



[4910-EX-P]

**DEPARTMENT OF TRANSPORTATION**

**Federal Railroad Administration**

**49 CFR Parts 240 and 242**

**Federal Motor Carrier Safety Administration**

**49 CFR Part 391**

**[Docket Numbers FMCSA–2015–0419 and FRA–2015–0111, Notice No. 2]**

**Evaluation of Safety Sensitive Personnel for Moderate-to-Severe Obstructive Sleep Apnea; Public Listening Sessions**

**AGENCIES:** Federal Motor Carrier Safety Administration (FMCSA) and Federal Railroad Administration (FRA), Department of Transportation (DOT).

**ACTION:** Notice of public listening sessions.

**SUMMARY:** FMCSA and FRA announce three public listening sessions on May 12, 17, and 25, 2016, to solicit information on the prevalence of moderate-to-severe obstructive sleep apnea (OSA) among individuals occupying safety sensitive positions in highway and rail transportation, and of its potential consequences for the safety of rail and highway transportation. FMCSA and FRA (collectively “the Agencies”) also request information on potential costs and benefits from possible regulatory actions that address the safety risks associated with motor carrier and rail transportation workers in safety sensitive positions who have OSA. The listening sessions will provide interested parties an opportunity to share their views and any data or analysis on this topic with

representatives of both Agencies. The Agencies will transcribe all comments and place the transcripts in the dockets referenced above for the Agencies' consideration. The Agencies will webcast the entire proceedings of all three meetings.

**DATES:** The listening sessions will be held on:

- Thursday, May 12, 2016, in Washington, DC;
- Tuesday, May 17, in, Chicago, IL; and
- Wednesday, May 25, in Los Angeles, CA.

All sessions will run from 10 a.m. to noon and 1:30 p.m. to 3:30 p.m., local time. If all interested parties have the opportunity to comment, the sessions may conclude early.

**ADDRESSES:** The May 12, 2016, listening session will be held at the National Association of Home Builders, 1201 15<sup>th</sup> Street, NW, Washington, DC 20005. The May 17, 2016, session will be held at the Marriott Courtyard Chicago Downtown/River North, 30 E. Hubbard Street, Chicago IL 60611. The final session will be held on May 25, 2016, at the Westin Bonaventure Hotel and Suites, 404 S. Figueroa Street, Los Angeles, CA 90071. In addition to attending the sessions in person, the Agencies offer several ways to provide comments, as described below.

Internet Address for Live Webcast. The Agencies will post specific information on how to participate via the Internet on the Agencies' Web sites at [www.fmcsa.dot.gov/calendar](http://www.fmcsa.dot.gov/calendar) and [www.fra.dot.gov/](http://www.fra.dot.gov/) in advance of the listening session. This Notice provides more information on the listening sessions below in Section II., Meeting Participation and Information the Agencies Seek from the Public.

QWritten comments. You may submit comments identified by Docket Numbers FMCSA–2015–0419 and FRA–2015–0111 using any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the online instructions for submitting comments;
- Mail: Docket Management Facility, U.S. Department of Transportation, Room W12-140, 1200 New Jersey Avenue, SE., West Building, Ground Floor, Washington, DC 20590-0001;
- Hand Delivery or Courier: West Building, Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays; and
- Fax: 202-493-2251.

See the Supplementary Information section below for more details on how to submit written comments.

**FOR FURTHER INFORMATION CONTACT:** For information about the listening sessions: Ms. Shannon L. Watson, Senior Policy Advisor, FMCSA, 1200 New Jersey Avenue, SE., Washington, DC 20590, by telephone at 202-366-2551, or by email at [shannon.watson@dot.gov](mailto:shannon.watson@dot.gov).

If you need sign language interpretation or any other accessibility accommodation, please contact Ms. Watson at least one week in advance of each session to allow us to arrange for such services. The Agencies cannot guarantee that interpreter services requested on short notice will be provided.

For other information on Obstructive Sleep Apnea:

FMCSA: Ms. Angela Wongus, Medical Programs Division, FMCSA, 1200 New Jersey Ave, SE, Washington DC 20590, by telephone at 202-366-3109, or by email at fmcsamedical@dot.gov.

FRA: Dr. Bernard Arseneau, Medical Director, Assurance and Compliance, FRA, 1200 New Jersey Avenue, SE, Washington, DC 20590, by telephone at 202-493-6232, or by email at bernard.arseneau@dot.gov.

**SUPPLEMENTARY INFORMATION:**

Submitting Comments

If you submit a comment, please include the docket numbers for this notice (FMCSA–2015–0419 and FRA–2015–0111), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. The Agencies recommend that you include your name and a mailing address, an e-mail address, or a phone number in the body of your document so the Agencies can contact you if there are questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov>, enter the docket numbers, FMCSA–2015–0419 and FRA–2015–0111, in the keyword box, and click “Search.” When the new screen appears, click on the “Comment Now!” button and

type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

The Agencies published the ANPRM on March 10, 2016 (81 FR 12642). The Agencies will consider all comments and material received before the end of the comment period on June 8, 2016, and may draft a notice of proposed rulemaking based on your comments and other information and analysis.

#### Viewing Comments and Documents

To view comments and any documents this preamble references as available in the docket, go to <http://www.regulations.gov>. Insert the docket number, FMCSA–2015–0419 and FRA–2015–0111, in the keyword box, and click “Search.” Next, click the “Open Docket Folder” button and choose the document to review. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12-140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue, SE, Washington, DC 20590, between 9 a.m. and 5 p.m., E.T., Monday through Friday, except Federal holidays.

#### Privacy Act

Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its potential rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to [www.regulations.gov](http://www.regulations.gov), as described in

the system of records notice (DOT/ALL-14 FDMS), which you can review at [www.transportation.gov/privacy](http://www.transportation.gov/privacy).

## **I. BACKGROUND**

### ***Advance Notice of Proposed Rulemaking***

On March 10, 2016, the Agencies published an advance notice of proposed rulemaking (ANPRM) requesting data and information regarding the prevalence of moderate-to-severe OSA among individuals occupying safety sensitive positions in highway and rail transportation, and on its potential consequences for the safety of rail and highway transportation. 81 FR 12642. The Agencies also requested information on potential costs and benefits from regulatory actions that address the safety risks associated with motor carrier and rail transportation workers in safety sensitive positions who have OSA. *Id.* The purpose of these listening sessions is to receive oral comments in response to the ANPRM.

### ***Legal Basis***

#### **Federal Motor Carrier Safety Administration**

FMCSA has authority under 49 U.S.C. 31136(a) and 31502(b)--delegated to the Agency by 49 CFR 1.87(f) and (i), respectively--to establish minimum qualifications, including medical and physical qualifications, for commercial motor vehicle (CMV) drivers operating in interstate commerce. Section 31136(a)(3) requires that FMCSA's safety regulations ensure that the physical conditions of CMV drivers enable them to operate their vehicles safely, and that medical examiners (MEs) trained in physical and medical examination standards perform the physical examinations required of such operators.

In 2005, Congress authorized FMCSA to establish a Medical Review Board (MRB) composed of experts “in a variety of medical specialties relevant to the driver fitness requirements” to provide advice and recommendations on qualification standards. 49 U.S.C. 31149(a). The position of FMCSA Chief Medical Examiner was authorized at the same time. 49 U.S.C. 31149(b). Under section 31149(c)(1), FMCSA, with the advice of the MRB and Chief Medical Examiner, is directed to “establish, review and revise . . . medical standards for operators of commercial motor vehicles that will ensure that the physical condition of operators of commercial motor vehicles is adequate to enable them to operate the vehicles safely.” FMCSA, in conjunction with the Chief Medical Examiner, asked the MRB to review and report specifically on OSA.

#### Federal Railroad Administration

Under 49 U.S.C. 20103, the Secretary of Transportation (Secretary) has broad authority to issue regulations governing every area of railroad safety. The Secretary has delegated rulemaking responsibility under section 20103 to the Administrator of FRA. 49 CFR 1.89(a). Moreover, FRA has exercised this safety authority to require other medical testing. FRA regulations require locomotive engineers (49 CFR 240.121) and conductors (49 CFR 242.117) to undergo vision and hearing testing as part of their qualification and certification at least every 3 years. There are individual medical circumstances that may lead a railroad to require some engineers or conductors to undergo more frequent testing. In addition, Congress has authorized the Secretary to consider requiring certification of the following other crafts and classes of employees: (1) car repair and maintenance employees; (2) onboard service workers; (3) rail welders; (4) dispatchers; (5) signal repair and maintenance employees; and (6) any other craft or class of

employees that the Secretary determines appropriate. Therefore, the Secretary, and the FRA Administrator by delegation, have statutory authority to issue regulations to address the safety risks posed by employees in safety sensitive positions with OSA.

***What is obstructive sleep apnea?***

OSA is a respiratory disorder characterized by a reduction or cessation of breathing during sleep. OSA is characterized by repeated episodes of upper airway collapse in the region of the upper throat (pharynx) that results in intermittent periods of partial airflow obstruction (hypopneas), complete airflow obstruction (apneas), and respiratory effort-related arousals from sleep (RERAs) in which affected individuals awaken partially and may experience gasping and choking as they struggle to breathe. Risk factors for developing OSA include: obesity; male gender; advancing age; family history of OSA; large neck size; and an anatomically small oropharynx (throat). OSA is associated as well with increased risk for other adverse health conditions such as: hypertension (high blood pressure); diabetes; obesity; cardiac dysrhythmias (irregular heartbeat); myocardial infarction (heart attack); stroke; and sudden cardiac death.

Individuals who have undiagnosed OSA are often unaware they have experienced periods of sleep interrupted by breathing difficulties (apneas, hypopneas, or RERAs) when they wake. As a result, the condition is often unrecognized by affected individuals and underdiagnosed by medical professionals.

***What are the safety risks in transportation?***

For individuals with OSA, eight hours of sleep can be less restful or refreshing than four hours of ordinary, uninterrupted sleep.<sup>1</sup> Undiagnosed or inadequately treated moderate to severe OSA can cause unintended sleep episodes and resulting deficits in attention, concentration, situational awareness, and memory, thus reducing the capacity to safely respond to hazards when performing safety sensitive duties. Therefore, OSA is a critical safety issue that can affect operations in all modes of travel in the transportation industry.

## **II. Meeting Participation and Information the Agencies Seek From the Public**

Each listening session is open to the public. Speakers should try to limit their remarks to 3-5 minutes. No preregistration is required. Attendees may submit material to the Agencies' staff at the session to include in the public dockets referenced in this notice.

Those participating in the webcast will have the opportunity to submit comments online that will be read aloud at the sessions with comments made in the meeting rooms. The Agencies will docket the transcripts of the webcast, a separate transcription of each listening session prepared by an official court reporter, and all other materials submitted to the Agencies' personnel.

The Agencies continue to request public comment on the questions below. In your response, please provide supporting materials and identify your interest in this rulemaking, whether in the transportation industry, medical profession, or other.

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<sup>1</sup> Gay, P., Weaver, T., Lube, D., Iber, C. (2006). Evaluation of positive airway pressure treatment for sleep related breathing disorders in adults. Positive Airway Pressure Task Force; Standards of Practice Committee; American Academy of Sleep Medicine. Sleep 29:381-401.

### *The Problem of OSA*

1. What is the prevalence of moderate-to-severe OSA among the general adult U.S. population? How does this prevalence vary by age?
2. What is prevalence of moderate-to-severe OSA among individuals occupying safety sensitive transportation positions? If it differs from that among the general population, why does it appear to do so? If no existing estimates exist, what methods and information sources can the agencies use to reliably estimate this prevalence?
3. Is there information (studies, data, etc.) available for estimating the future consequences resulting from individuals with OSA occupying safety sensitive transportation positions in the absence of new restrictions? For example, does any organization track the number of historical motor carrier or train accidents caused by OSA? With respect to rail, how would any OSA regulations and the current positive train control system requirements interrelate?
4. Which categories of transportation workers with safety sensitive duties should be required to undergo screening for OSA? On what basis did you identify those workers?

### *Costs and Benefits*

5. What alternative forms and degrees of restriction could FMCSA and 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?

6. What are the potential costs of alternative FMCSA/FRA regulatory actions that would restrict the safety sensitive activities of transportation workers diagnosed with moderate-to-severe OSA? Who would incur those costs? What are the benefits of such actions and who would realize them?
7. What are the potential improved health outcomes for individuals occupying safety sensitive transportation positions who would receive OSA treatment due to regulations?
8. What models or empirical evidence is available to use to estimate potential costs and benefits of alternative restrictions?
9. What costs would be imposed on transportation workers with safety sensitive duties by requiring screening, evaluation, and treatment of OSA?
10. Are there any private or governmental sources of financial assistance? Would health insurance cover costs for screening and/or treatment of OSA?

*Screening Procedures and Diagnostics*

11. What medical guidelines, other than those the American Academy of Sleep Medicine guidance the Federal Aviation Administration 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?

12. What were the safety performance histories of transportation workers with safety sensitive duties who were diagnosed with moderate-to-severe OSA, who are now successfully compliant with treatment before and after their diagnosis?
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?
14. What, if any, restrictions or prohibitions should there be on transportation workers' safety sensitive duties while they are being evaluated for moderate-to-severe OSA?
15. What methods are currently employed for providing training or other informational materials about OSA to transportation workers with safety sensitive duties? How effective are these methods at identifying workers with OSA?

*Medical Personnel Qualifications and Restrictions*

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?
17. With respect to FRA, should it use Railroad MEs to perform OSA screening, diagnosis, and treatment?
18. Should MEs or Agencies' other designated medical practitioners impose restrictions on a transportation worker with safety sensitive duties who self-reports experiencing excessive sleepiness while performing safety sensitive duties?

*Treatment Effectiveness*

19. What should be the acceptable criteria for evaluating the effectiveness of prescribed treatments for moderate-to-severe OSA?
20. What measures should be used to evaluate whether transportation employees with safety sensitive duties are receiving effective OSA treatment?

Issued on: April 22, 2016.

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Larry W. Minor,  
Associate Administrator for Policy

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