Medical Review Board
Task 21–3: Guidance to Medical Examiners and CMV Drivers When There Is a CPAP Recall

I. Task Title

Recommendations to the Agency regarding information for medical examiners and commercial motor vehicle (CMV) drivers when there is a recall of Continuous Positive Airway Pressure (CPAP) and Bi-level Positive Airway Pressure (BiPAP) devices and related devices for patients diagnosed with a form of sleep apnea.

II. Background

On June 14, 2021, Philips Respironics announced a voluntary recall notification for the United States for specific affected ventilator and sleep apnea treatment devices due to two issues related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in their CPAP and BiPAP devices.

On June 30, 2021, the U.S. Food and Drug Administration (FDA) issued an FDA Safety Communication concerning the Philips CPAP and BiPAP recall of affected devices manufactured between April 11, 2007 to April 22, 2021. FDA's communication directed users to the Philips Respironics website for details regarding the recall, to discuss suitable treatment options with their health care providers, and to follow the listed recommendations. Additionally, FDA published a list of frequently asked questions about the recall.

III. Task

FMCSA has received numerous inquiries from medical examiners and the motor carrier community requesting guidance on the Philips recall. FMCSA requests that the MRB provide recommendations for medical examiners and drivers who are currently treated with CPAP or BiPAP and are impacted by any such recall. FMCSA asks the MRB to review information from Philips, the FDA, and other relevant sources in developing its recommendations.

IV. Estimated Time to Complete Task

The MRB will provide its comments and recommendations in a written report to the Administrator on September 29, 2021.

V. FMCSA Technical Representatives

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