



DEPARTMENT OF TRANSPORTATION

[4910-EX-P]

Federal Motor Carrier Safety Administration

49 CFR Part 391

[Docket No. FMCSA–2005-23151]

RIN 2126-AA95

Medical Review Board Task Report on Insulin Treated Diabetes Mellitus and Commercial Motor Vehicle Drivers

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of availability; request for comments.

SUMMARY: In May 2015, FMCSA published a notice of proposed rulemaking (NPRM) in the Federal Register to allow drivers with stable, well-controlled insulin-treated diabetes mellitus (ITDM) to be qualified to operate commercial motor vehicles (CMVs) in interstate commerce. The comment period closed on July 6, 2015 and the Agency received over 1,250 comments. In that same month, FMCSA requested the Medical Review Board (MRB) to provide the Agency with advice by reviewing and analyzing the comments and providing recommendations to FMCSA for its consideration. The Agency announces the availability of the MRB's report and requests comments on the MRB recommendations. The Final MRB Task 15-01 Report is posted in the docket at FMCSA-2005-23151.

DATES: Comments must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA–2005-23151 using any of the following methods:

- *Federal eRulemaking Portal:* Go to www.regulations.gov. Follow the on-line instructions for submitting comments.

- *Mail:* Docket Management Facility; U.S. Department of Transportation, Room W12-140, 1200 New Jersey Avenue, SE, Washington DC 20590-0001.

- *Hand Delivery or Courier:* West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE, Washington DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal Holidays.

- *Fax:* 1-202-493-2251.

Each submission must include FMCSA and docket number FMCSA-2005-23151. Note that DOT posts all comments received without change to www.regulations.gov, including any personal information included in a comment. Please see the *Privacy Act* heading below.

Docket: For access to the docket to read background documents or comments, go to www.regulations.gov at any time or visit Room W12-140 on the ground level of the West Building, 1200 New Jersey Avenue, SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. The on-line FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to

www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at www.dot.gov/privacy.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, 1200 New Jersey Ave SE, Washington, DC 20590, or by phone at (202) 366-4001 or by email at FMCSAMedical@dot.gov. If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366-9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA-2005-23151), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an e-mail address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov>, put the docket number, FMCSA-2005-23151, in the keyword box, and click “Search.” When the new screen appears, click on the “Comment Now!” button and type your comment into the text box on the following screen. Choose whether you are submitting your comment as

an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider these comments, in addition to the comments submitted in response to the NPRM, in determining how to proceed with this rulemaking.

Viewing Comments and Documents

To view comments, as well as any documents mentioned in this notice as being available in the docket, go to <http://www.regulations.gov>. Insert the docket number, FMCSA-2005-23151, in the keyword box, and click “Search.” Next, click the “Open Docket Folder” button and choose the document to review. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12-140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue, SE, Washington, DC 20590, between 9 a.m. and 5 p.m., E.T., Monday through Friday, except Federal holidays.

II. Background

Diabetes mellitus is a disease manifested by the body’s inability to maintain normal function of insulin, a substance that controls glycemic levels in the blood. Diabetes presents a major health challenge, particularly those who drive CMVs in interstate commerce. Under 49 CFR 391.41(b)(3), a person is physically qualified to drive a commercial motor vehicle if that person has no established medical history or clinical diagnosis of diabetes mellitus currently requiring insulin for control. Since 2003,

FMCSA has maintained an exemption program for individuals that use insulin to treat their diabetes mellitus, that allows them to drive in interstate commerce if their diabetes is stable and they meet criteria of the program. 68 FR 52441 (Sept. 3, 2003), as revised, 70 FR 67777 (Nov. 8, 2005).

In May 2015, FMCSA issued an NPRM in the **FEDERAL REGISTER** to allow drivers with stable, well-controlled 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 documenting that the driver's condition is stable and well-controlled. The comment period on the NPRM closed on July 6, 2015, and the Agency received more than 1,250 comments.

MRB Tasking

The MRB was established to provide FMCSA with medical advice and recommendations on medical standards and guidelines for the physical qualifications of operators of CMVs, medical examiner education, and medical research. 49 U.S.C. 31149(a)(1). The MRB, in view of its statutory creation and advisory function, is chartered by the Department of Transportation as an advisory committee under the provisions of the Federal Advisory Committee Act. 5 U.S.C. App. See <http://www.facadatabase.gov/committee/committee.aspx?cid=2084&aid=47>. See also *Announcement of Establishment of the Federal Motor Carrier Safety Administration Medical Review Board*, 70 FR 57642 (Oct. 3, 2005). The members of the MRB are

appointed by the Secretary to reflect expertise in a variety of medical specialties relevant to the driver fitness requirements of FMCSA. 49 U.S.C. 31149(a)(2).

In an effort to assist in the development of the final rule, on July 15, 2015, FMCSA requested advice from the MRB for the Agency to consider. Specifically, FMCSA asked the members to review and analyze all comments from medical professionals and associations, and identify factors the Agency should consider when making a decision about the next steps in the diabetes rulemaking. A public meeting to discuss this matter was held by the MRB on July 21 and 22, 2015. The Agency received the MRB's final report on September 1, 2015. Details of the meeting, including the original task, final report and supporting materials used by the MRB are posted on the Agency's public website: <https://www.fmcsa.dot.gov/medical-review-board-mrb-meeting-topics>.

MRB Final Report

The MRB's final report is available in the docket for this rulemaking (in addition to being available on the Agency's public website). The final report contains a number of detailed recommendations for FMCSA to consider as it develops a final rule. The Agency believes that public comment on the recommendations will assist it in evaluating the advice it has received from the MRB. Comments must be limited to addressing the recommendations in the MRB final report. A summary of the report's major recommendations is set out below:

The MRB recommended that ITDM drivers be medically disqualified unless they meet the following requirements demonstrating their stable, well-controlled ITDM:

1. The driver must provide an *FMCSA Drivers With Insulin Treated Diabetes Mellitus Assessment Form* (set out in the recommendations) to a medical examiner that has been completed and signed by the treating clinician. The treating clinician must be a Doctor of Medicine, a Doctor of Osteopathy, a Nurse Practitioner or a Physician's Assistant who prescribed insulin to the driver and is knowledgeable regarding the treatment of diabetes.

2. The 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).

The MRB recommended that medical examiners be allowed to certify an ITDM driver as medically qualified for a time period of no longer than 1 year only if the driver has not experienced any of the 8 disqualifying factors below (which the MRB believes should be listed in 49 CFR 391.46):

1. Any episode of severe hypoglycemia within the previous 6 months.
2. Blood sugar less than 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. An episode of severe hypoglycemia, blood sugar less than 60 mg/dl, or hypoglycemic unawareness within the previous 6 months; the driver should be medically disqualified and must remain disqualified for at least 6 months.

5. Uncontrolled diabetes, as evidenced by Hemoglobin A1c (HbA1c) level greater than 10 percent. A driver could be reinstated when HbA1c level is less than or equal to 10 percent.

6. Stage 3 or 4 diabetic retinopathy; a driver should be permanently disqualified.

7. Signs of target organ damage; a driver should be disqualified until the matter is resolved by treatment, if possible.

8. Inadequate record of self-monitoring of blood glucose; a driver should be disqualified for inadequate records until the driver can demonstrate adequate evidence of glucose records (minimum 1 month).

In addition, the MRB stated that, if a driver is medically disqualified due to not meeting the ITDM criteria listed above, the driver should remain disqualified for at least 6 months.

Comments Requested

Comments are requested on any and all of the recommendations provided in the advisory final report from the Medical Review Board but only on those recommendations. To the extent possible, comments should include supporting materials, such as, for example, data analyses, studies, reports, or journal articles. FMCSA will consider these comments, in addition to the comments submitted in response to the NPRM, in determining how to proceed with this rulemaking.

Issued on: August 30, 2016.

Larry W. Minor
Associate Administrator for Policy

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