



MEDICAL REVIEW BOARD

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

September 1, 2015

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

Dear Mr. Darling:

On July 21-22, 2015, the Medical Review Board (MRB) met in public meetings to deliberate on *Medical Review Board Task 15-1* regarding public comments from medical professionals and associations on the Federal Motor Carrier Safety Administration's (FMCSA's) Notice of Proposed Rulemaking (NPRM) on insulin-dependent drivers of commercial motor vehicles with diabetes mellitus. In MRB Task 15-1, FMCSA requested that the MRB review and analyze the public comments from medical professionals and associations received on the Agency's NPRM and identify factors that FMCSA should consider with regard to making a decision about the next step in the insulin-treated diabetes mellitus (ITDM) rulemaking.

The attached report includes all of the MRB's recommendations related to MRB Task 15-1. On behalf of the MRB, I respectfully submit this report to FMCSA for its consideration.

Sincerely,

//signed//

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

Enclosure

MRB Task 15-1: Recommendations on the Disposition of Public Comments from Medical Professionals and Associations to the FMCSA’s Notice of Proposed Rulemaking (NPRM) on Insulin-Dependent Drivers of Commercial Motor Vehicles (CMVs) with Diabetes Mellitus

Task 15-1: In May 2015, FMCSA issued an NRPM announcing a proposal to allow drivers with stable, well-controlled insulin-treated diabetes mellitus (ITDM) to be qualified to operate CMVs in interstate commerce. The NPRM would enable individuals with ITDM to obtain a Medical Examiner’s Certificate (MEC) from a Certified Medical Examiner (CME) at least annually in order to operate in interstate commerce as long as evidence is presented by the treating clinician who prescribes insulin to the driver documenting that the condition is stable and well-controlled.

The Agency requested that the MRB provide a letter report to FMCSA outlining its recommendations regarding factors the Agency should consider in making a decision about the next step in the diabetes rulemaking after analyzing the public comments received from medical professionals and associations.

I. The baseline for acceptable risk should be the current Diabetes Exemption program.

- A. If FMCSA removes the prohibition on insulin-dependent individuals from being medically qualified, the Agency should replace it with a requirement that insulin-dependent drivers or commercial driver’s license (CDL) applicants are medically qualified to drive only if the individual complies with the ITDM program, as outlined in the regulation (49 CFR 391.46 lays out the proposed requirements in the NPRM).

II. Recommendations:

- A. In lieu of the current Diabetes Exemption program, the MRB recommends that ITDM drivers are medically disqualified unless they meet the following requirements demonstrating their stable, well-controlled ITDM:
 - 1. Driver must provide to the CME the FMCSA Drivers With Insulin Treated Diabetes Mellitus Assessment Form (see section II.E below) that has been completed and signed by the treating clinician, as defined by section II.D below.
 - 2. Driver must receive a complete ophthalmology or optometry exam, including dilated retinal exam, at least every 2 years documenting the presence or absence of retinopathy/macular edema and the degree of retinopathy and/or macular edema if present (using the International Classification of Diabetic Retinopathy and Diabetic Macular Edema). Increased frequency of exams should be advised based on a finding by the ophthalmological exam.
- B. Disqualifying Factors: CMEs may certify an ITDM driver as medically qualified for a time period of no longer than 1 year only if there are no disqualifying factors (which should be listed in 49 CFR 391.46):
 - 1. Any episode of severe hypoglycemia within the previous 6 months. For purposes of disqualification, severe hypoglycemia is defined as loss of

consciousness, seizures or coma, requiring the assistance of others or needing urgent treatment (glucagon injection or IV glucose).

2. Blood sugar < 60 milligrams per deciliter (mg/dL) demonstrated in current glucose logs.
3. Hypoglycemia appearing in the absence of warning symptoms (i.e., hypoglycemic unawareness).
4. If a driver has had an episode of severe hypoglycemia, blood sugar < 60 mg/dl, or hypoglycemic unawareness within the previous 6 months, the driver is medically disqualified and must remain disqualified for at least 6 months.
5. Uncontrolled diabetes, as evidenced by Hemoglobin A1c (HbA1c) level > 10 percent.
 - a. A driver can be reinstated when HbA1c level is \leq 10 percent.
6. Stage 3 or 4 diabetic retinopathy.
 - a. Permanent disqualification.
7. Signs of target organ damage, as evidenced by peripheral neuropathy, diabetic nephropathy, or cardiovascular disease with the risk of impairing the ability to operate a CMV safely.
 - a. Disqualification until resolved by treatment, if possible.
8. Inadequate record of self-monitoring of blood glucose (i.e., unreliable or absent capillary blood glucose measurements).
 - a. Disqualification for inadequate records is until the driver can demonstrate adequate evidence of glucose records (minimum 1 month).

C. If a driver is medically disqualified due to not meeting the ITDM program criteria above, the driver should remain disqualified for at least 6 months.

D. Definition of Treating Clinician (that would work with the CME to certify that ITDM driver can operate a CMV safely): The treating clinician is the Doctor of Medicine (MD), Doctor of Osteopathy (DO), Nurse Practitioner (NP), or Physician's Assistant (PA) who prescribed insulin to the driver and is knowledgeable regarding the treatment of diabetes.

E. FMCSA Drivers With Insulin Treated Diabetes Mellitus Assessment Form: FMCSA should develop a questionnaire for the treating clinician to send to the CME, which should include the following information, questions, and requests for information:

1. Introduction to the Form:
 - a. 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 insulin to treat diabetes. As the Certified Medical Examiner (CME), I am requesting that you review the Regulations as noted below [*provide treating clinician with list of diabetes-related disqualifications – See Item 16 below*], complete this questionnaire, and return it to me at the address specified below. By regulation, the

treating clinician must monitor the individual's diabetes and determine if within the previous 12 months the driver has:

- i. Had no severe hypoglycemic reaction resulting in a loss of consciousness or seizure, or requiring the assistance of another person, or resulting in impaired cognitive function and
 - ii. Properly managed his or her diabetes.
 - b. 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.
2. Insulin Regimen:
 - a. If the patient has type 2 diabetes on insulin, has the patient been on a stable medication regimen for the three (3) months prior to evaluation? Check Yes or No.
 - b. New insulin users:
 - i. For individuals who have been newly diagnosed with type 1 diabetes, the minimum period of insulin use may not be less than 2 months.
 - ii. For individuals who have type 2 diabetes and are converting to insulin use, the minimum period of insulin use may not be less than 1 month.
 - iii. Such new insulin users must have documentation of ongoing self-monitoring of blood glucose with a finger stick glucose reader (hand-written glucose logs are not acceptable). This must be done with a glucose meter that stores every reading, records date and time of readings, and from which data can be downloaded.
 - c. Established insulin users: Patient must have documentation of ongoing self-monitoring of blood glucose with a finger stick glucose reader (hand-written glucose logs are not acceptable). This must be done with a glucose meter that stores every reading, records date and time of readings, and from which data can be downloaded. Monitoring records must be available covering a minimum period of the most recent 3 months.
3. Blood Glucose Testing – Frequency:
 - a. How many times per day is the individual testing blood glucose? ____ times per day.
 - b. CMV drivers should test glucose each time before driving and every 4 hours while driving.
4. Has the patient been educated in diabetes and its management? Check Yes or No.
5. Does the patient understand the procedures that must be followed to monitor and manage his/her diabetes and what procedures should be followed if complications arise? Check Yes or No.
6. Has the patient had Hemoglobin A1c (HbA1c) measured intermittently over the last 12 months, with the most recent HbA1c measured in the last 3 months? Check Yes or No.
 - a. Require documentation of these dates and HbA1C values.

7. Impairing Events: Has the individual had any episodes of hypoglycemia within the past one (1) year as follows:
 - a. Severe hypoglycemia (loss of consciousness, seizures or coma, requiring the assistance of others or needing urgent treatment [glucagon injection or IV glucose]); or
 - b. Blood sugar < 60 mg/dl demonstrated in current glucose logs.
 - c. Treating clinician must advise a driver that he/she must report any such impairing events to the treating clinician.
8. Complete Eye Exam:
 - a. FMCSA requires a complete eye exam by a qualified ophthalmologist or optometrist, including dilated retinal exam, at least every 2 years documenting the presence or absence of retinopathy/macular edema and the degree of retinopathy and/or macular edema if present (using the International Classification of Diabetic Retinopathy and Diabetic Macular Edema). Increased frequency of exams is advised based on a finding by the ophthalmological exam.
 - b. The FMCSA Drivers With Insulin Treated Diabetes Mellitus Assessment Form should require certification that the treating clinician has reviewed the results from the ophthalmology or optometry report.
 - c. The patient's most recent ophthalmology or optometry report must be made available to the treating clinician upon request (use current Diabetes Exemption visual evaluation form – "Vision Evaluation Checklist, Federal Diabetes Exemption Program").
9. Does the patient exhibit evidence of diabetic neuropathy? Check Yes or No.
 - a. If yes, describe.
10. Does the patient exhibit evidence of diabetic cardiovascular disease? Check Yes or No.
 - a. If yes, describe.
11. Does the patient exhibit evidence of diabetic nephropathy? Check Yes or No.
 - a. If yes, describe.
12. Section for comments.
13. Signature area that requires certification that the treating clinician has reviewed the Driver's Role.
 - a. Signature should be required by both the driver/patient and the treating clinician.
 - b. Add to certification a commitment of the treating clinician to report any severe hypoglycemic episodes to the CME.
 - c. "It is my medical opinion that, with awareness of a CMV driver's role (consistent with "The Driver's Role" statement), my patient:
 - i. Has stable, well-controlled diabetes; and
 - ii. Has had no severe hypoglycemic episodes over the past year; and
 - iii. That neither the patient's diabetes nor diabetes-related medical conditions that would impair the ability to operate a CMV safely.
 - iv. Check response: Yes ___ No ___"

14. Driver may not be certified for more than one year.
15. Statement of the Drivers Role.
16. Statement of diabetes-related medical disqualifications.