Medical Review Board

c/o Federal Motor Carrier Safety Administration
1200 New Jersey Avenue, SE
Room W64-104
Washington, DC 20590

July 28, 2022

Robin Hutcheson
Deputy Administrator
Federal Motor Carrier Safety Administration
1200 New Jersey Avenue, SE
Washington, DC 20590

Dear Deputy Administrator Hutcheson:

In Task 21-3, the Federal Motor Carrier Safety Administration tasked the Medical Review Board (MRB) with providing recommendations for medical examiners and commercial motor vehicle drivers who are currently treated for a form of sleep apnea with Continuous Positive Airway Pressure (CPAP), Bi-level Positive Airway Pressure (BiPAP) devices, and related devices that are impacted by any such recall. MRB reviewed information from Philips Respironics, the Food and Drug Administration, and other relevant sources during its September 29, 2021, meeting. MRB's recommendations are outlined in this report.

On behalf of MRB, I respectfully submit this report for your consideration.

Sincerely,

Gina C. Pervall, MD
Chair

Enclosure

Medical Review Board
Task 21-3 Report: Recommendations to Medical Examiners and CMV Drivers When There Is a CPAP Recall
September 29, 2021

I. Task

The Federal Motor Carrier Safety Administration (FMCSA) has received numerous inquiries from medical examiners and the motor carrier community requesting guidance on the Philips Respironics (Philips) recall. FMCSA requests that the Medical Review Board (MRB) provide recommendations for medical examiners and commercial motor vehicle (CMV) drivers who are currently treated for a form of sleep apnea with Continuous Positive Airway Pressure (CPAP), Bi-level Positive Airway Pressure (BiPAP) devices, and related devices that are impacted by any such recall. FMCSA asks the MRB to review information from Philips, the Food and Drug Administration (FDA), and other relevant sources in developing its recommendations.

II. Overview

A. When making recommendations, MRB must consider how long such a recall could last. It is unknown when the impacted CPAP devices will be available for treatment at this point. MRB recommends that FMCSA and drivers prepare for the long-term.
   1. If only a few months, the Agency cannot expect drivers to explore other expensive/time-consuming treatments.
   2. If longer, alternative treatments may be more appealing.

B. Reemphasize that drivers with untreated obstructive sleep apnea (OSA) with an apnea hypopnea index (AHI) of 15 or greater are disqualified from operating commercial motor vehicles, per current advisory criteria. [MRB clarified that an AHI of 30 is considered severe OSA while an AHI of 15 to 29 is considered moderate OSA.] A sleep specialist must determine the AHI.

III. Alternative Treatments

A. Other treatment options for patients with severe OSA include positional therapy for positional dependent sleep apnea, tracheostomies, and jaw surgery. MRB has made such recommendations previously.

B. Oral Appliance Therapy (OAT) may provide a level of comfort and safety for drivers.
   1. Oral appliances can be ordered and fitted at home. Semi-custom trial devices cost approximately $120; Medicare provides a code for reimbursement. The driver may receive a more permanent device within 2-3 weeks. The adjustment period lasts about a week; a sleep study would be performed.

2. The minimum requirement for oral appliance usage is 4-5 hours a night for at least five days a week.

C. MRB should base its recommendations on AHI rather than “mild,” “moderate,” or “severe” terminology.
   1. An AHI of 20 falls into the moderate OSA range; however, “moderate” describes an AHI level as low as 15.
   2. An AHI of 30 or higher is considered to be severe OSA.

D. Some patients with sleep apnea can be treated with OAT if the sleep specialist has determined them to be good candidates based on the results of a sleep study. The appliance must be properly fitted by a dentist.

E. Must follow up with compliance reports with the treating physician.
   1. OAT devices should include a means of monitoring patients’ compliance.
   2. Drivers may explore other treatment options. Compliance of other treatments must be assessed by medical examiner (ME).

F. If drivers invest in new, effective treatment options, such as an oral appliance, for the interim, they may not want to return to using a CPAP machine.

G. MRB considered how much time a driver affected by a recall should be provided to find an alternative treatment.
   1. Current guidelines for drivers who receive a sleep apnea diagnosis require MEs to issue a temporary 90-day certification, pending a sleep study and start of treatment. This guidance does not apply to drivers diagnosed previously with sleep apnea.
   2. MEs may consider a 90-day certification if the driver is asymptomatic and not high risk. MEs should communicate with other specialists to make this determination, which is at the ME’s discretion.

H. Consider a compliance form for those who will be using alternative treatment such as OAT until CPAP is available again.

I. Update MRB’s November 2016 report recommendations (MRB Task 16-1) to include OAT as an acceptable treatment for those with moderate to severe sleep apnea.
   1. If no CPAP is available, untreated severe sleep apnea should disqualify drivers with moderate to severe OSA until a CPAP is available.
   2. This alternative is specific only to those affected by the Philips or similar recall.

J. MRB discussed the possibility of affected drivers receiving financial assistance, either through disability or coverage for the appliances.

IV. Recommendations

A. Drivers should determine whether their CPAP device is the subject of a recall.

B. Drivers should register their device at the manufacturer’s website to determine whether their specific device is impacted.

C. Drivers should follow the instructions concerning the inspection of the device at the manufacturer's website and consult with the prescribing physician to determine whether it is safe to continue using the device in the interim.

D. If a determination is made that the driver should discontinue use of the product, the driver should consult the treating clinician about alternatives.

E. Commercial drivers with an AHI of 15 or greater should be disqualified without evidence of treatment and compliance with CPAP.

F. Allow ME to consider giving 90-day card to drivers who are neither symptomatic nor high risk.

G. The following language from the November 2016 MRB-MCSAC recommendations on oral appliances still applies: A driver with a diagnosis of moderate to severe OSA should try CPAP 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 the latter case, the driver should have the option to pursue OAT to treat OSA.
   1. Rationale: Based on the available medical literature, drivers with a diagnosis of moderate to severe OSA are less likely to achieve resolution of moderate to severe OSA with an oral appliance than with PAP therapy.
   2. There is limited data regarding compliance and long-term efficacy of oral appliances.
   3. Addendum: In response to CPAP recall, appropriate oral appliance usage for recertification is accepted for drivers diagnosed with moderate to severe sleep apnea impacted by the Philips or other similar recall. This therapy will be accepted only until CPAP machines become available again for treatment of drivers impacted by such a recall.

H. Length of certification for drivers with established sleep apnea: up to a maximum of 90 days to provide evidence of appropriate treatment. No extensions beyond 90 days will be permitted.

I. Issue of compliance: for drivers new to OAT, initial certification should be up to 6 months.