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Comments on MRB Hearing for OSA in FMCSA/FRA:

Driving by truck drivers and bus drivers is a professional endeavor. There is a higher standard of safety held for these professional drivers than the general driver population. The CDL holder has the ability no matter what job they regularly do to take on commercial driving work even as a side job. Driving entails a complex set of tasks and skills as a professional driver with distinct cognitive, perceptual, motor, and decision-making activities as indicated on the DOT Physical Qualifications for Drivers section under the Drivers Role section. This section goes on further to add that a driver must constantly survey the ever-changing roadway environment from an elevated position to keep the vehicle in the lane and moving at an appropriate safe speed. Whether responsible for an accident or not, the professional driver is expected to avert error or accident because of the larger load one is responsible for and the significant damage it can cause to self and others. Therefore, surveillance of the road is important and involves 2 distinct visual tasks: estimating and responding to ongoing activities at risk earlier than the general population and controlling lane position. Divided attention on tasks involving speed and lane control as well as monitoring can be affected by distraction, fatigue, sleepiness,medications, and texting. To do this in a safe way requires careful attention and alertness which can be difficult when fatigue, sleep disorders, sleep deprivation, distraction, and obstructive sleep apnea (OSA) are present in addition to medications or sedative/stimulant substance abuse.

The DOT Regulations direct the certified medical examiner(CME) to qualify drivers who do not “have an established medical history or clinical diagnosis of a respiratory dysfunction likely to interfere with the ability to control and drive a commercial motor vehicle(CMV) safely”. Further the same section on respiratory dysfunction in 391.41(b)(5) goes on to state ”…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 maybe detrimental to safe driving.”

Sleep apnea is identified in the Respiratory Dysfunction section of qualification as one of the many conditions which interfere in oxygen exchange which could lead to incapacitation. As per the Respiratory Dysfunction section, “ –IF THE EXAMINER DETECTS A RESPIRATORY DYSFUCTION 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.” Thus this line in the current DOT regulations as a part of 391.41(b)(5) compels the CME to refer a driver if the CME detects a respiratory dysfunction without the mention of a diagnosis made to a specialist not any physician for further evaluation; this would mean typically a sleep specialist, neurologist, or pulmonologist.

OSA is a respiratory dysfunction which affects approximately 2-4% of the population. The exact nature of the derangement as noted in AASM guidelines is a repetitive collapse of the upper airway causing sleep fragmentation, hypoxemia, hypercapnia, excessive daytime sleepiness, loud snoring, witnessed breathing pauses, or regular awakenings due to gasping for breath or choking. Snoring loud is one of the major hallmarks of the disease and the higher the snoring scale score(SSS) for snoring the more severe the risk of OSA. The diagnosis of OSA goes back to the 1980’s so it has been a known disease with an ICD-10 code of G47.33.

Risk factors for OSA include the following: 1. Elevated BMI (the most predictive) 2. Neck circumference greater than 16 in. when incorporate both genders 3. Mallampati score 3 or 4. Hypognathia or similar facial dysmorphisms 5. Age greater > 50 6. Hypertension 7. Diabetes Mellitus 8. Excessive Snoring 9. Excessive daytime sleepiness. With this disease causing daytime sleepiness and decreased alertness plus fatigue, it is important to assess risk factors to identify the persons at significant risk. This is even more imperative with safety sensitive positions such as CDL drivers and FRA operators. As already cited, the DOT regulations do clearly state the CME must suspect and detect respiratory dysfunction like OSA which could impair driving. So it is in our CME role to use history and exam as part of our professional duty to ensure that OSA especially in a moderate to severe level is not present in the drivers we certify. The risk factors listed above are all objective except for the 8 and 9 ones which rely on subjective information of the drivers. As noted in the comments for the rules, the more objective the data the better for purposes of determining who needs a sleep study. In review of the screening tools for OSA, the STOP-BANG screen possesses the most objective surveyed information which includes at least 5 objective determinants plus much more direct questions about symptoms. The sensitivity of 4 or more on this screen is 89.5%. A 5 or more on this screen is considered high risk. Berlin has less objective data pieces and more subjectivity whereas the Epworth is all subjective self-reporting leading to under-reporting and much less sensitivity overall.

From the data on OSA risk factors, the strongest predictors of more severe OSA are BMI and neck circumference. The scientific reports used by AASM, the academic body of sleep experts, recommend that a BMI of greater than 35 is an important risk. The studies have shown that at this level the moderate to severe OSA percentage is at least 30%. For every 1 point increase in BMI, the risk of OSA increases by 14%. In my practice experience of seeing greater than 15,000 drivers for exams since 1988, 80% of my drivers with BMI greater than 40 have a moderate to severe OSA by full sleep testing. At greater the 50 BMI, the sleep studies in my drivers are 100% positive for moderate to severe sleep apnea. I consider that 80% or above to be a clear indicator of disease prevalence and of severe safety risk: we are not talking about mild disease here. On a related thought, my competitor occupational medicine MD in Hickory, N.C. Allen Edwards unsolicited provided his comments to FMCSA supporting the notion that BMI greater than 40 had a 90% positive sleep study for significant disease in his practice.

As in the commentaries provided to the FMCSA, Truckers for a Cause encouraged the agency to talk to sleep expert Dr. Phillips, a former MRB member. The preceding MRB had recommended an even lower BMI at 33 since the prevalence of moderate to severe disease was at that level greater than 30%. They also established a level of AHI of 20 for reason to start treatment for OSA to qualify. A similar listing of risk factors were also recommended back in 2007 by that board. I would recommend that each MRB member attempt to talk to Dr. Phillips as encouraged by Bob Stanton of the above group so to understand the background and current status of true scientific research outlining this disease, its risk factors, proper screening and diagnosis including desaturations which are at even greater risk for drivers, co-morbidity issues, and proper treatment.

I would recommend that any drivers who are proven with symptomatic OSA and not on CPAP be disqualified, not certified. They can regain certification after reaching compliance with CPAP. At this time FDA does not approve oral appliances for moderate to severe OSA so this is not accepted. Drivers who have fallen asleep on the job or have been in accidents where sleep was a risk factor or have witnessed sleep in the exam room or at home should be disqualified, not certified until in house sleep study done to cover more than OSA for appropriate diagnosis of the sleep issue. Any driver having significant healthy weight loss with a OSA diagnosis needs a sleep study to clear themselves of treatment for CDL qualification; as noted in past drafts of MRB, the bypass surgery group with OSA remain in that category until 6 months out from surgery to ensure stabilized when a sleep study can be done to clear them of OSA presence. UPPP surgery would also require a repeat OSA testing when stabilized and healed before could go off CPAP.

As for testing, I am still concerned about the lack of chain of custody for home sleep testing and the lack of completeness for sleep disorders which are all still important for our overall evaluations. The gold standard for sleep evaluations is the in house lab sleep studies. All home testing PSG can only be a first line screening test which means that if we suspect moderate to severe OSA, a high risk safety status, then even if the home PSG is negative, a lab sleep study is needed to fully vet and clear. The PSG is really only good for a positive result which then requires appropriate CPAP testing to get the right pressure measurement. All AHI of 20 or more must necessitate a hold on driving until start CPAP with proper print-out compliance of 70% of days 4 hour days. If the AHI is under 20 but significant symptoms are reported by the driver or indicated on study, then treatment is also a must. Another important test from the sleep study beyond AHI is desaturations below 90% on a regular basis. In this situation, treatment with CPAP is a must to restore oxygen levels which is also a respiratory dysfunction, hypoxemia.

The CME should look at multiple risk factors for OSA to decide on who with no history of diagnosis for OSA has to prove no evidence of risk of moderate to severe OSA to qualify in 3 months This is in the situation where there is no immediate reason to hold driver as noted above for automatic sleep study

The STOP-BANG would be the best tool to use for risk factor assessment. At 4 or above on this screen, a driver should be referred for a sleep study within a 3 month period thus receiving only a 3 month card on that exam date. In 3 months, the driver would have to prove no OSA or compliance with CPAP if positive on the study for AHI of 20 or greater or significant oxygen desaturations. I would advise also adding DM as a risk point score of 1 along with small jaw, or narrowed Mallampati of 3-4 to the objective side of the STOP-BANG tool since these are clear risk factors not included on this screen. When the BMI is over 50 without any other risk factors, the CME should do sleep studies regardless because the almost certain risk of moderate to severe OSA in these drivers.

Since we are focused on moderate to severe OSA for evaluation not mild as been asserted by many of the commentaries, then appropriate treatment for this disease is needed. No one would question not treating hypertension, diabetes, or heart disease at a moderate to severe level in these drivers including the more strident in the comment group. Therefore, the data does show that CPAP is effective treatment of OSA over oral appliances as seen in the data provided. Plus the FDA does not support the use of oral appliances in moderate to severe OSA. These appliances lack a good accountability for compliance and thus are not appropriate in my opinion at this moment for treatment. If a driver can not show the ability to adhere to proper use or compliance with CPAP then we can not certify them. Their options at that juncture with a positive OSA AHI 20 or more oxygen desaturations would have to seek surgery UPPP if appropriate or obesity by-pass surgery if necessary to possibly reach no need for treatment of OSA. Again as noted above, a sleep study after recovery is needed to clear. If significant weight gains occur in previous OSA group or a new at risk driver approximately 30 -40 lbs or more, then a sleep is needed to reevaluate or newly evaluate.

I do feel strongly as recommended for treatment in chronic opioid or sedative drivers that these drivers have proper sleep studies to ensure OSA is not present which could kill them or if present lead to accidents which would possibly injure others. We have determined that drivers meeting the Schedule 2 exemption protocol can drive. Possibly we should revisit whether these drivers cleared previously or presently should demonstrate to have no OSA problems by sleep study and thus can drive CDL after meeting opioid/sedative protocol. If positive on study, they would need to be compliant on CPAP to continue certification. We should look at this group as its own separate risk factor requiring OSA testing without other risk factors included to be certified. And we should include these medications as an additional risk factors to consider with the others for OSA.

My final thoughts are we five have an important responsibility to ensure that our drivers are safe to drive their 18 wheelers, buses, trains, or other at risk CDL vehicles. We must remember that ultimately our job is to protect the family of four driving in front of our certified drivers. As many of us in the exam room encounter, CDL drivers certifying or recertifying will ask how those guys they see out on the road can qualify to drive with their size or their breathlessness or their sleepiness; they ask me who is certifying them to drive. Our job is to make guidelines to help our fellow CMEs do their work better in certification of the health of drivers on the road so all are protected out there.