Alliance of
Sleep Apnea Partners

October 31, 2022

Ms. Christine A. Hydock
Chief, Medical Programs Division
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Docket Number FMCSA-2022-0111

RE: Qualifications of Drivers: Medical Examiner's Handbook and Medical Advisory Criteria Proposed Regulatory Guidance

Dear Ms. Hydock:

The Alliance for Sleep Apnea Partners (ASAP) thanks the FMCSA for the opportunity to submit comments on the proposed regulatory guidance concerning the updates to both the Medical Examiner's Handbook (MEH) and the Medical Advisory Criteria. As an organization supporting patients living with sleep apnea, we were glad to see the release of the updated handbook. This updated MEH along with the Medical Advisory Criteria will be useful in providing the necessary guidance and information to Medical Examiners (MEs) about regulatory requirements and guidance to consider when making physical qualification determinations in conjunction with established best medical practices.

After reviewing the section (4.8.3.6) on Obstructive Sleep Apnea (OSA), we have the following concerns and suggestions which we encourage the FMCSA to take into consideration when finalizing the draft handbook:

1. **"If left untreated, moderate-to-severe OSA may contribute to fatigue and unintended sleep episodes with resulting deficits in attention, concentration, situational awareness, and memory"** (para 1, page 57)**:** Besides the health consequences mentioned in the handbook, MEs need to know that untreated OSA has serious implications. One study in 2018 found a 2.5-fold increased risk for motor vehicle accidents in patients with OSA.[1] In another study, drivers diagnosed with OSA and non-

[1] Karimi, M., Hedner, J., Häbel, H., Nerman, O., & Grote, L. (2015). Sleep apnea-related risk of motor vehicle accidents is reduced by continuous positive airway pressure: Swedish Traffic Accident Registry data. *Sleep*, *38*(3), 341–349. https://doi.org/10.5665/sleep.4486

adherent to treatment has a five-fold greater risk of preventable crashes.[2] This study also found that the drivers who were not adherent to treatment were either discharged or quit soon after. In a most recent study conducted in 2020, 26% of drivers hospitalized in Level 1 trauma center following a motor vehicle crash were at high risk for OSA. This observation was based on the responses by the hospitalized drivers to a sleep apnea questionnaire (STOP-Bang) and questions surrounding the circumstances of their accidents.[3]

2. **"If treated, moderate-to-severe OSA does not preclude certification"** (para 1 page 57): Simply asking a patient whether they have been treated for OSA is not sufficient. Lack of adherence to Continuous Positive Airways Pressure (CPAP) therapy, a gold therapy for treating OSA, is a very serious concern to sleep physicians. Therefore, it is important to ask the CMV drivers whether they are adhering to CPAP therapy prior to certification. Furthermore, as recommended in the Medical Review Board (MRB) and the Motor Carrier Safety Advisory Committee (MCSAC) joint recommendations, it is important for MEs to only certify a driver if they are being "treated effectively." The definition of "treated effectively", according to the MRB and MCSAC joint recommendations, is the resolution of moderate to severe OSA to mild OSA or better. This can only be determined by a sleep specialist through objective data such as the download for compliance. If a CMV driver is not being "treated effectively" or has not obtained "effective treatment", the consequences can be life threatening.
3. **"The FMCSRs do not include requirements for MEs to screen CMV drivers for OSA or provide……. When making a medical certification determination, the ME may consider the driver's responses to the questions about sleep disorders on the Medical Examination Report Form, MCSA-5875, and readily identifiable risk factors for OSA identified during the physical examination"** (para 2, page 57): We were surprised that FMCSRs do not include requirements for MEs to screen CMV drivers for OSA or provide requirements whether to refer a driver for OSA screening. We believe that simply relying on CMV driver's responses may be problematic especially when a driver has undiagnosed OSA. Due to the risk of motor vehicle accidents due to untreated sleep apnea, standardized screening for sleep apnea has previously been suggested and

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[2] Burks, S. V., Anderson, J. E., Bombyk, M., Haider, R., Ganzhorn, D., Jiao, X., Lewis, C., Lexvold, A., Liu, H., Ning, J., Toll, A., Hickman, J. S., Mabry, E., Berger, M., Malhotra, A., Czeisler, C. A., & Kales, S. N. (2016). Nonadherence with Employer-Mandated Sleep Apnea Treatment and Increased Risk of Serious Truck Crashes. *Sleep*, *39*(5), 967–975. https://doi.org/10.5665/sleep.5734

[3] Purtle, M. W., Renner, C. H., McCann, D. A., Mallen, J. C., Spilman, S. K., & Sahr, S. M. (2020). Driving with undiagnosed obstructive sleep apnea (OSA): High prevalence of OSA risk in drivers who experienced a motor vehicle crash. *Traffic injury prevention*, *21*(1), 38–41. https://doi.org/10.1080/15389588.2019.1709175

should be performed by primary care physicians, especially by MEs in this instance .[2, 4] In fact, the MRB and MCSAC joint recommendations in Section IIIB provides extensive screening guidelines which should be followed by the MEs beyond the risk factors indicated in the draft handbook.

4. **"OSA is not a condition that requires testing on a regular schedule. Unless a driver reports symptoms have returned or a significant change in risk factors, typically, for drivers diagnosed with moderate-to-severe OSA treated with continuous positive airway pressure, retesting may occur between 3 and 5 years or as determined by the treating provider"** (para 4, page 57): For retesting to occur, the MRB and MCSAC joint recommendations specifically recommends a new sleep study only *if there is an appearance of one or more additional risk factors beyond those that required the original sleep study or a 10 percent increase in weight*. This should be explicitly stated in the handbook.
5. Regarding **"Considerations for an ME when making a physical qualification determination should include, but may not be limited to, the following"** (para 5, page 57): These considerations need to be very specific and with clear guidelines to MEs based on the MRB and MCSAC joint recommendations on when to certify or disqualify a driver. We recommend FMCSA and MRB to create a decision tree based on MRB and MCSAC joint recommendations that will allow MEs to make a proper physical qualification determination which should be applied to all drivers requiring certification or re-certification. We also recommend asking a driver to share a compliance report from sleep specialists if they are being treated for OSA.
6. **"With respect to OSA, the FMCSRs do not include any specific requirements for waiting periods, maximum certification periods, specific diagnostic procedures or treatment, or specific diagnostic results,"** (para 6, page 58): This statement in the handbook is particularly concerning considering extensive recommendations that were already put forth jointly by the MRB and MCSAC. Once again, we encourage the FMCSA to have specific guidance to MEs on screening criteria, testing methods, treatment criteria to make allow for proper certification and ensuring the safety of the drivers. Since MEs are not sleep or sleep medicine doctors, a clear guidance and criteria established by the FMCSA and the MRB are needed to guide the MEs on when to follow up with sleep specialists.

In conclusion, we emphasize the need for the FMCSA to issue a clear guidance to the MEs based on the MRB and MCSAC 2016 joint recommendations. These recommendations are specific and

[4] Gurubhagavatula, I., Maislin, G., Nkwuo, J. E., & Pack, A. I. (2004). Occupational screening for obstructive sleep apnea in commercial drivers. *American journal of respiratory and critical care medicine*, *170*(4), 371–376. https://doi.org/10.1164/rccm.200307-968OC

provide clear guidance, and FMCSA should encourage the MEs to review these recommendations upfront prior to making any decisions on certifications. We encourage FMCSA to highlight the link to these recommendations at the beginning of the section 4.8.3.6 on Obstructive Sleep Apnea. The American Academy of Sleep Medicine (AASM) is also supportive of this position as stated in their recent position statement.[5]

We once again thank the FMCSA for the opportunity to submit comments on the proposed regulatory guidance to MEs and encourage them to take our comments into considerations when finalizing the draft handbook.

Sincerely,

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Executive Director
Alliance of Sleep Apnea Partners

Sarah Gorman
President
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Alliance of Sleep Apnea Partners (ASAP) is a patient-oriented and a 501 c3 non-profit founded in 2018 by an all-volunteer group of patients, researchers, and healthcare providers. We are committed to providing patient education and resources, as well as advocacy on behalf of the patient community to advance the state of patient care and the life-long well-being of sleep apnea patients.

[5] Das, A. M., Chang, J. L., Berneking, M., Hartenbaum, N. P., Rosekind, M., Ramar, K., Malhotra, R. K., Carden, K. A., Martin, J. L., Abbasi-Feinberg, F., Nisha Aurora, R., Kapur, V. K., Olson, E. J., Rosen, C. L., Rowley, J. A., Shelgikar, A. V., Trotti, L. M., & Gurubhagavatula, I. (2022). Enhancing public health and safety by diagnosing and treating obstructive sleep apnea in the transportation industry: an American Academy of Sleep Medicine position statement. *Journal of clinical sleep medicine : JCSM : official publication of the American Academy of Sleep Medicine*, *18*(10), 2467–2470. https://doi.org/10.5664/jcsm.9670