

June 8, 2016

Federal Motor Carrier Safety Administration Federal Railroad Administration U.S. Department of Transportation 1200 New Jersey Avenue, SE Washington, D.C. 20590-0001

ATTN: FMCSA-2015-0419/FRA-2015-0111

On behalf of the more than 108,500 nationally-certified PAs (physician assistants) represented by the American Academy of PAs (AAPA), I am pleased to offer comments on the Federal Motor Carrier Safety Administration (FMCSA) and Federal Railroad Administration (FRA) joint request for information regarding the effects of obstructive sleep apnea (OSA) on commercial drivers and rail transportation workers in safety sensitive positions. PAs are currently eligible to be designated as certified medical examiners (MEs) within FMCSA, and they are able to conduct or supervise the vision and hearing tests required by FRA. In light of our members' ongoing role in the medical examination processes of these agencies, AAPA will provide background on PA education and practice and address questions 16-18 within the notice, which refer to medical personnel qualifications and restrictions.

Background: PA Education and Practice

PAs receive a broad medical education over approximately 27 months which consists of two parts. The didactic phase includes coursework in anatomy, physiology, biochemistry, pharmacology, physical diagnosis, behavioral sciences, and medical ethics. This is followed by the clinical phase, which includes rotations in medical and surgical disciplines such as family medicine, internal medicine, general surgery, pediatrics, obstetrics and gynecology, emergency medicine, and psychiatry. Due to these demanding rotation requirements, PA students will have completed at least 2,000 hours of supervised clinical practice in various settings and locations by graduation.

The majority of PA programs award a master's degree. PAs must pass the Physician Assistant National Certifying Examination and be licensed by a state in order to practice. The PA profession is the only medical profession that requires a practitioner to periodically take and pass a high-stakes comprehensive exam to remain certified, which PAs must do every ten years. PAs must also complete 100 hours of continuing medical education every two years.

PAs practice and prescribe medication in all 50 states, the District of Columbia, and all U.S. territories with the exception of Puerto Rico. They manage the full scope of patient care, often handling patients with multiple comorbidities. In their normal course of work, PAs conduct physical exams, order and interpret tests, diagnose and treat illnesses, assist in surgery, and counsel on preventative healthcare. The rigorous education and clinical training of PAs enables them to be fully qualified and equipped to manage patients with complex medical conditions.

AAPA Comments on Proposed OSA Rulemaking

AAPA shares FMCSA and FRA's belief that OSA has the potential to be a significant transportation safety risk factor for commercial drivers and railroad workers in safety sensitive positions. Under current FMCSA guidance, an ME may refer a patient suspected of having OSA to a specialist for further evaluation, either due to information provided by the patient or recognition by the ME of risk factors for OSA. A notable risk

factor is a body mass index (BMI) of 35 or above —a threshold which was jointly recommended to FMCSA in 2011 by the FMCSA Motor Carrier Safety Advisory Committee (MCSAC) and Medical Review Board (MRB). In light of the enactment of legislation (P.L. 113-45) in 2013 requiring FMCSA to issue new or revised requirements on OSA via the rulemaking process, as well as calls for FRA to engage in rulemaking on this matter, AAPA recognizes that additional screening or intervention requirements may need to be added to the current medical examination process. AAPA would support efforts to increase education for MEs regarding OSA and to require additional screening to determine whether commercial driver or railroad workers in a safety sensitive position may suffer from OSA.

Specifically, AAPA would like to address the following questions within the notice:

• 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? AAPA believes PAs who are certified as MEs within FMCSA are clearly qualified to screen for OSA. Similarly, AAPA believes PA MEs are qualified to perform OSA screening for FRA examinees, and we support the idea of creating a screening result threshold at which an ME would refer a patient at high risk for OSA to a specialist for a sleep study or similar testing.

Regarding the qualifications or credentials required for a medical practitioner who diagnoses and treats OSA, AAPA feels a PA ME is qualified to recognize the likely presence of OSA and to obtain appropriate diagnostic testing and referral to a sleep medicine specialist, as indicated by the particular case and applicable FMCSA or FRA guidance or regulations. The PA ME is qualified to then review the results of diagnostic testing and treatment and reach an informed conclusion regarding the status of that examinee's OSA. The role of the ME in making medical qualification examination decisions does not require the ME to be a sleep medicine specialist, but rather requires the ability to recognize the need for diagnosis and to determine whether diagnosed OSA is effectively treated for the purposes of transportation safety, as well as for the personal health of the examinee. At the same time, it is important to note that there are PAs who practice as members of care teams alongside physicians who specialize in sleep medicine and pulmonology. FMCSA and FRA must consider these PAs to be qualified to diagnose and treat examinees who have been referred for specialty evaluation if those duties have been delegated to them by the physician with whom they practice.

Question 17: With respect to FRA, should it use Railroad MEs to perform OSA screening, diagnosis, and treatment? AAPA believes the need for safety is the same on railroads as it is on highways, and that the risk factors which have the potential to interfere with this safety are the same for both modalities. Therefore, AAPA supports establishing within FRA an ME program which mirrors that found within FMCSA, including PAs as FRA MEs. This approach would ensure consistency of medical standards and expectations within the Department of Transportation, and it would enhance railroad safety.

AAPA believes the appropriate role of the ME within either FMCSA or FRA is 1) to perform OSA screening and to determine whether the examinee is at significant risk for OSA; 2) if so, to determine whether the examinee actually has OSA, and to what degree of severity; 3) to determine whether the examinee with existing or newly diagnosed OSA has been effectively treated and demonstrates compliance with that prescribed treatment; and 4) to make appropriate medical qualification decisions in the interest of both highway and railroad safety and the best medical interests of the examinee. In this process, the ME would make appropriate referrals to sleep medicine specialists, obtain appropriate documentation of diagnosis and response to treatment, and provide education to the examinee regarding the personal health risks and the risks to the public of untreated OSA. While it is possible the ME may also be the primary care provider of the examinee, the primary role and responsibility of the ME in FMCSA and FRA medical qualification examinations is the protection of the public.

It is noted that since not all MEs limit their medical practice to performing FMCSA and FRA examinations, the examinee's interaction with the ME may not necessarily be limited to one or two visits culminating in a signature on a certificate, and AAPA believes that the inclusion of non-physician providers like PAs and nurse practitioners in the ME system means that many drivers/operators are able to see their normal primary care provider for their federally-required examinations. In these cases, the ME may in their primary care provider role work with the patient to ensure they have the resources necessary to mitigate excessive sleepiness, whether through lifestyle/nutrition counseling, screening for OSA or other conditions, or referral to a specialist.

Question 18: Should MEs or other Agencies' designated medical practitioners impose
restrictions on a transportation worker with safety sensitive duties who self-reports
experiencing excessive sleepiness while performing safety sensitive duties? AAPA
believes the role of the ME for transportation workers with safety sensitive duties requires the
highest priority to be ensuring the safety of the public, as well as transportation workers. This may
require that transportation workers who report excessive sleepiness while performing safety
sensitive duties be found temporarily "not qualified" until such time as the underlying condition is
diagnosed and effectively treated.

AAPA agrees with FMCSA and FRA that ensuring the nation's highways and railroads are safe for the travelling public, as well as for the transportation workers themselves should be given the highest priority, and we are committed to working with both agencies as they consider updating regulations to address the risks presented by OSA. Please do not hesitate to contact Sandy Harding, AAPA Senior Director of Federal Advocacy, at 571-319-4338 or sharding@aapa.org with any questions.

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Sincerely,

Jeffrey A. Katz, PA-C, DFAAPA

President and Chair of the Board of Directors

American Academy of PAs