function under emergency conditions (when greater oxygen supply is necessary for performance) may be detrimental to safe driving.

There are many conditions that interfere with oxygen exchange and may result in incapacitation, including emphysema, chronic asthma, carcinoma, tuberculosis, chronic bronchitis and sleep apnea. If the medical examiner detects a respiratory dysfunction, that in any way is likely to interfere with the driver's ability to safely control and drive a commercial motor vehicle, the driver must be referred to a specialist for further evaluation and therapy. Anticoagulation therapy for deep vein thrombosis and/or pulmonary thromboembolism is not unqualifying once optimum dose is achieved, provided lower extremity venous examinations remain normal and the treating physician gives a favorable recommendation.

Based on the above advisory criterion, it is clear that FMCSA has considered OSA a respiratory dysfunction that interferes with oxygen exchange. And the Agency recommends that, if a medical examiner believes the driver's respiratory condition is in any way likely to interfere with the driver's ability to safely control and drive a commercial motor vehicle, the driver should be referred to a specialist for further evaluation and therapy. This advisory criterion is helpful to medical examiners when the examiner has sufficient experience or information to recognize certain risk factors for OSA, or when a driver tells the examiner that he or she has been diagnosed with OSA. Under these circumstances, the medical examiner should consider referring the driver to a specialist for evaluation before issuing a medical examiner's certificate, or request additional information from the driver and his or her treating healthcare professional about the management of the driver's OSA, respectively.

Role of Medical Examiners' Clinical Judgment in the Medical Certification Process

FMCSA's physical qualifications standards and advisory criteria do not provide OSA screening, diagnosis or treatment guidelines for medical examiners to use in determining whether an individual should be issued a medical certificate. Medical examiners may exercise their medical judgment and expertise in determining whether a driver exhibits risk factors for having OSA and in determining whether additional information is needed before making a decision whether to issue the driver a medical certificate and the duration of that medical certification.

FMCSA urges medical examiners to explain clearly to drivers the basis for their decision concerning the issuance of a medical certification for a period of less than two years or the denial of a medical certification. The Agency encourages medical examiners to consider the following in making the medical certification decision:

- The primary safety goal regarding OSA is to identify drivers with moderate-to-severe OSA to ensure these drivers are managing their condition to reduce to the greatest

extent practical the risk of drowsy driving. Moderate-to-severe OSA is defined by an apnea-hypopnea index (AHI)¹ of greater than or equal to 15.

- The Agency does not require that these drivers be considered unfit to continue their driving careers; only that the medical examiner make a determination whether they need to be evaluated and, if warranted, demonstrate they are managing their OSA to reduce the risk of drowsy driving.
- **Screening:** With regard to identifying drivers with undiagnosed OSA, FMCSA's regulations and advisory criteria do not include screening guidelines. Medical examiners should consider common OSA symptoms such as loud snoring, witnessed apneas, or sleepiness during the major wake periods, as well as risk factors, and consider multiple risk factors such as body mass index (BMI), neck size, involvement in a single-vehicle crash, etc.
- **Diagnosis:** Methods of diagnosis include in-laboratory polysomnography, at-home polysomnography, or other limited channel ambulatory testing devices which ensure chain of custody.
- **Treatment:** OSA is a treatable condition, and drivers with moderate-to-severe OSA can manage the condition effectively to reduce the risk of drowsy driving. Treatment options range from weight loss to dental appliances to Continuous Positive Airway Pressure (CPAP) therapy, and combinations of these treatments. The Agency's regulations and advisory criteria do not include recommendations for treatments for OSA and FMCSA believes the issue of treatment is best left to the treating healthcare professional and the driver.

Conclusion

FMCSA relies on medical examiners to make driver qualification decisions based on their clinical observations, findings and standards of practice. The current regulations and advisory criteria do not include guidelines concerning OSA screening, diagnosis and treatment. Medical examiners should rely upon their medical training and expertise in determining whether a driver exhibits symptoms and/or multiple risk factors for OSA, and they should explain to the driver the basis for their decision if the examiner decides to issue a medical certificate for a period of less than two years to allow for further evaluation, or to deny a driver the medical certificate.

¹ AHI = (apneas + hypopneas)/hours of sleep. Apnea is a term for the involuntary suspension of breathing during sleep. During an apnea there is no movement of the respiratory muscles and the volume of air in the lungs initially remains unchanged. Hypopnea is a term for a disorder which involves episodes of overly shallow breathing or an abnormally low respiratory rate. This differs from apnea in that there remains some flow of air. Hypopnea events may happen while asleep or while awake.