FEDERAL MOTOR CARRIER SAFETY ADMINISTRATION
U.S. DEPARTMENT OF TRANSPORTATION
DOCKETS # FMCSA-2015-0419

Evaluation of Safety Sensitive Personnel for Moderate-to-Severe Obstructive Sleep Apnea

SUBMITTED BY:
American Trucking Associations, Inc.
950 North Glebe Road
Suite 210
Arlington, VA 22203

July 8, 2016

Contact:
Megan Bush
Manager, Safety Policy
703-838-7950

I. Introduction
American Trucking Associations, Inc., (ATA) submits these comments to the Federal Motor Carrier Safety Administration’s (FMCSA) Advance Notice of Proposed Rulemaking on the Evaluation of Safety Sensitive Personnel for Moderate-to-Severe Obstructive Sleep Apnea.\(^1\) American Trucking Associations is the national trade association representing the American trucking industry.\(^2\) As a safety-first organization, ATA is committed to enhancing and promoting the safety of the trucking industry and our nation’s highways. As such, ATA is vitally interested in matters affecting highway safety, including steps to address obstructive sleep apnea among commercial truck drivers.

II. Summary of ATA’s position
ATA recognizes the growing interest in obstructive sleep apnea as a safety concern. As with any regulation, any future rule to require OSA screening and treatment for commercial truck drivers should be based on sound data and analysis, including the potential costs and benefits. It is also vital that FMCSA have a firm understanding of the actual crash risk that OSA poses, of which there has been minimal data to date. FMCSA should study and evaluate the percentage of CMV crashes that are caused by OSA prior to issuing a formal notice of proposed rulemaking. To encourage drivers to be forthcoming with essential health information during medical examinations, the agency should also include in any sleep apnea proposal an education component to make drivers aware that OSA alone, if properly treated, is not a disqualifying condition.

---

\(^1\) 81 Federal Register 47, 12642
\(^2\) ATA is a united federation of motor carriers, state trucking associations, and national trucking conferences created to promote and protect the interests of the trucking industry. Directly and through its affiliated organizations, ATA encompasses over 34,000 motor carriers and suppliers of every type and class of operation in the United States, Canada, and Mexico.
Should FMCSA proceed with a formal rulemaking, OSA testing and treatment options should, to the maximum extent possible, minimize the costs that would be imposed on motor carriers and commercial motor vehicle drivers. FMCSA should consider the effectiveness of all viable OSA screening and treatment options, including in-lab polysomnography (PSG), home-based sleep testing, continuous positive air pressure (CPAP), oral appliances, and other effective alternative treatments. To further minimize cost and operational burdens, MEs should be authorized to grant conditional qualification status to drivers they refer for sleep studies, unless their MEs determine that allowing them to continue to operate would pose an imminent safety risk on the highway. Similarly, FMCSA should also permit drivers that are adjusting to CPAP therapy to continue to operate during the initial adjustment phase, so long as they are being monitored for compliance. The agency should also avoid requiring a driver who has previously undergone a sleep test to submit to a follow-up test when seeking to renew his/her medical certification, unless the ME determines that the driver has developed additional risk factors.

Far too often, drivers are singled out for OSA screening by MEs because they exhibit a single risk factor. Required OSA screening should be focused on drivers who show multiple risk factors indicative of moderate-to-severe OSA. MEs should also be directed in any proposed OSA rule to be cautious when using body mass index (BMI) to assess a driver’s risk for OSA, as BMI can be a misleading indicator of overall health. Finally, many motor carriers have invested substantial resources to develop in-house programs to address OSA among their driver workforces. Any OSA rule promulgated by FMCSA should not hinder the efforts and investments made by these carriers.

III. Comments

ATA has long-recognized that OSA is a health and safety concern in the transportation sector, particularly among drivers of commercial motor vehicles (CMVs). As such, we appreciate the opportunity to comment on the ANPRM and offer the following principles that FMCSA should be mindful of during this process.

Any Rule Should be Data and Science-Based

As with any regulation, a rule to require OSA screening and treatment for commercial truck drivers should be based on sound data and analysis. In order to craft an effective rule, FMCSA must consider the prevalence of moderate-to-severe OSA among the driver workforce, the options to treat it, the potential costs to drivers and the supply chain to address it, including monitoring compliance, and any corresponding safety benefits of doing so.

Crashes are often the result of multiple factors, of which fatigue caused by untreated OSA may be a primary or secondary contributor. FMCSA has historically contended that approximately 7% of crashes involving CMVs are caused by driver fatigue. In order to understand the scope of the problem, FMCSA must have a full understanding of the actual crash risk that OSA poses and should determine the percentage of CMV crashes caused by OSA versus other causes (e.g. a driver failing to use off-duty time

to get adequate rest). In other words, what portion of the 7% of crashes caused by driver fatigue are attributable to OSA? Moreover, the agency must determine how many crashes will be prevented by promulgating a sleep apnea rule. Only then can FMCSA truly determine whether expected safety benefits, if any, will outweigh the substantial costs such a rule will impose on drivers, carriers, shippers, and ultimately, American consumers.

To date, studies to determine the crash risk of sleep apnea have been mixed. A 2004 FMCSA study on sleep apnea crash risk concluded “results from this study showed that the presence and severity of sleep apnea in commercial truck drivers are not good predictors of motor vehicle crash involvement.” Furthermore, “no compelling statistical evidence was found that supports the hypothesis that sleep apnea increases crash risk among commercial drivers.” The study also found no evidence in the data analyzed to suggest that crash risk was impacted prior to and after a sleep apnea diagnosis.

A recent study published in the journal *Sleep* purported to find a higher crash risk among OSA-positive drivers who failed to adhere to their employer-mandated treatment compared to drivers who complied with their prescribed treatment. However, the study also showed that the crash risk for non-adherent drivers remained quite small at .070 crashes per 100,000 miles, or .7 crashes per one million miles. This equates to one crash per 1.42 million miles. Given that drivers average 25,594 miles per year, this equates to 55 years between crashes. FMCSA must consider the rarity of such events when evaluating the need to address sleep apnea and the need for expensive testing and treatment.

Furthermore, it appears that the number of drivers that fail to adhere to treatment is quite small. The American Transportation Research Institute (ATRI) recently conducted a survey of CMV drivers on issues relating to sleep apnea. According to the survey, only 1.95% of drivers with moderate-to-severe OSA indicated that they were non-adherent to their OSA treatment.

The *Sleep* study could not conclusively demonstrate whether the higher crash rate among untreated OSA drivers was directly responsible for the higher crash risk associated with those drivers. As the study’s authors noted, while non-adherent drivers had a higher crash risk, “it is not possible to conclude that this difference was caused by the effect of untreated OSA.” After all, drivers who fail to adhere to employer-mandated treatment may also tend to violate other safety rules and regulations at a higher

---

7 Burks, Stephen V. et al. “Non-Adherence with Employer Mandated-Sleep Apnea Treatment and Increased Risk of Serious Truck Crashes”, 2016
8 \[
\frac{100,000}{0.07} = \frac{x}{0.07} = \frac{100,000}{0.07}; x = 1,428,571
\]
10 Boris, C. and Brewster, R. *Commercial Driver Perspectives on Obstructive Sleep Apnea*, American Transportation Research Institute, May 2016.
11 Burks, Stephen V. et al. “Non-Adherence with Employer Mandated-Sleep Apnea Treatment and Increased Risk of Serious Truck Crashes”, 2016
rate compared to treatment-adherent drivers, which could account for their enhanced crash risk. In order for FMCSA to develop a reasoned, cost-effective rule to address OSA, more conclusive data on the actual crash risk OSA poses is needed.

It will likely take time to acquire the data needed to determine the costs and safety benefits of a regulation pertaining to OSA screening and treatment. Hence, ATA cautions FMCSA against rushing to impose a hastily conceived rule, especially since the agency is under no statutory requirement or deadline to issue such a regulation. In the ANPRM, FMCSA notes that “Congress enacted Public Law 113-45...directing FMCSA to issue any new or revised requirements concerning sleep disorders, including OSA, by rulemaking.” This should not be interpreted to mean that FMCSA must promulgate new screening, testing and treatment rules. Rather, the statute simply states that FMCSA may implement such requirements only if they have been adopted through the rulemaking process. Also, because FMCSA’s mission is to promote and improve safety, the agency should have solid data that a proposed rule to address OSA will actually improve safety before moving forward. Given the potential impact such a rule will have on drivers and the supply chain, a cautious approach is necessary.

Driver Awareness is Important for Accurate and Quality Medical Examinations

In order for the medical certification process to be effective, it is imperative that drivers provide accurate and complete health history information to medical examiners. The ANPRM describes several crashes - only one of which involved a CMV driver - in which the National Transportation Safety Board had determined that OSA had played a role. In the crash involving a tractor-trailer, the ANPRM reports that its driver “had been diagnosed with and undergone surgery for OSA, but had not indicated either the diagnosis or the surgery on examinations for medical certification.” This case demonstrates the necessity of driver honesty when completing the Medical Examination Report Form (MCSA-5875). However, today, drivers may be reluctant to report symptoms of, or a prior diagnosis of, OSA to MEs out of the fear that they will lose their ability to drive. So as not to provide an incentive for drivers to withhold such critical health information from MEs, any proposal should include a mechanism to educate drivers that OSA is not a disqualifying condition if a driver adopts and adheres to treatment via CPAP, oral appliance, or other effective method as deemed appropriate by an ME.

Consistency is Needed in OSA Diagnosis Referrals and Screening

ATA appreciates that FMCSA has taken this first step to bring much-needed uniformity to the medical qualification process as it pertains to the screening for OSA. When determining whether a driver must seek further evaluation for OSA, MEs currently are guided only by FMCSA’s bulletin on how the current physical qualification standard concerning the respiratory system applies to OSA. This has led to an uneven application and treatment in not just how drivers are selected for further evaluation, but also whether or not they may continue to operate pending the results of a sleep evaluation. Today, some drivers considered to be at risk for OSA are disqualified from operating CMVs pending sleep tests, while others are conditionally certified or not held to any standard at all. In addition, some drivers may be allowed to use an at-home test, while others must submit to a costlier, more inconvenient in-lab sleep

---

12 81 Federal Register 47, 12645
13 Public Law 113-45: https://www.congress.gov/bill/113th-congress/house-bill/3095/text?q=%7B%22search%22%3A%5B%22%5B%22%3A%22%5C%22pl113-45%5C%22%5D%7D&resultIndex=1
14 81 Federal Register 47, 12643
study. This lack of consistency is problematic for MEs, drivers, and motor carriers. Any proposal pertaining to OSA must establish clear guidelines that will provide consistency in the screening and referral process. Moreover, not all OSA cases pose the same level of safety risk. As such, the agency must determine the level of OSA severity (i.e. moderate or severe) that should trigger mandatory treatment, as well as clearly define the Apnea Hypopnea Index (AHI) thresholds for what constitutes “moderate” or “severe” OSA.

Economic and Operational Impact on Drivers and Carriers Should be Minimized

OSA screening costs can be significant. Drivers in the aforementioned ATRI sleep apnea survey incurred an average of $1,220 in out-of-pocket expenses to obtain a sleep test.\(^\text{15}\) To put these costs into context, consider that the weekly median wage for a truck driver in 2015 was $805, according to the Bureau of Labor Statistics.\(^\text{16}\) It should be noted that 85% of these drivers underwent an in-lab sleep study, while only 15% completed in-home sleep studies, which can cost far less than in-lab testing.

OSA testing options should, to the maximum extent possible, minimize the economic and operational impact to drivers and motor carriers. For drivers who have been referred for further testing, they should have the option to use an at-home sleep test in lieu of a costly in-lab polysomnogram (PSG). The federal government has previously recognized the effectiveness of sleep tests designed for home usage. In 2008, the Centers for Medicare & Medicaid Services (CMS) issued a memo permitting coverage of Continuous Positive Airway Pressure (CPAP) therapy when a beneficiary has been diagnosed with OSA using a clinical evaluation and a positive PSG performed in a sleep lab or by an unattended home sleep monitoring device that measures at least three channels (i.e. heart rate, oxygen saturation, airflow, etc.).\(^\text{17}\) As CMS has determined that a positive test performed by an in-home device is acceptable as an OSA diagnostic tool, in combination with a clinical evaluation, FMCSA should permit the usage of home sleep tests with proper chain of custody protections. That said, as carriers may not allow any driver to operate a CMV if they have a condition that would affect their ability to safely operate the vehicle, any rule from FMCSA pertaining to OSA should allow carriers to select which sleep apnea testing method their drivers must take if referred for further evaluation for OSA.

Drivers should have a wide variety of treatment options depending on their particular needs as determined by their physicians, which may include, but not be necessarily limited to, CPAP, oral appliances, and certain surgical procedures. While CPAP is most frequently prescribed to treat OSA, many individuals are unable to tolerate it and limit their use or quit the treatment altogether. According to the ATRI survey, 21% of drivers that utilize CPAP machines to treat their OSA do not find it to be effective.\(^\text{18}\) Oral appliances can be an effective treatment alternative for many of these patients. While oral appliances have not previously been considered as a treatment option because there was no mechanism to ensure driver adherence, there are appliances on the market today that have a micro

---

\(^\text{15}\) Boris, C. and Brewster, R. *Commercial Driver Perspectives on Obstructive Sleep Apnea*, American Transportation Research Institute, May 2016.


\(^\text{17}\) “Coverage Decision Memorandum for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA)” Centers for Medicare and Medicaid Services; CAG-00093R2; March 13, 2008

\(^\text{18}\) Boris, C. and Brewster, R. *Commercial Driver Perspectives on Obstructive Sleep Apnea*, American Transportation Research Institute, May 2016.
recorder installed in the appliance that can detect and record usage and ultimately transmit that information to a carrier, sleep professional, or medical examiner.\textsuperscript{19}

In addition, certain surgical procedures should also be considered by FMCSA as acceptable treatment options if a driver eliminates or reduces the number of sleep apnea occurrences he/she experiences. Bariatric surgery, for example, could be an effective treatment for a driver whose weight is a primary cause of their OSA. Facial bone surgeries, as well as tracheostomies and other procedures that are successful in preventing a patient’s airway from being blocked, should also be accepted by FMCSA as effective OSA treatments. Similarly, positional therapy can be effective in treating drivers who have sleep apnea when they sleep on their backs. Weight management and other lifestyle changes can also reduce OSA symptoms. In any circumstance, the acceptance of these alternative treatment options should be predicated on eliminating or reducing the number of apnea events that occur to an acceptable level. As interest in OSA grows, FMCSA should leave open the possibility for improvements and advances in the treatment of OSA.

**Conditional Qualification for Drivers Seeking Further Evaluation and Adjusting to CPAP Treatment**

Any regulation that is developed must also address the qualification status of a driver when an ME determines that he or she needs to undergo a sleep test. ATA believes it would be unnecessarily costly and ineffective to automatically disqualify a driver prior to the completion of a sleep study. Except in the most severe cases, the driver should not be disqualified until the study has been performed, a diagnosis is rendered, and the driver is receiving treatment – within certain time limits.

FMCSA must also consider issues pertaining to medical recertification. Unless an ME determines a driver is an imminent safety risk on the highway, he/she should give the driver the opportunity to undergo a sleep test before disqualifying him/her from operating. MEs currently have the ability to provide some flexibility to drivers. During the course of a medical exam, if an ME decides that a driver must undergo a sleep test before the ME can determine the driver’s medical qualification, the ME has the authority to place the driver in a “determination pending” status. This status allows the medical exam to remain valid for 45 days, during which time the driver can schedule and obtain a sleep test. If the driver fails to return to the ME with the results of the sleep test within 45 days, the driver’s medical exam is considered invalid and he/she must submit to a new exam in order to be medically certified.

Oftentimes, however, drivers do not have the opportunity to schedule a medical exam more than 45 days before their medical card expires. If a driver is referred for a sleep test but is unable to undergo the test prior to the expiration of his/her medical card, the driver cannot work unless the ME provides a temporary certification. If FMCSA moves forward with a rulemaking, the agency must allow MEs – based on his/her medical judgement and clinical evaluation - to issue a temporary certification to a driver who has fewer than 45 days remaining on his/her current medical card. This would give the driver sufficient time to undergo a sleep test and begin treatment, if necessary, without disrupting his/her ability to work. This would also reduce the likelihood of putting qualified drivers who end up testing negative for OSA out of work because they were unable to schedule a sleep test prior to the expiration of their medical card.

\textsuperscript{19} BRAEBON Medical Corporation: [https://www.braebon.com/products/dentitrac/](https://www.braebon.com/products/dentitrac/)
medical card, a situation which imposes financial constraints on drivers and carriers, while presenting no additional safety benefits.

While there are a number of treatment options for OSA, CPAP is likely to remain the predominant treatment option for drivers with moderate-to-severe OSA. As such, FMCSA must consider the length of time it can take a patient to adjust and fully adhere to the treatment. While studies have shown that CPAP use can be effective in treating OSA quickly, it can take two weeks or longer for many patients to adapt to the use of a CPAP device. Requiring drivers to stay off the road while they adjust to CPAP treatment will impose significant financial hardships on many drivers and exacerbate the industry’s driver shortage. Moreover, it would discourage drivers from seeking treatment. Relative to the short-term safety risks, these hardships are not justified and should not be imposed – except in the most extreme circumstances. As such, drivers that are receiving CPAP treatment should be permitted to continue to drive during the initial treatment period so long as they are being monitored for compliance by the carrier, medical examiner, and/or a sleep professional.

**Frequency of OSA Screening is a Concern**

Under 391.41, CMV drivers must be medically certified by a registered medical examiner every two years, or more frequently if needed. ATA believes it would be unnecessarily costly and potentially discriminatory to require a driver that has previously been screened and tested negative for OSA to submit to a repeat test when that driver seeks to renew his/her certification based only upon the fact that he/she was previously referred for screening. Requiring a driver whose health has improved or remained stable since his/her previous DOT medical certification to take another sleep test would impose additional and unnecessary costs on the driver and his/her motor carrier. ATA recognizes that it is possible for a driver to have developed OSA since his/her last DOT medical exam. As such, the ME should refer the driver for a follow-up study if the ME determines that the driver exhibits new risk factors for OSA or previous indicators have worsened (i.e. the driver has gained weight, developed Type II diabetes, reports experiencing excessive sleepiness while awake, etc.).

**Referrals for Further Evaluation Should be Based on Multiple Risk Factors**

Current screening procedures for OSA are forcing many qualified drivers to obtain unnecessary sleep tests, imposing excessive costs on drivers and motor carriers. In the ATRI survey, 36% of drivers who had completed sleep studies were not diagnosed with moderate or severe OSA. However, they were still required to pay for a costly sleep evaluation. To minimize the costs to drivers and carriers, any rule addressing OSA screening must reduce the number of drivers that are subject to unnecessary and costly sleep tests.

Far too often, drivers without OSA are referred for sleep tests because they exhibit a single risk factor for OSA. This is problematic because of the monetary and opportunity costs that unnecessary OSA testing imposes on drivers and carriers. Under any proposed rule concerning sleep apnea testing, MEs should be directed to refer for further evaluation only those drivers that exhibit multiple risk factors.

---

20 Boris, C. and Brewster, R. *Commercial Driver Perspectives on Obstructive Sleep Apnea*, American Transportation Research Institute, May 2016.
indicative of moderate-to-severe OSA. Doing so would reduce the likelihood of requiring a driver without OSA to obtain a sleep test and subsequent treatment.

There are numerous risk factors for OSA. However, many MEs today tend to focus on three specific indicators when assessing a driver for possible sleep apnea: weight, neck circumference, and body mass index (BMI). While the consideration of these factors may help to identify many drivers with undiagnosed OSA, it is important to recognize that the list is not all-inclusive. An ME who primarily looks at weight, neck size, and BMI, for example, would fail to identify drivers that fall within the normal range for those categories, but may have a higher risk for OSA due to other physical characteristics, advancing age, or the presence of other medical conditions.

**Caution Needed When Considering BMI as Risk Factor**

Caution should be exercised when an ME predicates a referral decision based on the presence of a high BMI. A driver’s BMI, on its own, can be a poor indicator of overall health. Recently, a study was conducted to test the assumption that a high BMI equates to poorer overall health. Specifically, the researchers reviewed data from over 40,000 participants in the 2005-2012 National Health and Nutrition Examination Survey, and assessed the participants’ health based upon several metrics, including blood pressure, triglyceride, cholesterol readings and insulin resistance. The study found that 47% of individuals that were categorized as overweight based upon their BMI— including 29% of whom were labeled obese – were metabolically “healthy.” Meanwhile, 30% of normal weight individuals were found to be “unhealthy.” Furthermore, BMI measures can be misleading because the BMI cannot differentiate between an individual’s body fat and muscle content. In March 2016, the authors of a study that examined the relationship between BMI, body fat, and mortality found that BMI may be an “inappropriate surrogate for adiposity”, which could explain why some studies have actually shown an association between mild obesity (BMI of 30 to 34.5 kg/m²) and decreased mortality risk.

Today, an individual who is OSA-free may be forced to undergo an unnecessary sleep test because his/her BMI may technically be within the range that could indicate the presence of OSA. In order to minimize false positive and negative results, MEs should consider BMI to be an OSA risk factor when a driver’s level breaches a certain threshold. However, given the previously stated difficulties in relying upon BMI as a sole indicator of an individual’s health, MEs should be directed to refer only those drivers that exceed this BMI threshold and exhibit other risk factors for OSA.

**Any Rule Should Not Hinder Carrier Sleep Apnea Screening and Treatment Programs**

As FMCSA considers whether to embark upon a rulemaking regarding OSA screening and treatment, the agency should keep in mind that many carriers have been proactive in this area. Many companies have already invested significant resources into developing their own in-house sleep apnea programs. Under these employer-provided programs, company drivers are required as a condition of employment to be screened for OSA and, if they are diagnosed with the disorder, to adhere to treatment and

---


22 Padwal, R. et al., Relationship Among Body Fat Percentage, Body Mass Index, and All-Cause Mortality, Annals of Internal Medicine, 2016
monitoring or face dismissal. These companies are to be commended for proactively addressing the issue and helping drivers with undiagnosed OSA to receive treatment that will not only allow them to continue to work but will improve their quality of life. Any rule issued by FMCSA pertaining to OSA screening and treatment should not preclude or hinder the programs that these companies have developed.

IV. Conclusion

As FMCSA considers whether to move forward on a rulemaking to require OSA screening and treatment for commercial truck drivers, the importance of having a solid scientific-based understanding of the prevalence of OSA among drivers and the actual crash risk posed by sleep apnea versus other sources of fatigue cannot be overstated. The agency must carefully weigh whether the safety benefits would outweigh the costs a rule would impose on drivers, motor carriers, and the U.S. supply chain. If FMCSA determines that a rule is necessary, the costs that would be imposed on drivers and carriers must be considered and minimized. For instance, the agency should consider the effectiveness of all viable OSA screening and treatment options including in-lab and home-based sleep testing, CPAP, oral appliances, surgical procedures, and other alternative treatment options. Also, FMCSA should direct MEs to grant conditional qualification status to drivers they refer for sleep studies, unless it is determined that they would pose an imminent safety risk while driving. Given the often lengthy adjustment period for a CPAP patient to fully adjust to treatment, the agency should also authorize drivers that are being monitored for compliance to continue to operate during their transition to CPAP use.

If a rule is promulgated, FMCSA should ensure that a driver who has been screened and tested negative for OSA is not required to undergo additional sleep tests when seeking to renew his/her medical certification, unless an ME determines that a follow-up test is necessary due to changes in the driver’s health since his/her previous medical certification. To avoid singling drivers out for sleep testing based upon a single risk factor, any rule should require drivers to exhibit multiple risk factors indicative of moderate-to-severe OSA. Similarly, if FMCSA were to establish guidelines for MEs to follow when referring drivers for OSA screening, the agency should direct MEs to be cautious when using BMI to assess a driver’s risk for OSA, as the measure can provide a distorted picture of an individual’s health. FMCSA must also be mindful of the significant resources that many motor carriers have invested to develop their own OSA screening and treatment programs.

Thank you for the opportunity to provide our input and concerns regarding this matter.

Sincerely,

Megan Bush
Manager, Safety Policy