

The FMCSA and Sleep Disorders: History, Present and Future of Regulations in Trucking

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NU: Transportation Center
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H.R. 3095: An Act

- To ensure that any new or revised equipment providing for the screening, testing or treatment of individuals operating commercial motor vehicles for sleep disorders is adopted pursuant to a rulemaking proceeding, and for other purposes.

PHYSIOLOGICAL DETERMINANTS OF FATIGUE



Consecutive Waking Hours

Night Sleep Duration

Biological Time of Day
(circadian rhythms)

- Sleep Inertia

Use of Stimulants or Hypnotics

- Medical Condition;
Clinical Sleep Disorders; Age

Current FMCSA Medical Qualification Standard is only obliquely relevant to OSA

- Current standard
- 49 CFR 391.41 (b) (5) of the Federal Motor Carrier Safety Regulations
 - No established medical history or clinical diagnosis of respiratory dysfunction likely to interfere with the ability to control and drive a commercial motor vehicle safely

Effects of Disruptive Sleep and Circadian Rhythms: Impacts on Physical and Mental Health

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NTSB Board Members

Honorable Deborah A. P. Hersman Chairman	Honorable Christopher A. Hart Vice Chairman	Honorable Robert L. Sumwalt Member	Honorable Mark R. Rosekind Member	Honorable Earl F. Weener Member
				

2009 NTSB Recommendations to FMCSA

- Implement a program to identify commercial drivers at high risk for obstructive sleep apnea and require that those drivers provide evidence through the medical certification process of having been appropriately evaluated and, if treatment is needed, effectively treated for that disorder before being granted unrestricted medical certification. (NTSB Recommendation H-09-15)”

2009 NTSB Letter to FMCSA

- “In spite of ... limited guidance regarding drivers who are excessively sleepy or already diagnosed with OSA, the **FMCSA currently provides no guidance regarding how to identify commercial drivers at risk for OSA.** The FMCSA Medical Review Board recommended in January 2008 that the FMCSA require screening for OSA in all drivers with a BMI over 30, *but the FMCSA has not acted on this recommendation.*”

-Dr. Deborah Hersman, Chair, National Transportation Safety Board

History

- Conference on Neurological Disorders and Commercial Drivers (1988)
 - The patient with sleep apnea syndrome having symptoms of excessive daytime somnolence cannot take part in interstate driving, **because they likely will be involved in hazardous driving and accidents resulting from sleepiness.**

Recommendations of 1991 OMC Consensus Conference on Medical Qualification Standard for OSA: **Not implemented by FMCSA**

- Conference on Pulmonary/Respiratory Disorders and Commercial Drivers (1990)
 - Individuals with suspected or untreated sleep apnea (symptoms of snoring and hypersomnolence) should be considered medically unqualified to operate a commercial vehicle **until the diagnosis has been dispelled or the condition has been treated successfully. They should also undergo yearly multiple sleep latency testing (MSLT).**

2000 FMCSA revised the commercial driver medical examination form

New question asks whether the driver “has a sleep disorder, pauses in breathing while asleep, daytime sleepiness, or loud snoring.”*

In a case series of 1,443 consecutive CDMEs using the new CDME form, **none of the 1,443 CMV drivers examined checked “yes” to the question** on the CDME medical examination form “Sleep disorders, pauses in breathing while asleep, daytime sleepiness, loud snoring”

2005 Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU)

“The Secretary, acting through the Federal Motor Carrier Safety Administration—shall establish and maintain a current national registry of medical examiners who are qualified to perform examinations and issue medical certificates.”

2008 FMCSA issued NPRM for a National Registry of Certified Medical Examiners (NRCME)—No final rule issued

Recommendations of 2006 Joint Task Force* on OSA in CMV drivers: **Not implemented by FMCSA**

Screening Recommendation for Commercial Drivers With Possible or Probable Sleep Apnea

Medically Qualified to Drive Commercial Vehicles If Driver Meets Either of the Following	In-Service Evaluation (ISE) Recommended If Driver Falls Into Any One of the Following Five Major Categories (3 mo maximum certification)	Out-of-Service Immediate Evaluation Recommended If Driver Meets Any One of the Following Factors
<ol style="list-style-type: none"> 1. No positive findings or any of the numbered in-service evaluation factors 2. Diagnosis of OSA with CPAP compliance documented 	<ol style="list-style-type: none"> 1. Sleep history suggestive of OSA (snoring, excessive daytime sleepiness, witnessed apneas) 2. Two or more of the following: <ol style="list-style-type: none"> a) BMI ≥ 35 kg/m²; b) Neck circumference greater than 17 inches in men, 16 inches in women; c) Hypertension (new, uncontrolled, or unable to control with less than 2 medications). 3. ESS > 10 4. Previously diagnosed sleep disorder; compliance claimed, but no recent medical visits/compliance data available for immediate review (must be reviewed within 3-mo period); if found not to be compliant, should be removed from service (includes surgical treatment) 5. AHI > 5 but < 30 in a prior sleep study or polysomnogram and no excessive daytime somnolence (ESS < 11), no motor vehicle accidents, no hypertension requiring 2 or more agents to control 	<ol style="list-style-type: none"> 1. Observed unexplained excessive daytime sleepiness (sleeping in examination or waiting room) or confessed excessive sleepiness 2. Motor vehicle accident (run off road, at-fault, rear-end collision) likely related to sleep disturbance, unless evaluated for sleep disorder in the interim 3. ESS ≥ 16 or FOSQ < 18 4. Previously diagnosed sleep disorder: <ol style="list-style-type: none"> d) Noncompliant (CPAP treatment not tolerated); e) No recent follow up (within recommended time frame); f) Any surgical approach with no objective follow up. 5. AHI > 30

Hartenbaum N, Collop N, Rosen IM, Phillips B, George CPF, Rowley JA, Freedman N, Weaver TE, Gurubhagavatula I, Strohl K, Leaman HM, Moffitt GL, Rosekind MR, *J Occup Environ Med.* 2006;48: S1–S3.

AHI indicates apnea-hypopnea index; BMI, body mass index; CPAP, continuous positive airway pressure; ESS, Epworth Sleepiness Scale; FOSQ, Functional Outcomes of Sleep Questionnaire; OSA, obstructive sleep apnea.

*American College of Chest Physicians, American College of Occupational and Environmental Medicine, National Sleep Foundation

**2007 FMCSA Medical Expert Panel
Recommendations Adopted by MRB in 2008:
Obstructive Sleep Apnea and Commercial Motor Vehicle
Driver Safety
NONE IMPLEMENTED by FMCSA**

Medical Expert Panel Members:

Sonia Ancoli-Israel PhD

Charles A Czeisler, PhD, MD, FRCP

Charles F P George, MD, FRCPC

Christian Guilleminault, MD, Bioid

Allan I Pack, MB, ChB, PhD

2008 FMCSA MEP Recommendation 2: Specific Guidance—Drivers who should be disqualified immediately or denied certification

- Individuals who report that they have experienced excessive sleepiness while driving, **OR**
- Individuals who have experienced a crash associated with falling asleep, **OR**
- Individuals with an AHI greater than 20, until such an individual has been adherent to Positive Airway Pressure (PAP). They can be conditionally certified based on the criteria for Continuous Positive Airway Pressure (CPAP) compliance as outlined in Guideline 3

2008 FMCSA MEP Recommendation 13: Patient Education

– The consequences of untreated OSA include:

- Loss of certification
- Crash
- Hypertension
- Cognitive dysfunction
- Heart disease
- Reduced quality of life
- Reflux
- Headaches
- Shorter survival
- Sleep disruption

2008 FMCSA MEP Recommendation 14: Areas Requiring Development of Guidance

- Other causes of excessive daytime sleepiness:
 - Insufficient sleep
 - Insufficient time in bed/sleep deprivation
 - Medical illnesses
 - e.g. chronic pain syndromes
 - Other primary sleep disorders
 - Narcolepsy
 - Idiopathic hypersomnia
 - Restless Legs Syndrome
 - Shift work sleep disorder
 - Hours of service

Recommendations from The Medical Expert Panel

- The FMCSA consider creating incentives for large trucking companies to develop fatigue risk management programs (e.g., Schneider, J.B. Hunt)
- The FMCSA should couple a dissemination strategy derived from these model programs

Division of
SLEEP MEDICINE



HARVARD MEDICAL SCHOOL



JEFF COOPER / Salina Journal © 2007 and 2008 Salina Journal
Smoke rolls off the wrecked tractor-trailer that was involved in the crash on Interstate Highway 135 near the Mentor interchange, south of Salina.

Addressing Obstructive Sleep Apnea in
Commercial Motor Carrier Drivers
Medical Review Board & Motor Carrier
Safety Advisory Committee, Federal
Motor Carrier Safety Administration
Department of Transportation
December 7, 2011

Charles A. Czeisler, Ph.D., M.D.*
Harvard Medical School

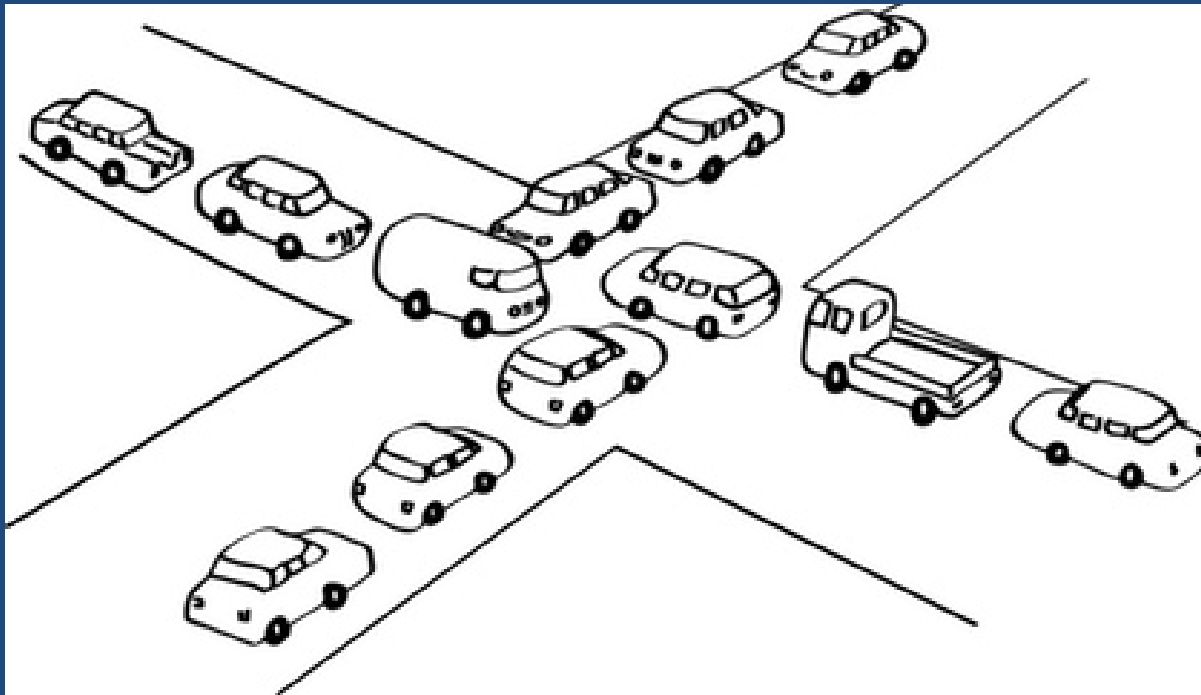
**Chief, Division of Sleep Medicine,
Department of Medicine, Brigham & Women's Hospital**

The Present

- December 2011: Medical Review Board and Motor Carrier Safety Advisory Committee at the FMCSA of the DOT: Do something!
- January 2013: Act Introduced to the 113th USA Congress: Pursuant to a rule making proceeding – FMCSA cease and desist all rulemaking on sleep disorders (apnea).
- October 15, 2013: Has passed both the House and Senate. President has signed and has been made Law.

The Future: DEADLOCK

- Nothing will be done despite 25 years of activity to accomplish something



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 A portrait of Deborah A. P. Hersman, the Chairman of the NTSB. She is a woman with dark hair, wearing a red jacket and a necklace, smiling slightly. The background is a dark blue wall with an American flag.	 A portrait of Christopher A. Hart, the Vice Chairman of the NTSB. He is a man with short dark hair, wearing a dark suit, white shirt, and patterned tie. The background is a dark blue wall with an American flag.	 A portrait of Robert L. Sumwalt, a member of the NTSB. He is a man with short light-colored hair, wearing a dark suit, blue shirt, and red tie. The background is a dark blue wall with an American flag.	 A portrait of Mark R. Rosekind, a member of the NTSB. He is a man with grey hair and a mustache, wearing a dark suit, blue shirt, and purple tie. The background is a dark blue wall with an American flag.	 A portrait of Earl F. Weener, a member of the NTSB. He is an older man with white hair, wearing a dark suit, white shirt, and patterned tie. The background is a dark blue wall with an American flag.

“Be out front of the Regulators.”

- Mark Rosekind to AWO, Craig Phillip, Jim Farley and Fred Turek at NTSB Headquarters, Spring 2012

Towboat/Barge Industry

**Sleep Apnea
and Health
Regulations:
Coming Soon**





Credit: NASA Earth Observatory/NOAA NGDC (April & October, 2012)

