**Meeting Minutes**

**August 22–23, 2016**

The Federal Motor Carrier Safety Administration’s (FMCSA) Medical Review Board (MRB) met on August 22–23, 2016, in Arlington, VA. In accordance with the provisions of Pub. L. 92-463, the meeting was open to the public. Gina Pervall, MD, MRB Chairman, called the meeting to order at 9:00 a.m. on Monday, August 22.

The following individuals attended the meeting:

**MRB COMMITTEE MEMBERS**

Gina C. Pervall, M.D., C.I.M.E., Chairman

Christine M. Cisneros, M.D., M.P.H., Ph.D.

Michael T. Kelley, M.D., M.P.H.

Brian T. Morris, M.D., J.D., M.B.A., M.P.H.

**FMCSA AND OTHER GOVERNMENTAL REPRESENTATIVES**

Christine Hydock, Chief, Medical Programs Division, Office of Policy, FMCSA

Mary Pat McKay, MD, Chief Medical Officer, National Transportation Safety Board (NTSB)

Larry Minor, Associate Administrator for Policy, FMCSA, and Designated Federal Officer (DFO), MRB

Mark Patterson, Executive Officer for Safety Operations, Federal Railroad Administration (FRA)

Jana Price, NTSB

Cynthia Shaffer, U.S. DOT

Shannon Watson, Senior Policy Advisor, FMCSA

**OTHER ATTENDEES**

Harry Adler, Truck Safety Coalition

Larry Baird, FusionHealth

Lauren Beaven, iBiz

Rebecca Brewster, American Transportation Research Institute (ATRI)

Brett Brocki, N3Sleep

Brandon Buchanan, American Bus Association (ABA)

Megan Bush, American Trucking Associations (ATA)

Glyn Carver, Rolling Strong LLC

Keith Charles, National Motor Freight Traffic Association (NMFTA)

Charity Coleman, iBiz

Donnie Colston, International Brotherhood of Electrical Workers (IBEW)

Matthew Erim, NMFTA

Philip Goglas II, Sleep Research Society

Jay Grimes, Owner-Operator Independent Driver's Association (OOIDA)

Alan Lankford, MD, Sleep Safe Drivers

Erin Mabry, Virginia Tech Transportation Institute

Jeff Moller, Association of American Railroads (AAR)

Mark Murphy, American Federation of State, County, and Municipal Employees (AFSCME)

Roy Novick, MD, N3Sleep

Sarah Powers, IFC International

Ken Presley, United Motorcoach Association (UMA)

Tzu-Yuan Su, National Rural Electric Cooperative Association (NRECA)

Michael Twery, National Institutes of Health/Department of Health and Human Services

Nate Watson, MD, American Academy of Sleep Medicine (AASM)

Ronna Weber, National School Transportation Association (NSTA)

Nicholas Webster, MD, NTSB

Angela Wongus, Medical Programs Division, FMCSA

**REMARKS AND COMMITTEE ACTION**

The Committee approved the meeting minutes from the September 21­–22, 2015, joint meeting with the Motor Carrier Safety Advisory Committee (MCSAC).

**OTHER REMARKS**

Ms. Shannon Watson reviewed the procedures for public comments. Members of the public may seek recognition by the chair, who will accommodate the comment depending on the flow of the conversation. Commenters need to state their name/organization prior to making their remarks.

## ****1. Task 16-1, Review of Comments on Obstructive Sleep Apnea (OSA) Advance Notice of Proposed Rulemaking (ANPRM) and MCSAC/MRB Task 11-5 Report Recommendations****

Mr. Larry Minor noted that attendees’ participation would help the Agency determine the best direction for proposed rulemaking regarding OSA and would help the MRB to make any changes or revisions to the 2012 recommendation.

## 2. Obstructive Sleep Apnea: Overview of Advance Notice of Proposed Rulemaking (Presentation): Mark Patterson

Mr. Mark Patterson, FRA Executive Officer for Safety Operations, presented an overview of the OSA ANPRM.

Discussion Points

* Drivers are reluctant to undergo sleep studies more than once.
* FRA is interested in gathering more information on OSA within a broader context of health; a single rulemaking strictly regarding OSA may be premature at this point.
* Cost is an important issue. The American Academy of Sleep Medicine (AASM) released an analysis, entitled “Hidden Health Crisis Costing America Billions,” suggesting that treating sleep apnea saves money in the long run.
	+ **Action Item:** FMCSA will post this report to the website. It is also available on the AASM website at <http://www.aasmnet.org/sleep-apnea-economic-impact.aspx>.

## 3. Commercial Driver Perspectives on OSA (Presentation): Rebecca Brewster

Ms. Rebecca Brewster, ATRI President and CEO, presented results from an OSA driver survey and commercial driver perspectives.

Public Comments

* [Mr. Brett Brocki, N3Sleep] Dental appliances should be a treatment option. The lack of conversation about dental appliances is due to this not being a well-known treatment.
	+ [Dr. Brian Morris] Dental appliances do not allow for the same level of documentation as continuous positive airway pressure (CPAP) treatment does.
	+ [Dr. Christine Cisneros] OSA is not always associated with dental problems. Treatment must be tailored to the pathology of the patient’s OSA. Dental appliances may be a good form of treatment for some candidates, but not all.
* [Mr. Brocki, N3Sleep] Screenings in sleep labs may be uncomfortable to the point of ineffective. Drivers should have the option to do home sleep tests.
* [Mr. Glyn Carver, Rolling Strong LLC] Medical personnel making a discretionary diagnosis should not be able to make a commission off that diagnosis.
	+ [Ms. Brewster, ATRI] Compliance monitoring for looking into business relationships would become an issue.
* [Mr. Jay Grimes, OOIDA] Cost is the number one factor for drivers. Drivers would like to see more cost-effective options for screening and treatment.
* [Dr. Roy Novick, N3Sleep] OSA is progressive. Use of a dental appliance at the early stages of OSA may prevent progression to moderate or severe.
* [Dr. Alan Lankford, Sleep Safe Drivers] There needs to be more information on cost effectiveness of oral appliances. Testing has found that the cost of oral appliances is as high as CPAP, including required dentist referral, return visits to that dentist, and repeated home sleep tests to demonstrate effectiveness.
	+ [Mr. Brocki, N3Sleep] CPAP costs and oral appliance costs are similar. However, oral appliances may have the ability to resolve medical conditions, whereas CPAP only reduces symptoms.
	+ [Dr. Lankford, Sleep Safe Drivers] There need to be published results to support this.

## 4. Obstructive Sleep Apnea in Rail and Highway Accidents: Recent History and Recommendations (Presentation); Mary Pat McKay, MD

Dr. Mary Pat McKay, NTSB Chief Medical Officer, presented a recent history of sleep-related rail and highway accidents, their severity, and resulting NTSB recommendations.

Discussion Points

* OSA and fatigue-related issues act in unison. Because NTSB investigations are sampled according to set constraints, there are no examples of strictly OSA-caused crashes.
* **Action Item:** FMCSA will provide data on exam counts by type of examiner.

## 5. Review of Matrix Comments from OSA ANPRM: Preliminary Thoughts from Committee Members

Dr. Michael Kelley thanked comment submitters and noted:

* The Committee relied heavily on the information from the American College for Occupational and Environmental Medicine that The American Academy of Sleep Medicine (AASM) cited.
* There was good discussion and literature to support the use of oral devices.
* Economic issues indicate some form of in-home screening should be considered.

Dr. Morris noted the following:

* Guidance should be based on clinical evidence.
* Measuring compliance with oral devices is difficult, but technology is now more reliable.
* Comments noted that risk factors other than body mass index (BMI) and neck circumference should be considered.
* In-home screenings may be practical from a financial standpoint, but they must be verifiable. If in-home screening comes back negative for at-high risk patients, medical personnel should be able to request a formal study in a sleep lab.

Dr. Cisneros noted that it is important to create awareness of the signs and symptoms of OSA.

## 6. Screening Criteria

Discussion Points

* Research from 2012 indicates that a BMI of 35 or higher indicates significant risk.
* [Dr. Morris] BMI should not be the only factor.
* BMI levels can warrant a test, but the floor needs to be higher.
	+ BMI of 40 or higher should be an automatic trigger.
	+ BMI of 33 to 39 should be a trigger in combination with other risk factors.

Public Comments

* [Dr. Watson, AASM] AASM suggests a list of criteria for screening. The suggestions include mandatory screenings for drivers with a BMI of 40 or higher and for drivers involved in a sleep-related crash.
	+ A large majority of drivers with a BMI of 40 or higher have sleep apnea. You could make a comfortable case for drivers with a BMI of 33.
* [Mr. Brandon Buchanan, ABA] The frequency of screening will be important.
* [Mr. Carver, Rolling Strong LLC] The frequency of screening will be important. We want to incentivize checkups to better identify problems before they drastically affect driver life expectancy and road safety.
* BMI is a major factor, but sometimes it is not the only indicator of increased risk.
* Important to keep in mind that screening initiates personal costs for drivers, time off work, and effort to arrange for screenings. Some carriers do not allow drivers to work until they are screened once risk is identified. It is important not to cast too big a net.
	+ [Dr. Cisneros] Certified medical examiners often give drivers conditional medical cards unless the driver’s condition is a safety hazard. Carriers are being pressured by insurance companies to pull those drivers.
	+ [Ms. Jana Price, NTSB] Many companies are comfortable with letting drivers operate with a medical card.
* [Ms. Megan Bush, ATA] We want our drivers and everyone on the road to be safe. Focusing on one risk factor is somewhat of a bait and switch. The Committee should look at the actual crash risk from sleep apnea vs. other fatigue issues.
	+ [Dr. Kelley] If the Agency has to demonstrate crash risk, the issue will never be addressed. Risk considered here is based on best judgement.
	+ [Mr. Minor, FMCSA] Any ruling on OSA would be significant. Part of that exercise would be to demonstrate crash risk, and crashes/injuries prevented.
* [Dr. Watson, AASM] Sleepiness on the job should be included as an automatic trigger for screening.
	+ [Mr. Carver, Rolling Strong LLC] Drivers will not admit to sleepiness on the job. Including this as an automatic trigger suggests you do not understand the environment in which regulations would be employed.
* [Dr. Watson, AASM] When determining how many risk factors to use (in addition to a BMI of 33 or higher) to determine screening, it is important to keep in mind that there is a high prevalence of OSA in this population. AASM recommends using two factors in addition to BMI.

Recommendations

* Drivers should be disqualified immediately and referred for OSA diagnostic testing if they admit fatigue or sleepiness during the wake period, or following involvement in a sleep-related motor vehicle crash or near-crash.
* Individuals with the following should be referred for diagnostic sleep evaluations:
	+ A BMI ≥ 40 mg/kg2.
	+ A BMI ≥ 33 and < 40 mg/kg2 and at least three additional risk factors.

Committee members voted on whether three risk factors in addition to BMI ≥ 33 and < 40 mg/kg2 is appropriate: 3 in favor (Dr. Cisneros, Dr. Kelley, and Dr. Pervall); 1 against (Dr. Morris). Dr. Morris recommends at least four additional risk factors.

Table 1: Vote on Number of Risk Factors to Require in Addition to a BMI of 33 to 39

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Member | Organization | Aye | Nay | Abstain |
| Pervall | Johns Hopkins University Applied Physics Laboratory Services; MRB Chairman | 1 |  |  |
| Cisneros | Peoria Occupational Physicians | 1 |  |  |
| Kelley | Ambulatory Services, OhioHealth Neighborhood Care | 1 |  |  |
| Morris | AllOne Health, Inc. |  | 1 |  |
|  | TOTALS | 3 | 1 |  |

## 7. Frequency of Screening

Discussion Points

* The Committee deliberated the length of time for certification.
* There may be false negatives upon the first round of screening; therefore, consideration of additional risk factors is crucial.
* Handling of additional risk factors not exhibited by a driver previously, or increases in risk factors such as body weight or BMI.
* Sleep specialists should make decisions related to screening and testing for sleep apnea.
* [Dr. Morris] There may not be enough clinical evidence regarding retesting to make hard and fast rules.

Recommendations

* CMEs cannot issue a medical card for more than 1 year to a driver with an established diagnosis of OSA, regardless of severity.
* Conditional certification should include the following elements:
	+ A driver determined at risk for OSA based on BMI (with or without risk factors) may be certified for 90 days pending sleep study and treatment (if diagnosed).
	+ Within 90 days, a driver compliant with OSA treatment may be certified for no more than 1 year. Drivers with a diagnosis of moderate-to-severe OSA should be recertified based on documented effective treatment and compliance.
* CMEs should have the discretion to disqualify drivers appearing extremely high risk.
* Frequency of OSA diagnostic testing
	+ MRB recommendation: For a driver with a sleep evaluation that returned a negative diagnosis for sleep apnea or a diagnosis of mild sleep apnea, a new sleep study should be triggered by the appearance of one or more additional risk factors beyond those requiring the original sleep study, or a 10 percent weight gain.
		- Caveat: If age of 42 is the only additional risk factor, there should be a 3-year period between the prior sleep study and a new recommended study.
		- Dr. Morris expressed concerns that not enough evidence exists regarding retesting. For this reason, he recommends that requirement for retesting should be left at the discretion of the CME.

## 8. Method of Diagnosis

Discussion Points

* Only some types of home sleep apnea tests monitor whether the user is actually asleep.
* Some home sleep apnea tests can to monitor electroencephalogram (EEG).
* Most CMEs unable to recommend the best type of home sleep apnea test.
* Some patients may attempt to falsify an in-home sleep test.
* Other potential sleep disorders may also lead to daytime sleepiness.
* More effective in-home sleep testing methods may emerge.

Public Comments

* [Dr. Watson, AASM] AASM encourages relationships between primary care providers and sleep specialists. Telemedicine is becoming increasingly important and is helping change the availability of specialists.
* [Dr. Watson, AASM] Drivers at risk of mild OSA may not be the best candidates for in-home sleep testing, as the tests are less likely to pick up on mild OSA. Healthy, high-risk drivers would be good candidates for in-home sleep testing.
* [Dr. Watson, AASM] Since in-home sleep testing is not as accurate as in-lab testing, it is important that in-home testing results are accurately interpreted. The best way to ensure this is to have a sleep specialist read the results.
* [Dr. Watson, AASM] There is not sufficient evidence to claim that additional home tests provide additional accuracy. Best recommendation is to follow up on an inconclusive or inadequate in-home test with an in-lab test.

Recommendations

* Methods of diagnosis include in-lab polysomnography and at-home sleep apnea testing that ensures chain of custody.
	+ In-lab polysomnography should be considered when the clinician suspects:
		- Another medical disorder occurring during sleep (e.g., a seizure disorder, restless leg syndrome, narcolepsy, central sleep apnea), and/or
		- Significant co-morbidities (e.g., neuromuscular disorder or COPD).
	+ All sleep studies must be interpreted by a board-certified sleep specialist.

## 9. Treatment: Compliance

Discussion Points

* While sleep specialists may interpret information from testing, diagnose OSA, and prescribe CPAP therapy, other medical professionals may assume care afterward.
* Remarks made regarding compliance with treatment and conditional certification.
* Potential educational element regarding treatment of OSA.

Public Comments

* [Dr. Watson, AASM] It is important to ensure that patients adhere to treatment and that treatment is effective.
* [Dr. Watson, AASM] AASM’s Sleep, Alertness and Fatigue Education for Drivers (SAFE-D) is available education on the signs, causes, and effects of driver fatigue that touches on treatment options.
* [Erin Mabry, Virginia Tech Transportation Institute] Virginia Tech Transportation Institute offers educational modules on driver safety and fatigue.

Recommendations

* Drivers found noncompliant with treatment should be disqualified immediately until evaluated and treated effectively.

## 10. Treatment: PAP

Discussion Points

* A year’s worth of documentation using CPAP may not be feasible.
* Concern about sufficiency of 30 days to show compliance throughout the year.
* Drivers unable to produce sufficient compliance data are likely not in compliance.

Public Comments

* [Dr. Watson, AASM] Obtaining a full year’s worth of data is not difficult with modern technology.
* [Dr. Watson, AASM] Requiring compliance only for 4 hours per night on 70 percent of nights demonstrates an extreme minimum compliance standard.
* [Mr. Mark Murphy, AFSCME] Requiring a full year’s worth of data will be too problematic. There could be extenuating circumstances that do not allow for this.

Recommendations

* PAP therapy is the preferred OSA treatment.
* Adequate PAP pressure should be established through titration study with polysomnography, or an auto-titration system.
* A driver may be certified initially for up to 1 year if the following conditions are met:
	+ Documented PAP use for no less than 30 consecutive days,
	+ At least 4 hours per night use on 70 percent of nights, and
	+ No excessive sleepiness during the major wake period.
* A driver may be recertified for up to 1 year if the following conditions are met:
	+ Documented PAP use for no less than the number of days between the expiration of previous medical card and a medical exam,
	+ At least 4 hours per night use on 70 percent of nights, and
	+ No excessive sleepiness during the major wake period.
* If a driver fails to meet compliance standards, the CME may provide a 30-day certification to allow the driver to produce 30 days of consecutive PAP use data.

## 11. Treatment: Oral Appliance

Discussion Points

The following remarks were made regarding oral appliances used to treat OSA:

* Oral appliances may decrease AHI, but not to a level that ensures driver safety while operating vehicles.
	+ **Action Item:** The Committee requests comments from experts on the use of oral appliances.
* The order of OSA treatment.
* Definition of CPAP intolerance.

Recommendations

* A driver with a diagnosis of moderate-to-severe OSA should try PAP therapy before oral appliance therapy, unless a board-certified sleep specialist has determined that an alternative therapy such as PAP is intolerable for a driver, in which case the driver should have the option to pursue oral appliance therapy.
* A driver may be certified or recertified for up to 1 year if these conditions are met:
	+ A repeat sleep study shows resolution of moderate-to-severe OSA,
	+ Clearance by the treating clinician, and
	+ No excessive sleepiness during the major wake period.

## 12. Treatment: Bariatric Surgery

Discussion Points

The following remarks were made regarding bariatric surgery:

* Bariatric surgery does not instantly cure sleep apnea. Drivers will have to adhere to interim treatment.
	+ Interim treatment may be PAP therapy.
	+ Oral appliances may not be adequate interim treatment.

Recommendations

* Post-op, first 6 months: A driver with an established diagnosis of moderate-to-severe OSA may be certified if he/she:
	+ Has been cleared by the treating clinician, and
	+ Is able to provide evidence of compliance with PAP or oral device OSA therapy (see recommendations for each).
* Post-op, after 6 months: After 6 months have passed since surgery, a driver may be certified, provided that:
	+ A repeat sleep study shows that the driver no longer has a moderate-to-severe OSA diagnosis, and
	+ The driver does not report excessive sleepiness during the major wake period.

## 13. Treatment: Oropharyngeal Surgery, Facial Bone Surgery

Discussion Points

* The Committee questioned if drivers can use CPAP or an oral device after facial surgery. It was noted that drivers may be able to use a CPAP mask, but not an oral device.
* **Action Item:** The committee requests comments from experts on CPAP and oral device use after facial surgery.

Recommendations

* Post-op, less than 1 month: A driver with an established diagnosis of moderate-to-severe OSA may be certified if he/she:
	+ Has been cleared by the treating clinician, and
	+ Is able to provide evidence of compliance with PAP or oral device OSA therapy (see recommendations for each).
* One month post-surgery a driver may be certified if:
	+ A repeat sleep study shows that the driver no longer has a moderate-to-severe OSA diagnosis, and
	+ The driver does not report excessive sleepiness during the major wake period.

## 14. Treatment: Tracheostomy

Recommendations

* Post-op, less than 1 month: A driver with an established diagnosis of moderate-to-severe OSA may be certified if he/she:
	+ Has been cleared by the treating clinician, and
	+ Is able to provide evidence of compliance with PAP or oral device OSA therapy (see recommendations for each).
* One month post-surgery, a driver may be certified if:
	+ A repeat sleep study shows that the driver no longer has a moderate-to-severe OSA diagnosis, and
	+ The driver does not report excessive sleepiness during the major wake period.

**ACTION ITEMS**

1. FMCSA will post this report to the website. It is also available on the AASM website at <http://www.aasmnet.org/sleep-apnea-economic-impact.aspx>.
2. The Committee requests data for how many exams are done by which form of examiner.
3. The Committee requests comments from experts on the use of oral appliances.
4. The committee requests comments from experts on CPAP and oral device use after facial surgery.

**PRESENTATIONS**

|  | Presenter | Presentation |
| --- | --- | --- |
| 1 | Mark Patterson, Executive Officer for Safety Operations, FRA | Obstructive Sleep Apnea: Overview of Advance Notice of Proposed Rulemaking  |
| 2 | Rebecca Brewster, President and CEO, ATRI | Commercial Driver Perspectives on OSA  |
| 3 | Mary Pat McKay, MD, Chief Medical Officer, NTSB | Obstructive Sleep Apnea in Rail and Highway Accidents: Recent History and Recommendations  |

**ADJOURNMENT:** The meeting was adjourned at 4:30 p.m. on Tuesday, August 23.

We hereby certify that, to the best of our knowledge, the foregoing minutes are accurate and complete.

//Signed//\_\_\_\_\_\_\_\_\_

Gina C. Pervall, MD

Chairman, MRB

//Signed//\_\_\_\_\_\_\_\_\_

Larry W. Minor

Designated Federal Officer, MCSAC and MRB