

October 13, 2014

Mr. Stephen C. Owings, Chairman Motor Carrier Safety Advisory Committee C/O: Federal Motor Carrier Safety Administration 1200 New Jersey Avenue, SE Washington, DC 20590

Dear Chairman Owings:

On September 10, 2013, The Medical Review Board (MRB) and the Motor Carrier Safety Advisory Committee (MCSAC) met jointly to hear presentations on Licit Use of Schedule II medications. On September 11, 2013, the MRB met separately to deliberate on *Medical Review Board Task 13-01* regarding regulation of Schedule II medications. MRB Task 13-01 requested that the MRB provide information, ideas, and concepts that the Federal Motor Carrier Safety Administration (FMCSA) should consider relating to the issue of Schedule II medications and commercial motor vehicle (CMV) drivers. On October 22, 2013, the MRB submitted such information in the form of recommendations on guidance that should be explored to ensure the safe operation of CMVs by drivers who have been prescribed Schedule II medications.

Following the receipt of these recommendations, FMCSA revised MRB Task 13-01 as the Agency would like to allow more time for the MRB to review an updated evidence report furnished subsequent to its deliberations on *Schedule II Opioids and Stimulants & CMV Crash Risk and Driver Performance: Evidence Report and Systematic Review*. FMCSA directed the MRB to consider this report's findings and confer with the MCSAC on this task at a joint meeting in October 2014. Enclosed for consideration by the MCSAC are the MRB's revised Schedule II medications recommendations after considering the new evidence report in public meetings on July 29-30, 2014.

Sincerely,

//signed//

Gina C. Pervall, MD, CIME Chairman, Medical Review Board

Enclosures

MRB Task 13-01: Schedule II Controlled Substances and Commercial Motor Vehicle Drivers

Task 13-01: The MRB should prepare a letter report to the Agency presenting recommendations the Agency should pursue to ensure the safe operation of commercial motor vehicles (CMVs) by drivers who have been prescribed Schedule II medications.

Originally assigned for completion in September 2013, the Agency would like to allow more time for the MRB to review an updated evidence report furnished subsequent to its deliberations on Schedule II Opioids and Stimulants & CMV Crash Risk and Driver Performance: Evidence Report and Systematic Review. FMCSA directs the MRB to consider the report's findings and confer with its colleagues on the Motor Carrier Safety Advisory Committee (MCSAC) on this task at a joint meeting in October 2014. The two committees would incorporate their recommendations into a letter report to the FMCSA Administrator, to be finalized and submitted by year's end.

<u>Introduction</u>: The Medical Review Board (MRB) discussed the tasks, as noted below, in considering Task 13-01 to provide information, ideas, and concepts that the Federal Motor Carrier Safety Administration (FMCSA) should consider relating to the issue of Schedule II medications and CMV drivers in developing regulatory guidance for medical examiners, CMV drivers, prescribing physicians and motor carriers on medical certification of these CMV drivers. The MRB's tasks included the following:

- Review the updated evidence report, *Schedule II Opioids and Stimulants & CMV Crash Risk and Driver Performance: Evidence Report and Systematic Review;*
- Consider medical certification requirements of CMV drivers and issues relevant to Schedule II Medication use;

The MRB's review of the 2006 evidence, the 2014 updated evidence report, key questions outlined in the December 9, 2006 Expert Panel Commentary and Recommendations Report: Licit Schedule II Drug Use and Commercial Motor Vehicle Driver Safety, and existing Department of Transportation (DOT) regulatory guidance formed the basis of the following MRB recommendations. The MRB recommends the following by unanimous agreement with the exception of note of dissent regarding the CMV Driver Medication Questionnaire under Recommendation II.

I. Standardized CMV Driver Medication Questionnaire for Commercial Driver Medical Examiners

A. The FMCSA should develop a standardized Medication Questionnaire to assist the Commercial Driver Medical Examiner (CDME) when reviewing prescription medications that have been disclosed by the Medical Review Officer (MRO) or CMV driver during the history and physical examination for certification.

II. Format of the Standardized CMV Driver Medication Questionnaire

A. The MRB recommends that the standardized CMV Driver Medication Questionnaire referenced in Recommendation #1 include the following information and questions (see attached form):

- 1. Questionnaire should be titled 391.41 CMV Driver Medication Questionnaire.
- 2. Questionnaire should request the following information:
 - a. Identifying name and date of birth (DOB) of the CMV driver.
 - b. Name, signature, date, address and contact information of the CDME.
 - c. Introductory paragraph stating purpose of the CMV Driver Medication Questionnaire.
 - d. Statements of 391.41(b)(12) (Physical Qualifications of Drivers relating to driver use of scheduled substances) and *The Driver's Role*, as found in the Medical Examination Report form found at the end of 49 CFR 391.43 (*Medical Examination; Certificate of Physical Examination*).
 - e. Name, state of licensure, signature, address and contact information of the prescribing health care provider, as well as the date the form was completed.
- 3. Questionnaire should include the following questions:
 - a. Question 1 List all medications and dosages.
 - b. Question 2 What medical conditions are being treated with these medications?
 - c. Question 3 It is my medical opinion that, considering the mental and physical requirements of operating a CMV and with awareness of a CMV driver's role (consistent with *The Driver's Role* statement on page 2 of the form), I believe my patient: (1) has no medication side effects that would impair the ability to operate a CMV safely; and (2) has no medical condition(s) that would impair the ability to operate a CMV safely.
- 4. Note: One MRB member dissented to the CMV Driver Medication Questionnaire because he felt the explanatory statement should be expanded to include additional information.

III. Education for CDMEs Regarding Medications that may Impair Driver's Ability to Operate a CMV Safely

- A. Several classes of medications have the potential to impair the driver's ability to operate a CMV safely.
- B. Therefore, FMCSA should educate the CDME regarding safety concerns related to these medications and advise the CDME that during the certification process particular attention should be given to the following classes of medications: Anticoagulants, Antivirals, Anxiolytics, Barbiturates, Chemotherapeutic Agents, Experimental, Hypoglycemic, Investigational, Mood-ameliorating, Motion Sickness, Narcotic, Sedating Antihistaminic, Sedative, Steroid drugs, and Tranquilizers; as well as medications with an FDA Black Box warning of side effects that include syncope, loss of consciousness, seizure provoking, arrhythmia, hypoglycemia, and psychosis.

IV. Review Updated Medical Expert Panel Report

A. In the September 2014 joint meeting, the MRB and the MCSAC should consider the new evidence report, *Schedule II Opioids and Stimulants & CMV Crash Risk and Driver Performance: Evidence Report and Systematic Review*, and review the updated Medical Expert Panel Report based on the new evidence report.

V. Expert Panel Review of Potentially Impairing Medications

A. The FMCSA should develop a panel of experts to review medications as well as categories of medications in order to develop lists of both medications that are permitted and potentially disqualifying medications, based on potential adverse side effects.

VI. Guidance Regarding CMV Driver Use of Narcotics

- A. The MRB based this recommendation on its review of the updated evidence report, Schedule II Opioids and Stimulants & CMV Crash Risk and Driver Performance: Evidence Report and Systematic Review. Specifically, this recommendation is based on the following conclusions from the post-2006 evidence report:
 - 1. There is moderate evidence to support the contention that the licit use of opioids increases the risk of a motor vehicle crash and negatively impacts indirect measures of driver performance.
 - a. Several large and recent studies link opioid use to increased risk of driver fatalities, driver injury, crash risk, and unsafe driver actions.
 - 2. There is moderate evidence that licit use of opioids negatively impacts indirect measures of driver performance.
 - a. Studies generally found indicators of impairment, especially for drug-naïve individuals. Impairment was most pronounced on psychomotor vigilance tasks related to pertinent driving skill such as attention, vision, auditory perception, and reaction time.
 - 3. There is weak evidence to support the contention that licit use of stimulants and other Schedule II medications increases the risk of a motor vehicle crash.
- B. <u>MRB Recommendations</u>: The MRB believes that a driver should not be qualified medically to operate a CMV while he/she is under treatment with narcotics or any narcotic derivative without exception.
 - 1. However, while the current exception remains in the Federal Motor Carrier Safety Regulations (FMCSRs) (see 49 CFR 391.41(b)(12)(ii)), the MRB recommends that FMCSA provide the following guidelines regarding use of narcotics to CDMEs:
 - a. A CDME should consider whether the underlying medical condition requiring the use of the narcotic(s) is sufficiently impairing to affect whether a driver is medically qualified to perform safety-sensitive duties, including driving a CMV.
 - b. A driver should not be under the influence of narcotics while performing safety-sensitive duties, including driving a CMV.
 - c. If a driver uses narcotics while off duty, he/she must not use the narcotic for a minimum of 8 hours (if using short-acting narcotics) or 12 hours (if using long-acting narcotics) before resuming safety-sensitive duties, including driving a CMV.
 - d. The CDME should consider using the CMV Driver Medication Questionnaire or similar document to aid in determining the qualification of the driver. The CDME should obtain medical records and ensure that the use of the narcotic medication(s) or narcotic derivative is consistent with current best practices for chronic pain and disease management.

- i. If it is determined that the driver can be qualified medically, certification should be for no more than 1 year.
- e. The CDME should consider disqualifying a driver for the usage of other impairing or habit-forming drugs when used in combination with a narcotic or narcotic derivative.
- 2. FMCSA should consider issuing guidelines to CDMEs relating to other impairing or habit-forming drugs, including benzodiazepines, amphetamines, etc.