

DEPARTMENT OF TRANSPORTATION

[4910-EX-P]

Federal Motor Carrier Safety Administration

49 CFR Part 391

Federal Railroad Administration

49 CFR Parts 240 and 242

[Docket Numbers FMCSA–2015–0419 and FRA–2015–0111]

RIN 2126 –AB88 and 2130-AC52

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

ACTION: Advance notice of proposed rulemaking; request for public comments.

SUMMARY: The Federal Motor Carrier Safety Administration (FMCSA) and Federal Railroad Administration (FRA) request data and information concerning the prevalence of moderate-to-severe obstructive sleep apnea (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. FMCSA and FRA (collectively “the Agencies”) also request 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. For instance, the agencies request comment on the costs and benefits of requiring motor carrier and rail transportation workers in safety sensitive positions who exhibit multiple risk factors for OSA to undergo evaluation and treatment by a healthcare professional with expertise in sleep disorders.

DATES: You must submit comments on or before [INSERT DATE 90 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER.]

ADDRESSES: You may submit comments identified by either of the docket numbers listed at the beginning of this notice using any one of the following methods:

Federal Rulemaking Portal: www.regulations.gov.

Fax: 202-493-2251.

Mail: Docket Services (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590-0001.

Hand delivery: Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

To avoid duplication, please use only one of these four methods. See the "Public Participation and Request for Comments" heading under the SUPPLEMENTARY INFORMATION section below for instructions regarding submitting comments.

FOR FURTHER INFORMATION CONTACT:

FMCSA: Ms. Christine Hydock, Chief of the Medical Programs Division, FMCSA, 1200 New Jersey Ave, SE, Washington DC 20590-0001, by telephone at 202-366-4001, 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.

If you have questions about viewing or submitting material to the docket, call Ms. Cheryl Collins, Dockets Manager, Docket Services, telephone 202-493-0402.

SUPPLEMENTAL INFORMATION:

Public Participation and Request for Comments

The Department encourages the public to participate in this advance notice of proposed rulemaking (ANPRM), by submitting comments and related materials to the appropriate dockets. Where possible, the Department would like the public to provide scientific peer-reviewed data to support comments.

Submitting Comments

If you submit a comment, please include the docket number for this ANPRM (FMCSA–2015–0419 and FRA–2015–0111), indicate the heading of 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, by fax, mail, or hand delivery, but please use only one of these means. The Department recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so an Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to www.regulations.gov, type the docket number, “FMCSA-2015–0419” or “FRA-2015-0111 in the “Keyword” box, and click “Search.” When the new screen appears, click the “Comment Now!” button and type your comment into the text box in 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. The Agencies will consider all comments and material received during the comment period and will use them to inform any future rulemaking proposals.

Viewing Comments and Documents

To view comments and any document mentioned in this preamble, go to www.regulations.gov, insert the docket number, “FMCSA-2015–0419” or “FRA-2015-0111” in the “Keyword” box, and click “Search.” Next, click the “Open Docket Folder” button and choose the document listed to review. If you do not have access to the Internet, you may view the docket online by visiting the Docket Services 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. ET, 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, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at www.dot.gov/privacy.

Legal Basis for the Rulemaking

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.” As discussed below, FMCSA, in conjunction with the Chief Medical Examiner, asked the MRB to review and report specifically on OSA. The MRB’s recommendations are described in the *MRB and Motor Carrier Safety Advisory Committee (MCSAC) Recommendations* section of this ANPRM.

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). The railroad incidents discussed below illustrate the risks to railroad safety posed by railroad employees that have moderate-to-severe OSA. 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, has statutory authority to issue regulations to address the safety risks posed by employees in safety sensitive positions with OSA.

BACKGROUND:

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). Additionally, OSA is associated 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 awaken in the morning. 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.¹ 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. Thus, OSA is a critical safety issue that can affect operations in all modes of travel in the transportation industry.

The following paragraphs provide some examples of accidents where the National Transportation Safety Board (NTSB) determined that OSA played a role in causing an accident (or near-accident) involving motor carriers and trains.

Work Zone Collision, Jackson, Tennessee

On July 26, 2000, the driver of a tractor-trailer traveling on Interstate 40 near Jackson, Tennessee, collided with a Tennessee Highway Patrol vehicle trailing construction vehicles, killing the state trooper inside. The tractor-trailer then traveled across the median and collided with a Chevrolet Blazer heading in the opposite direction, seriously injuring the driver of the Blazer. The tractor-trailer driver was 5 feet, 11 inches tall, weighed 358 pounds, and had been diagnosed with and undergone surgery for OSA, but had not indicated either the diagnosis or the surgery on examinations for medical certification. The NTSB found that the driver's unreported OSA, untreated hypothyroidism, or complications from either or both conditions predisposed him to impairment or incapacitation, including falling asleep at the wheel while driving. The NTSB determined the probable cause of the accident was the driver's incapacitation, which

¹ Gay, P., Weaver, T., Loubé, 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.

resulted from the failure of the medical certification process to detect and remove a medically unfit driver from service.²

BNSF Railway Collision, Red Oak, Iowa

On April 17, 2011, at approximately 6:55 a.m. CDT, an eastbound BNSF Railway (BNSF) coal train traveling near Red Oak, Iowa collided with the rear end of a standing BNSF maintenance-of-way equipment train. The collision resulted in the derailment of two locomotives and 12 cars, a diesel fuel fire, and the deaths of both crewmembers on the striking train. In its investigative report, the NTSB noted that neither of the fatally injured train crewmembers had undergone a sleep study prior to the incident. However, in each case, medical records indicated that both crewmembers had multiple risk factors for OSA.³ NTSB determined that the probable cause of the accident was “the failure of the crew of the striking train to comply with the signal indication requiring them to operate in accordance with restricted speed requirements and stop short of the standing train because they had fallen asleep due to fatigue resulting from their irregular work schedules and their medical conditions.”⁴ NTSB recommended that FRA “require railroads to medically screen employees with safety sensitive duties for sleep apnea and other sleep disorders.”⁵

Metro-North Railroad Derailment, Bronx, NY

On December 1, 2013, at approximately 7:20 a.m. EST, southbound Metro-North Railroad (Metro-North) passenger train 8808 derailed as it approached the Spuyten Duyvil

² *Work Zone Collision Between a Tractor-Semitrailer and a Tennessee Highway Patrol Vehicle, Jackson, Tennessee, July 26, 2000*, Highway Accident Report NTSB/HAR-02/01 (Washington, DC: National Transportation Safety Board, 2002), available at <http://www.nts.gov/investigations/AccidentReports/Reports/HAR0201.pdf>.

³ NTSB, Railroad Accident Report, RAR-12/02, Collision of BNSF Coal Train with the Rear End of Standing BNSF Maintenance-of-Way Equipment Train, Red Oak, Iowa, April 17, 2011, pp. 43-44.

⁴ <http://www.nts.gov/investigations/AccidentReports/Reports/RAR1202.pdf>.

⁵ *Id.* at 72.

⁵ *Id.* at 73.

Station in New York City. All passenger cars and the locomotive derailed, and, as a result, four passengers died and at least 61 passengers were injured. The train was traveling at 82 mph when it derailed in a section of curved track where the maximum authorized speed was 30 mph. Following the accident, the engineer reported that: (1) he felt dazed just before the derailment;⁶ and (2) his wife had previously complained about his snoring. The engineer then underwent a sleep evaluation, which identified excessive daytime sleepiness, followed by a sleep study, which diagnosed severe OSA. Based on its investigation of the derailment, the NTSB concluded that the engineer had multiple OSA risk factors, such as obesity, male gender, snoring, complaints of fatigue, and excessive daytime sleepiness. Even though the engineer exhibited these OSA risk factors, neither his personal health care provider nor his Metro-North occupational health evaluations had screened the engineer for OSA.⁷ NTSB determined that the probable cause of the accident was the “engineer’s noncompliance with the 30-mph speed restriction because he had fallen asleep due to undiagnosed severe obstructive sleep apnea exacerbated by a recent circadian rhythm shift required by his work schedule.”⁸

Union Pacific Railroad and BNSF Railway Chaffee Collision

On May 25, 2013, at approximately 2:30 a.m., a Union Pacific Railroad (UP) freight train collided with a BNSF freight train at an interlocking near Chaffee, Missouri. The collision resulted in the derailment of 13 cars from the BNSF train, two locomotives and 11 cars from the UP train, and a diesel fuel fire. The two crew members from the UP train were injured and transported to a local hospital. The derailing train cars struck nearby highway bridge supports,

⁶ NTSB, Railroad Accident Brief, RAB-14/12, Metro-North Railroad Derailment, October 24, 2014, p. 2. <http://www.nts.gov/investigations/AccidentReports/Reports/RAB1412.pdf>.

⁷ Id. at 3.

⁸ Id. at 5.

resulting in the collapse of portions of the bridge, two motor vehicle accidents, and injury to five motor vehicle occupants. NTSB estimated the total damages to be more than \$11 million.⁹

NTSB determined the probable cause of the accident to be “failure of the Union Pacific Railroad train crewmembers to comply with wayside signals leading into the Rockview Interlocking as a result of their disengagement from their task, likely because of fatigue-induced performance degradation.” NTSB concluded that a contributing factor to the engineer’s fatigue was undiagnosed OSA.¹⁰

NTSB also concluded that absence of positive train control (PTC)¹¹ was a contributing factor in each of the above train accidents.¹² FRA agrees that PTC is an important technology that may prevent certain types of accidents in which OSA is a contributing factor. Nevertheless, PTC is not required on all track segments and any potential OSA regulations could have substantial positive impact at those locations. Potential OSA regulations could also have benefits even where PTC is fully implemented. For instance, compliance with potential OSA regulations could prevent incidents that PTC is not designed to prevent. Even in a situation when an engineer with OSA falls asleep and PTC functions as intended and stops a moving train before certain incidents,¹³ there may be delay costs to passengers and other trains from attending to the engineer that could be avoided by potential OSA regulations. The three examples of train

⁹ NTSB, Railroad Accident Report 14/02, Collision of Union Pacific Railroad Freight Train with BNSF Railway Freight Train Near Chaffee, Missouri, May 25, 2013, p. ii.

<http://www.nts.gov/investigations/accidentreports/reports/rar1402.pdf>.

¹⁰ *Id.* at 42.

¹¹ The NTSB report for the Red Oak accident concluded that a lack of a PTC system “that identifies the rear of a train and stops a following train if a safe braking profile is exceeded” contributed to the accident. NTSB Railroad Accident Report, RAR-12/02 at 72. NTSB further concluded that the type of PTC system that was in development or being deployed at the time of the report (2011) would not address this type of accident. *Id.* at 71.

¹² *See id.* at 72; NTSB Railroad Accident Brief, RAB-14/12 at 5; and NTSB Railroad Accident Report 14/02 at 37-38, and 50.

¹³ *See* 49 CFR 236.1005(a).

accidents described above are illustrative of the consequences that could result from accidents that occur due to OSA.

What actions have the Department's Operating Administrations taken?

The Department promotes the safety of America's transportation system through information, websites, regulations, guidelines, and policies. The Department's operating administrations regulate transportation safety following authorizations from the Congress. The authorities for determining and ensuring that transportation operators engaged in interstate commerce are physically qualified differ among the Department's operating administrations. Several administrations have been working for many years, in some instances along with advisory groups, to improve policies on medical fitness for duty of personnel in safety-critical functions. The sections below summarize the initiatives that several DOT operating administrations have taken to address OSA under their current authority.

Federal Aviation Administration (FAA)

Although this ANPRM covers how FMCSA and FRA will potentially treat OSA, FAA's history of its OSA screening of pilots is instructive. The FAA was created to provide the safe and efficient use of the national air space; that mission has evolved to providing the safest, most efficient aerospace system in the world. While the United States has an impressive safety record, the FAA continues to work with the aviation and medical communities to maintain medical certification standards to keep our skies safe. The FAA has always considered OSA a disqualifying condition, but has used its special issuance process¹⁴ to certificate airman if the hazard of OSA was satisfactorily treated or mitigated.

¹⁴ https://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/app_process/general/si

In November 2013, FAA proposed guidance that would have required pilots with a body mass index (BMI) of 40 or more to be evaluated for OSA. Key aviation industry stakeholders, as well as members of Congress, expressed concerns about this single-factor enhanced screening as lacking a sufficient evidentiary basis, and thus being an example of overregulation by the FAA.

In response, FAA worked with stakeholders, to revise the guidance to address those concerns and issued new medical guidance to Aviation Medical Examiners (AMEs) on March 2, 2015, which balanced industry and Congressional concerns with the FAA and NTSB's safety concerns about pilots flying with OSA. Under the new guidance, AMEs screen airman for OSA using an integrated assessment of history, symptoms, and physical/clinical findings. If screening identifies a need for further evaluation, an OSA risk factor evaluation will be done by the AME at the time of the physical examination using the American Academy of Sleep Medicine (AASM) guidance provided in the *Guide for Aviation Medical Examiners*.¹⁵

A pilot identified as being at risk for OSA will be issued a medical certificate, and shortly thereafter receive a letter from FAA's Federal Air Surgeon requesting that an OSA evaluation be completed within 90 days. The evaluation may be done by any physician (including the AME), not just a sleep medicine specialist. If the evaluating physician determines, using the AASM guidelines, that a laboratory sleep study or home study is warranted, it should be ordered at that time. The pilot will have 90 days (or longer under special circumstances) to accomplish this, as outlined in the Federal Air Surgeon's letter. The pilot may continue flying during the evaluation period until they have been diagnosed with OSA. A pilot is not allowed to fly once diagnosed with OSA, but upon submitting documentation of effective treatment to FAA, the FAA will then consider the pilot for a special issuance medical certificate, which allow the pilot to resume

¹⁵ https://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/

flying. More information on FAA guidance can be found at:

https://www.faa.gov/news/fact_sheets/news_story.cfm?newsId=18156

Federal Motor Carrier Safety Administration

FMCSA's October 5, 2000, Advisory Criteria

In 2000, FMCSA issued advisory criteria providing interpretive guidance to MEs concerning its physical qualifications standards. These advisory criteria are recommendations from FMCSA to assist MEs in applying the minimum physical qualification standards. The advisory criteria were published with the Federal Motor Carrier Safety Regulations as part of the medical examination report form in 49 CFR. 391.43 (Physical Qualification of Drivers; Medical Examination; Certificate, 65 FR 59363 (October 5, 2000)).

The advisory criterion for section 391.41(b)(5), which has been unchanged since 2000, provides the following guidance for MEs in making the determination whether a driver satisfies the respiratory standard:

[Because] a driver must be alert at all times, any change in his or her mental state is in direct conflict with highway safety. Even the slightest impairment in respiratory function under emergency conditions (when greater oxygen supply is necessary for performance) may be detrimental to safe driving.

There are many conditions that interfere with oxygen exchange and may result in incapacitation, including emphysema, chronic asthma, carcinoma, tuberculosis, chronic bronchitis and sleep apnea. If the MEs detect a respiratory dysfunction that in any way is likely to interfere with the driver's ability to safely control and drive a commercial motor

vehicle, the driver must be referred to a specialist for further evaluation and therapy. . . .

Based on the above advisory criterion, it is clear that FMCSA considers OSA to be a respiratory dysfunction that interferes with oxygen exchange. As such, if a ME believes a driver's respiratory condition is, in any way, likely to interfere with the driver's ability to safely control and drive a commercial motor vehicle, the examiner may refer the driver to a specialist for further evaluation and therapy. This advisory criterion is helpful to MEs when the examiner has sufficient experience or information to recognize certain risk factors for OSA and when a driver tells the examiner that he has been diagnosed with OSA. Under these circumstances, MEs may consider referring the driver to a specialist for evaluation before issuing a ME's certificate, or request additional information from the driver and his treating healthcare professional about the management of the driver's OSA, respectively. However, the current guidance is not helpful if the ME does not have sufficient experience or information to suspect the driver may have OSA, or the driver does not share with the examiner any previous diagnosis that he has the condition.

MRB and MCSAC Recommendations

In consideration of the limitations of the current advisory criterion, FMCSA tasked its MRB and MCSAC in 2011 to provide recommendations that FMCSA should consider to (1) develop new OSA standards for motor carriers, commercial vehicle drivers, and MEs and (2) determine whether drivers with this respiratory condition should receive an unrestricted two-year medical certificate to operate CMVs in interstate commerce. The MCSAC also recommended interim actions that FMCSA could take to help MEs address the issue before completing a rulemaking. A copy of the task statement, all presentations provided to the MCSAC, MRB, and

the Committees' December 13, 2011, letter report to the FMCSA Administrator are included in the docket referenced at the beginning of this notice and also at the MCSAC webpage at <https://www.fmcsa.dot.gov/advisory-committees/mcsac/2012-past-meetings>.

During the deliberations of the MCSAC and MRB, experts indicated that studies¹⁶ show that a using a BMI of 33 as a screening indicator for OSA is the value at which false positives and false negatives are minimized. A false positive would require a driver who does not have moderate-to-severe OSA to undergo a sleep study unnecessarily, while a false negative would fail to require a driver who actually has moderate-to-severe OSA to undergo a sleep study. The medical experts participating in the meeting indicated that approximately 75 percent of moderate-to-severe OSA cases would be correctly identified by requiring a sleep study for drivers with a BMI of 33 or greater; however, approximately 25 percent of drivers with moderate-to-severe OSA would be missed with this cutoff. Because the likelihood of OSA in patients with BMIs of 35 or greater rises to nearly 80 percent, the MCSAC and MRB agreed to use a BMI of 35 (rather than 33) in their interim advice to MEs screening drivers for referral to a specialist. A copy of the MCSAC and MRB discussion notes is included in the docket referenced at the beginning of this notice.

The chairs of the MRB and MCSAC considered their December 13, 2011, report as a first step towards recommendations for addressing OSA. The two committees completed more detailed recommendations in February 2012 to support a future notice-and-comment rulemaking. A copy of those recommendations is included in the docket referenced at the beginning of this notice.

¹⁶ Numerous studies were cited in presentations to the groups; links to two relevant presentations are: (1) <https://www.fmcsa.dot.gov/advisory-committees/mcsac/addressing-obstructive-sleep-apnea-cmv-drivers>, and (2) <https://www.fmcsa.dot.gov/advisory-committees/mcsac/screening-osa-commercial-vehicle-operators>.

Before FMCSA issued a notice requesting public comment on proposed regulatory guidance, several stakeholder groups expressed concerns about the agency addressing OSA through regulatory guidance, even on an interim basis. These groups requested that FMCSA pursue the matter through a notice-and-comment rulemaking process.

In 2013, Congress enacted Public Law 113-45 (127 Stat. 557, October 13, 2013, in a note to 49 U.S.C. 31305) directing FMCSA to issue any new or revised requirements concerning sleep disorders, including OSA, by rulemaking. Such requirements would include those for sleep apnea screening, testing, and treatment of CMV drivers.

On January 12, 2015, FMCSA issued a bulletin to healthcare professionals on the National Registry of Certified Medical Examiners regarding OSA. The bulletin reminded healthcare workers of the current physical qualifications standards and advisory criteria concerning the respiratory system, and specifically how those requirements apply to drivers that may have OSA. It encouraged MEs to explain to drivers the distinction between actions based on the current regulations and advisory criteria versus actions based on the MEs' professional judgment.

Federal Railroad Administration

The FRA has taken various regulatory and non-regulatory actions to address the risk of accidents in which fatigue and/or OSA may be a contributing factor.

FRA Hours of Service Laws and Regulations

FRA enforces laws and has issued regulations regarding hours of service for certain railroad employees. See 49 U.S.C. chapter 211 and 49 CFR part 228. The hours of service (HOS) laws and regulations establish maximum hours of work and minimum hours of rest for train employees, signal employees, and dispatching service employees, as defined at 49 U.S.C. 21101.

HOS laws and regulations are a necessary component of mitigating risk associated with work schedules, including potential fatigue-related risks. However, HOS laws and regulations do not adequately mitigate risks associated with undiagnosed or inadequately treated OSA, even if the work schedules comply with the HOS laws and regulations, as they assume that the sleep that occurs during off-duty time is normal, restful sleep.

Fatigue Management Plans

RSIA also requires certain railroads to establish a fatigue management plan. See 49 U.S.C. 20156(f). FRA is currently working with the Railroad Safety Advisory Committee (RSAC) to draft a regulation to implement this mandate. The RSIA requires plans to be “designed to reduce the fatigue experienced by safety-related railroad employees and to reduce the likelihood of accidents, incidents, injuries, and fatalities caused by fatigue.” Id. at section 20156(f)(1). Further, the RSIA requires a railroad to consider the need to include in its fatigue management plan, as applicable, “opportunities for identification, diagnosis, and treatment of any medical condition that may affect alertness or fatigue, including sleep disorders.” Id. at section 20156(f)(3)(B). However, RSIA does not specifically mandate that the regulation require railroads to screen and evaluate safety-related railroad employees for OSA or other sleep disorders.

FRA Safety Advisory 2004-04

On September 21, 2004, FRA issued Safety Advisory 2004-04 to alert the railroad community, and especially those employees with safety sensitive duties, to the danger associated with degradation of performance resulting from sleep disorders that are undiagnosed or not successfully treated. 69 FR 58995 (Oct. 1, 2004). FRA recommended that the railroad community take the following actions:

1. Establish training and educational programs to inform employees of the potential for performance impairment as a result of fatigue and sleep related issues;
2. Develop standardized screening tools for diagnosis, referral, and treatment of sleep disorders (especially sleep apnea);
3. Develop rules to encourage voluntary reporting of sleep disorders by employees with safety sensitive duties;
4. Implement policies that would prohibit employees in safety sensitive positions who have incapacitation or performance-impairing medical conditions related to sleep from performing any safety sensitive duties until the medical condition appropriately responds to treatment; and
5. Implement policies to: (a) promote self-reporting; (b) encourage participation in evaluation and treatment; and (c) establish dispute resolution to resolve any issues regarding fitness of those employees who have reported sleep-related issues.

RSAC Medical Standards Working Group

In September 2006, the RSAC established the Medical Standards Working Group to develop standards for identifying conditions that could lead to sudden incapacitation or impairment of safety-critical personnel. The Working Group established a Physicians Task Force that developed draft medical standards and protocols. FRA put the Medical Standards Working Group on hiatus due to the requirement to focus on activities mandated in the Rail Safety Improvement Act of 2008.

Railroaders' Guide to Healthy Sleep Website

As part of its non-regulatory efforts to address fatigue, FRA sponsors the *Railroaders' Guide to Healthy Sleep* website.¹⁷ This website is set up to disseminate educational information to railroad employees and their families about sleep disorders, the relevance of healthy sleep to railroad safety, and information about improving the quality of the railroaders' sleep. The website was developed in conjunction with the Division of Sleep Medicine at Harvard Medical School, WGBH Educational Foundation, and Volpe – The National Transportation Systems Center.

Why do the Agencies believe regulatory action may be necessary?

Based on the potential severity of OSA-related transportation incidents and accidents, and the varied, non-regulatory, OSA-related actions taken by the Department's Operating Administrations to date, the Agencies are considering taking regulatory action to ensure consistency in addressing the safety issue presented by transportation workers with safety sensitive duties who are at risk for OSA.

The Agencies seek information from interested parties regarding OSA, in order to better inform their decision on whether to take regulatory action and, if so, how to craft the most effective and efficient regulation to address the potential safety risks associated with OSA.

REQUEST FOR COMMENTS

The Agencies 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.

The Problem of OSA

¹⁷ <https://www.railroaderssleep.org/>

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 PTC 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?

Cost & 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 and 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 & Diagnostics

11. What medical guidelines other than the AASM 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?
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 a 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 & 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 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?

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?

RULEMAKING ANALYSES AND NOTICES

Executive Order (E.O.) 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

Under E.O. 12866, “Regulatory Planning and Review” (issued September 30, 1993, published October 4 at 58 FR 51735, and discussed above in the “Background” section), as supplemented by E.O. 13563 and DOT policies and procedures, if a regulatory action is determined to be “significant,” it is subject to Office of Management and Budget (OMB) review. E.O. 12866 defines “significant regulatory action” as one likely to result in a rule that may:

(1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal government or communities.

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency.

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof.

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O.

The Department has determined this ANPRM is a “significant regulatory action” under E.O. 12866, and significant under DOT regulatory policies and procedures due to significant public interest in the legal and policy issues addressed. Therefore, this notice has been reviewed by OMB.

Issued under the authority of delegations in 49 CFR 1.87(f) and (i) and 49 CFR 1.89(a), respectively:

T.F. Scott Darling III, Acting Administrator
Federal Motor Carrier Safety Administration

Sarah Feinberg, Administrator
Federal Railroad Administration