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

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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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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.
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**

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<th>Screening Recommendation for Commercial Drivers With Possible or Probable Sleep Apnea</th>
<th>In-Service Evaluation (ISE) Recommended If Driver Falls Into Any One of the Following Five Major Categories (3 mo maximum certification)</th>
<th>Out-of-Service Immediate Evaluation Recommended If Driver Meets Any One of the Following Factors</th>
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<td>Medically Qualified to Drive Commercial Vehicles If Driver Meets Either of the Following</td>
<td>1. Sleep history suggestive of OSA (snoring, excessive daytime sleepiness, witnessed apneas)</td>
<td>1. Observed unexplained excessive daytime sleepiness (sleeping in examination or waiting room) or confessed excessive sleepiness</td>
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| 1. No positive findings or any of the numbered in-service evaluation factors | 2. Two or more of the following:  
a) BMI $\geq$ 35 kg/m$^2$;  
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). | 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 |
| 2. Diagnosis of OSA with CPAP compliance documented | 3. ESS $\geq$ 10 | 3. ESS $\geq$ 16 or FOSQ $< 18$ |
| | 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) | 4. Previously diagnosed sleep disorder:  
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 >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 | 5. AHI $> 30$  

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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
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
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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“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