



MOTOR CARRIER SAFETY ADVISORY COMMITTEE

C/O: Federal Motor Carrier Safety Administration
1200 New Jersey Avenue, SE
Washington, DC 20590



MEDICAL REVIEW BOARD

C/O: Federal Motor Carrier Safety Administration
1200 New Jersey Avenue, SE
Washington, DC 20590

December 16, 2014

The Honorable T. F. Scott Darling, III
Acting Administrator
Federal Motor Carrier Safety Administration
1200 New Jersey Avenue, SE
Washington, DC 20590

Dear Acting Administrator Darling:

Enclosed for your consideration are the Medical Review Board (MRB) and the Motor Carrier Safety Advisory Committee (MCSAC) joint recommendations relating to the use of Schedule II medications by commercial motor vehicle (CMV) drivers as requested in Joint Task Statement 14-3. On September 10, 2013, the MRB and MCSAC met jointly to hear presentations on the licit use of Schedule II medications. On September 11, 2013, the MRB met separately to deliberate on MRB Task 13-01 regarding regulation of Schedule II medications, which requested that the MRB provide information that the Federal Motor Carrier Safety Administration (FMCSA) should consider relating to CMV driver use of these medications. On October 22, 2013, the MRB submitted these recommendations to FMCSA.

Following the receipt of these recommendations, FMCSA revised MRB Task 13-01 so that the MRB could review an updated evidence report and the Expert Panel opinion that was 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 topic at a joint meeting in October, 2014. The MRB met in public meetings on July 29-30, 2014, and developed Schedule II medications recommendations. The MRB presented these recommendations to the MCSAC in a joint public meeting on October 27, 2014, where they were deliberated by both committees in response to joint Task 14-3.

We respectfully submit this report to FMCSA for its consideration.

Sincerely,

//signed//

Stephen C. Owings
Chairman, Motor Carrier Safety Advisory Committee

//signed//

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

Enclosures

MRB and MCSAC Joint Task 14-3: Schedule II Controlled Substances and CMV Drivers

Introduction

Task 14-3 directed the MRB and MCSAC to prepare a letter report to the Agency presenting recommendations regarding how FMCSA can ensure that Certified Medical Examiners (CMEs) responsible for issuing medical certificates for commercial motor vehicles (CMV) drivers communicate with health care professionals responsible for prescribing the use of certain medications to:

- (1) Fully understand the reasons the medications have been prescribed; and
- (2) Determine whether the use of the medications and the underlying condition being treated preclude the issuance of a 2-year medical certificate.

On September 10, 2013, the MRB and MCSAC met jointly to hear presentations on Licit Use of Schedule II medications. On September 11, 2013, the MRB met separately to deliberate on MRB Task 13-01 regarding regulation of Schedule II medications. In public meetings on July 29-30, 2014, the MRB met to develop Schedule II medications recommendations based on its consideration of the updated evidence report, *Schedule II Opioids and Stimulants & CMV Crash Risk and Driver Performance: Evidence Report and Systematic Review*. The MRB presented these recommendations to the MCSAC in a joint public meeting on October 27, 2014. After considering the presentations provided on the 2014 Evidence Report and Medical Expert Panel recommendations, the MRB and MCSAC agreed to send forward to FMCSA a slightly modified version of the MRB's Schedule II medications recommendations, which are laid out in this report. Nineteen of the joint committee members agreed to send the recommendations below to the Acting Administrator with two abstentions. No members voted "no" on the recommendations.

I. Guidance Regarding CMV Driver Use of Narcotics

- A. Recommendations: The MRB and MCSAC believe 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 and MCSAC recommend that FMCSA provide the following guidelines regarding use of narcotics to CMEs:
 - a. A CME should consider whether the underlying medical condition requiring the use of the narcotic(s) is sufficiently impairing to affect whether a driver is qualified medically 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 CME should consider using the CMV Driver Medication Questionnaire or similar document to aid in determining the qualification of the driver. The CME should consider obtaining medical records to 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 CME 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 CMEs relating to other impairing or habit-forming drugs, including benzodiazepines, amphetamines, etc.
- B. **Rationale:** The MRB and MCSAC 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 impacts indirect measures of driver performance negatively.
 - 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 impacts indirect measures of driver performance negatively.
 - a. Generally, studies found indicators of impairment, especially for drug-naïve individuals (i.e., for those not having previously used a particular drug). Impairment was most pronounced on psychomotor vigilance tasks related to pertinent driving skill such as attention, vision, auditory perception, and reaction time.

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

- A. **Recommendation:** FMCSA should develop a standardized Medication Questionnaire to assist the Certified Medical Examiner (CME) when reviewing prescription medications that have been disclosed during the history and physical examination for certification.

III. Format of the Standardized CMV Driver Medication Questionnaire

- A. **Recommendations:** The MRB and MCSAC recommend that the standardized CMV Driver Medication Questionnaire referenced in Recommendation I.A include the following information and questions (see attached “391.41 CMV Driver Medication Questionnaire”):
 - 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. Introductory paragraph stating purpose of the CMV Driver Medication Questionnaire.

- c. 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)*.
 - d. Name, state of licensure, signature, address and contact information of the prescribing health care provider, as well as the date the form was completed.
 - e. Name, signature, date, address and contact information of the CME.
3. Questionnaire should include the following questions:
- a. Question 1 – List all medications and dosages that you have prescribed to the above named individual.
 - b. Question 2 – List any other medications and dosages that you are aware have been prescribed to the above named individual by another treating health care provider.
 - c. Question 3 – What medical conditions are being treated with these medications?
 - d. Question 4 – 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: (a) has no medication side effects from medication(s) that I prescribe that would adversely affect the ability to operate a CMV safely; and (2) has no medical condition(s) that I am treating with the above medication(s) that would adversely affect the ability to operate a CMV safely.

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

- A. Several classes of medications have the potential to affect adversely the driver's ability to operate a CMV safely.
- B. Recommendations:
 - 1. Therefore, FMCSA should educate the CME regarding safety concerns related to such medications and advise the CME 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 a U.S. Food and Drug Administration (FDA) Black Box warning of side effects that include syncope, loss of consciousness, seizure provoking, arrhythmia, hypoglycemia, and psychosis.
 - 2. FMCSA should provide the following guidance/educational statement to CMEs regarding over-the-counter medications: CMEs should discuss with a driver relevant over-the-counter medications that may have side effects that could affect adversely a driver's ability to operate a CMV safely.
 - 3. FMCSA should develop an educational brochure that CMEs or employers could provide to drivers to educate them regarding over-the-counter medications that may have side effects that could affect adversely a driver's ability to operate a CMV safely.

V. Expert Panel Review of Potentially Impairing Medications

- A. Recommendation: 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.

391.41 CMV DRIVER MEDICATION QUESTIONNAIRE

Driver Name: _____ DOB: _____

The above patient/driver is being evaluated to determine whether he/she meets the medical standards of the Federal Motor Carrier Safety Administration (FMCSA) to operate a commercial motor vehicle (CMV). During the medical evaluation, it was determined this individual is taking medication(s) that may impair his/her ability to operate a CMV safely. As the Certified Medical Examiner (CME), I request that you review the Regulations as noted below, complete this questionnaire, and return it to me at the address specified below. The final determination as to whether the individual listed in this form is physically qualified to drive a CMV will be made by the CME.

49 CFR 391.41, Physical Qualifications for Drivers: A person is physically qualified to drive a CMV if that person ... (12)(i) Does not use any drug or substance identified in 21 CFR 1308.11 Schedule I, an amphetamine, a narcotic, or other habit-forming drug. (ii) Does not use any non-Schedule I drug or substance that is identified in the other Schedules in 21 part 1308 except when the use is prescribed by a licensed medical practitioner, as defined in § 382.107, who is familiar with the driver’s medical history and has advised the driver that the substance will not adversely affect the driver’s ability to safely operate a CMV.

1. List all medications and dosages that you have prescribed to the above named individual.

2. List any other medications and dosages that you are aware have been prescribed to the above named individual by another treating health care provider.

3. What medical conditions are being treated with these medications?

4. 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), my patient:

(a) has no medication side effects from medication(s) that I prescribe that would affect adversely the ability to operate a CMV safely; and

(b) has no medical condition(s) that I am treating with the above medication(s) that would affect adversely the ability to operate a CMV safely.

Yes **No** (check response)

Signature of Prescribing Health Care Provider

Date

Printed Name of Prescribing Health Care Provider

State of Licensure

Street Address

City, State, Zip Code

Phone/Fax

Email

391.41 CMV DRIVER MEDICATION QUESTIONNAIRE

THE DRIVER'S ROLE

49 CFR 391.43

Responsibilities, work schedules, physical and emotional demands, and lifestyles among commercial drivers vary by the type of driving that they do. Some of the main types of drivers include the following: turn around or short relay (drivers return to their home base each evening); long relay (drivers drive 9-11 hours and then have at least a 10-hour off-duty period), straight through haul (cross country drivers); and team drivers (drivers share the driving by alternating their 5-hour driving periods and 5-hour rest periods.) The following factors may be involved in a driver's performance of duties: abrupt schedule changes and rotating work schedules, which may result in irregular sleep patterns and a driver beginning a trip in a fatigued condition; long hours; extended time away from family and friends, which may result in lack of social support; tight pickup and delivery schedules, with irregularity in work, rest, and eating patterns, adverse road, weather and traffic conditions, which may cause delays and lead to hurriedly loading or unloading cargo in order to compensate for the lost time; and environmental conditions such as excessive vibration, noise, and extremes in temperature. Transporting passengers or hazardous materials may add to the demands on the commercial driver. There may be duties in addition to the driving task for which a driver is responsible and needs to be fit. Some of these responsibilities are: coupling and uncoupling trailer(s) from the tractor, loading and unloading trailer(s) (sometimes a driver may lift a heavy load or unload as much as 50,000 lbs. of freight after sitting for a long period of time without any stretching period); inspecting the operating condition of tractor and/or trailer(s) before, during and after delivery of cargo; lifting, installing, and removing heavy tire chains; and, lifting heavy tarpaulins to cover open top trailers. The above tasks demand agility, the ability to bend and stoop, the ability to maintain a crouching position to inspect the underside of the vehicle, frequent entering and exiting of the cab, and the ability to climb ladders on the tractor and/or trailer(s). In addition, a driver must have the perceptual skills to monitor a sometimes complex driving situation, the judgment skills to make quick decisions, when necessary, and the manipulative skills to control an oversize steering wheel, shift gears using a manual transmission, and maneuver a vehicle in crowded areas.

Signature of Certified Medical Examiner

Date

Printed Name of Certified Medical Examiner

Email

Street Address

City, State, Zip Code

Phone/Fax