July 7, 2016

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

Re: FMCSA-2015-0419 — Evaluation of Safety Personnel for Moderate-to-Severe Obstructive Sleep Apnea

Dear Acting Administrator Darling:

The Urgent Care Association of America (UCAOA) appreciates the opportunity to comment on the Federal Motor Carrier Safety Administration's (FMCSA) request for public comment as the Administration, in conjunction with the Federal Railroad Administration, considers whether to take regulatory action to ensure consistency in addressing the safety issue presented by transportation workers with safety sensitive duties who are at risk for obstructive sleep apnea (OSA).

The UCAOA represents more than 6,000 individual members working at more than 3,125 urgent care centers throughout the United States. The majority of our urgent care centers have clinicians listed on the National Registry of Certified Medical Examiners (NRCME) on staff, and UCAOA has offered mobile testing sites in conjunction with UCAOA meetings, as well as medical examiner training courses.

Examiners in urgent care centers often encounter resistance from commercial drivers when they attempt to conduct OSA screenings. We believe much of this resistance is driven by a lack of understanding by drivers that a diagnosis of OSA, if medically managed, will not result in a loss of a commercial license.

UCAOA has reviewed the questions included in the advance notice of proposed rulemaking published on March 10, 2016 in the *Federal Register* and offers comment on those within the scope of our experience and expertise.

Question #5 — What alternative forms and degrees of restriction could FMCSA and Federal Railroad Administration (FRA) place on the performance of safety-sensitive duties by transportation workers with moderate-to-severe OSA, and how effective would these restrictions be in improving transportation safety? Should any regulations differentiate requirements for patients with moderate, as opposed to severe, OSA?

Consistent with the recommendations from the Motor Carrier Safety Advisory Committee (MCSAC) and the Medical Review Board (MRB) completed in February 2012, UCAOA recommends that a driver with an OSA diagnosis should be required to be recertified annually, regardless of whether the driver is undergoing medical treatment or management for OSA. In cases where the driver is undergoing treatment, the driver must be able to demonstrate to the medical examiner compliance with that treatment.

UCAOA further agrees with the recommendations of the MCSAC and MRB that drivers should be denied certification or immediately disqualified if any of the following conditions are met:

- The driver has crashed, including a single-vehicle crash, associated with fatigue, falling asleep or "fogginess" or single vehicle crash.
- The driver admits to excessive daytime sleepiness during the major wake period while driver, or if driver sleepiness is observed by the medical examiner, motor carrier or other interested party.
- The driver has been found to be non-compliant with medical treatment.

In cases where the driver exhibits risk factors for OSA, drivers should be granted a 60-day certification, at the discretion of the medical examiner. We believe 60 days are necessary to allow for testing (Home Sleep Tests or Polysomnography), sleep specialty consultation and initiation of treatment, if indicated, with one week minimum compliance with treatment at the 60-day visit.

At 60 days, the transportation worker should be re-examined, at which time the transportation worker would need to demonstrate a one week minimum compliance with treatment. If the transportation worker has been compliant at 60 days, 90 days later the worker would be evaluated for recertification. If certification is granted at 90 days, the transportation worker would be recertified again at one year and annually thereafter if compliance is maintained. If a transportation worker is found to be non-compliant at any juncture, he/she would be disqualified until compliance can be demonstrated with the above process being repeated. UCAOA suggests that nothing should preclude a re-examination at 30 days, rather than 60 days, at the request of the transportation worker.

Question #7 — What are the potential improved health outcomes for individuals occupying safety sensitive transportation positions and would receive OSA treatment due to regulations?

As the ANPRM appropriately highlights, OSA is associated with increased risk factors for other serious adverse health conditions, including heart attack and stroke. We also know that when individuals are treated for OSA other positive results can be derived, including improved management of weight, blood pressure, diabetes, and other associated conditions, as well as more energy, less fatigue, reduced health care costs and general disability.

UCAOA would like to draw the Administration's attention to a study published in the *Journal of Occupational & Environmental Medicine* which found that drivers treated for OSA exhibited lower total health plan costs, fewer missed workdays because of short-term disability, and a lower rate of short-term disability claims during the two years following initiation of treatment, resulting in more than $6,000 in total health plan and disability cost savings per treated driver.[1] Drivers with OSA who were not treated did not experience any significant changes in costs, disability or lost workdays.

Question #9 — What costs would be imposed on transportation workers with safety sensitive duties by requiring screening, evaluation, and treatment of OSA?

First, UCAOA does not have access to average costs of screening, evaluation and treatment of OSA in the United States. However, UCAOA believes it is important for transportation workers to clearly understand through appropriate education the benefits of OSA detection and treatment, including the diminished risk of other medical conditions and the risk of long-term disability. However, we acknowledge that the cost of evaluation and treatment of OSA could be a barrier to some and could result in the potential loss of employment.

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[1] Hoffman B, Wingenbach D, Kagey A, Schaneman J, Kasper D. The Long-Term Health Plan and Disability Cost Benefit of Obstructive Sleep Apnea Treatment in a Commercial Motor Vehicle Driver Population. J Occupational & Environmental Medicine. 2010;52:473-477.

Appropriately educated medical examiners and effective initial screening tools can lead to a reduction in unnecessary further testing and cost. We recommend that specific content guidelines be developed by the FMCSA to be included in the National Registry of Certified Medical Examiners certification training. We further suggest that this content be developed with the assistance of board certified sleep experts.

There are a number of screening tools available to physicians and other medical examiners for conducting OSA screening. We believe it is important that these tools be individually evaluated for their effectiveness. Published studies suggest that evaluation algorithms used in conjunction screening tools allow for a more precise determination of those individuals who require further investigation or diagnostic tests.[2] Follow-up tests for suspected OSA can be costly; therefore, the use of effective screening tools and evaluation algorithms can help reduce the number of unnecessary referrals for additional testing.

We also suggest that medical examiners should provide drivers who are suspected of OSA with options (when available within a certain geographic radius) for additional sleep testing. We encourage the Administration to consider the creation of a driver's "Bill of Rights", which could include, among other things:

- Give the driver the right to choose where to receive OSA testing and evaluation, so long as the provider is a sleep specialist.
- Prohibit OSA screening by examiners who have financial ties to OSA diagnosis and treatment.
- OSA treatment decisions should be made between the specialist and the driver; however, FMCSA and FRA would retain the ability to determine which treatments are acceptable for commercial motor vehicle drivers.
- Ensure prompt access to diagnosis and treatment.
- Encourage insurance carriers and other payers that physical risk factors alone are sufficient for risk of OSA and payment for diagnosis and treatment should not be denied because an individual is asymptomatic.

Question #11 — What medical guidelines other than the American Academy of Sleep Medicine (AASM) the Federal Aviation Administration (FAA) currently uses are suitable for screening transportation workers with safety sensitive duties that are regulated by FMCSA/FRA for OSA? What level of effectiveness are you seeing with these guidelines?

UCAOA recognizes the following factors, as recommend by the MCSAC and MRB, for the assessment of OSA. However, we believe the lack of a guideline results in inconsistency of screening by medical examiners. Guidelines would serve to reduce confusion among examiners and transportation workers.

1. A BMI of 35 or above

2. Symptoms of OSA, including loud snoring, witnessed apneas, or sleepiness during the major wake period;

3. Identification of multiple risk factors for OSA to be used in the evaluation…. including:
   - Small or recessed jaw
   - Small airway (Mallampati Scale score of Class 3 or 4)
   - Neck size (≥) 17 inches (male), 15.5 inches (female)
   - Hypertension (treated or untreated)
   - Type 2 diabetes (treated or untreated)
   - Hypothyroidism (untreated)

[2] Frances Chung, M.B.B.S.; Yiliang Yang, M.D.; Russell Brown, M.D.; Pu Liao, M.D. Alternative Scoring Models of STOP-Bang Questionnaire Improve Specificity To Detect Undiagnosed Obstructive Sleep Apnea. http://dx.doi.org/10.5664/jcsm.4022

- BMI greater than or equal to 28 kg/m2
- Age 42 and older
- Family history
- Male or post-menopausal female
- Experienced a single-vehicle crash

Question #13 — When and how frequently should transportation workers with safety sensitive duties be screened for OSA? What methods (laboratory, at-home, split, etc.) of diagnosing OSA are appropriate and why?

UCAOA strongly believes that all transportation workers with safety sensitive duties be regularly assessed for OSA, using a non-invasive tool, at the time of their regular certification exam. Requiring OSA screening adds neither expense nor added inconvenience to the driver or examiner.

Question #14 — What, if any, restrictions or prohibitions should there be on a transportation workers' safety sensitive duties while they are being evaluated for moderate-to-severe OSA?

Per our above response to Question #5, in cases where the driver exhibits risk factors for OSA, drivers should be granted a 60-day conditional certification, at the discretion of the medical examiner to allow for evaluation and testing and the initiation of treatment, if indicated. In cases where treatment is initiated, drivers would need to prove at if the transportation worker has been compliant at 60 days and at 90 days later the worker would be evaluated for recertification. UCAOA suggests that nothing should preclude a re-examination at 30 days, rather than 60 days, at the request of the transportation worker.

Question #16 — What qualifications or credentials are necessary for a medical practitioner who performs OSA screening? What qualifications or credentials are necessary for a medical practitioner who performs the diagnosis and treatment of OSA?

With regard to medical practitioners who perform OSA screening, UCAOA believes the certifying medical examiners who are appropriately licensed and credentialed would perform these examinations. We feel that medical doctors, both allopathic and osteopathic, would be the best choice. Appropriately trained nurse practitioners and physician assistants would also be acceptable assuming this falls within their approved scope of practice.

With regard to the diagnosis and treatment, OSA is a medical diagnosis. We suggest that a sleep medicine specialist should make the diagnosis and initiate treatment and report back to the medical examiner, similar to what would be expected for a cardiac, orthopedic or neurologic condition for which consultation is sought.

#20 -- What measures should be used to evaluate whether transportation employees with safety sensitive duties are receiving effective OSA treatment?

Regarding evaluation of whether transportation employees are receiving effective OSA treatment, UCAOA refers the Administration to the rational for measure #279 - SLEEP APNEA: ASSESSMENT OF ADHERENCE TO POSITIVE AIRWAY PRESSURE THERAPY as stated in the 2016 Physician Quality Reporting System (PQRS) Measures Groups Specifications Manual. The manual states that there is "overwhelming evidence at all levels indicating patients with OSA overestimate their PAP use time." However, when objective adherence is assessed and an intervention is employed – either in the clinic or via the telephone, use is increased. Meter reads (on the machines) or card reads provide a longitudinal assessment of use and prevent the potential for overuse of stimulant therapy and daytime testing of

sleepiness with multiple sleep latency tests. Similarly, the 2016 Physician Quality Reporting System (PQRS) Measures Groups Specifications Manual states that studies show patient's estimation of time of continuous positive airway pressure (CPAP) is low or over-estimated by patients. Consequently, the clinical recommendation is that CPAP usage should be objectively monitored to help assure utilization. Close follow-up for PAP usage and problems in patients with OSA by appropriately trained health care providers is indicated to establish effective utilization patterns and remediate problems, if needed.

We suggest that the Administration review the PQRS quality measures for sleep apnea and consider how they could be applied for use in evaluating and treating transportation employees for OSA. As a suggestion, FMCSA could require that transportation workers with suspected OSA receive testing and follow-up treatment from an approved network of sleep specialists who attest to use of sleep apnea quality measures.

The UCAOA appreciates the FMCSA's consideration of its comments on the evaluation of safety personnel for moderate-to-severe OSA. UCAOA offers itself as a resource to the Administration as it considers future rulemaking on this topic of great importance to public safety. Should you have any questions or require additional information, please contact Camille Bonta, UCAOA policy consultant, at (202) 320-3658 or Laurel Stoimenoff, PT or Nathan Newman, MD, FAAFP, Co-Chairs, UCAOA Health & Public Policy Committee via UCAOA CEO, P Joanne Ray, at 877-698-2262 or jray@ucaoa.org.

Sincerely,

Steve Sellars
President
Urgent Care Association of America