**Meeting Minutes**

**July 21 – 22, 2015**

The Federal Motor Carrier Safety Administration’s (FMCSA) Medical Review Board (MRB) met on July 21 – 22, 2015, in Arlington, VA. In accordance with the provisions of Public Law 92-463, the meeting was open to the public. Dr. Gina Pervall, MRB Chairman, called the meeting to order at 9:00 a.m.

The following individuals attended the meeting:

**MRB COMMITTEE MEMBERS**

Gina C. Pervall, M.D., C.I.M.E., Chairman

Christine M. Cisneros, M.D., M.P.H., Ph.D.

Michael T. Kelley, M.D., M.P.H.

Brian T. Morris, M.D., J.D., M.B.A., M.P.H.

Albert James Osbahr, III, M.D., M.S.

**FMCSA AND OTHER GOVERNMENTAL REPRESENTATIVES**

Larry Minor, Associate Administrator for Policy and Designated Federal Officer (DFO), FMCSA

Shannon Watson, Deputy DFO, FMCSA

Christine Hydock, FMCSA

Nancy Scibek, FMCSA

Cynthia Shaffer, USDOT

**OTHER ATTENDEES**

Nana Agyemang, CBS News

Brandon Buchanan, American Bus Association

Mirna Gustave, iBiz

Katie Hathaway, American Diabetes Association (ADA)

Dennis Jamison, CBS News

Daniel Lorber, M.D, Fellow of the American College of Physicians, Certified Diabetes Educator, ADA

Erika Miller, American Academy of Physician Assistants

Kelly McNelis, iBiz

Nick St. Clair, The National Registry of Certified Medical Examiners Training Institute, LLC

Steve St. Clair, M.D., M.P.H., The NRCME Training Institute, LLC

Sarah Powers, ICF International

Bill Putnam, CBS News

Mark Valentini, Owner Operated Independent Drivers Association (OOIDA)

**REMARKS AND COMMITTEE ACTION**

The Committee approved the meeting minutes from the October 27, 2014, joint meeting with the Motor Carrier Safety Advisory Committee.

**OTHER REMARKS**

New procedures for public comments allow members of the public to raise their hand requesting an opportunity to speak. The committee Chair will be notified and accept at the next natural opportunity. Public commenters are asked to stand and state their name/organization before speaking.

All MRB members were invited to the MCSAC meeting on September 21 – 22 in Arlington, VA. The topic of this meeting will be the new driver wellness initiative. The Medical Handbook will not be ready for review at this time; Ms. Watson will update the board as necessary.

**1. Task 15-1: Review of Responses to FMCSA’s Notice of Proposed Rulemaking (NPRM) on Diabetes Mellitus from Medical Professionals and Associations**

The board reviewed Task 15-1, as well as some responses to FMCSA’s NPRM on allowing drivers with Insulin Treated Applicants with Diabetes Mellitus (ITDM) to drive commercial motor vehicles (CMVs). Discussion included the following:

* ITDM can directly impair blood glucose levels of CMV drivers, leading to hyperglycemia and hypoglycemia**.** It is not possible to concentrate on blood sugar levels only, as these risks are associated with chronic complications and diseases.
* It is important to receive health information from insulin subscribing doctors. The agency relies heavily on healthcare professionals to ensure drivers with ITDM are healthy enough to drive their vehicles.
	+ There are currently over 2,500 drivers under theDiabetes Exemption Program. There is room for the Diabetes Exemption Program to be revoked under different guidelines and paperwork. More ITDM drivers currently drive than the number participating in the Diabetes Exemption Program.
* ITDM drivers have higher crash risk than non-ITDM counterparts.
* Data from an occupational medicine statistical course show that many ITDM drivers do not follow healthy regimes.
* Economic factors force people to become truck drivers, even if it is ill-advisable.
* Task Statement 15-1 as written does not provide enough information for medical examiners to sign the medical card confidently.
* [Dr. Lorber, ADA] Diabetes is a teamwork disease in which patients and doctors exchange knowledge to develop a care plan for each individual. The blanked bands across the board do not give everyone the opportunity to share knowledge. There needs to be conversation about different diseases that can occur. This is a place where knowledge can be combined. It is important to work together and smooth the road for as many people as possible who are on insulin and cannot afford the monthly delay to go through an exemption process to get back on the road.
	+ [Dr. Lorber, ADA] There is no definition of well-controlled diabetes. This is based on the individual.
* What are the extremes of stable?
	+ [Dr. Lorber, ADA] The issue is hypoglycemia. Eighty percent of the episodes come in about 20 percent of patients. Targeting every veteran and under-privileged driver with ITDM is a mistake.
* If the duty is to charge clinicians with stable controlled ITDM driver exams, what is the guidance?
	+ [Dr. Lorber, ADA] There is a difference between stable and well-controlled. There is no “on and off” switch that shows which of the instabilities are “poorly controlled.” The only relevant instability is hypoglycemia; this is not as relevant with younger drivers as it is with older drivers. In order for ITDM to be stable and well controlled, drivers need to be as specific and honest with their doctors as possible.
* What is looked at in order to make sure drivers are honest?
	+ [Dr. Lorber, ADA] Meter or emergency records. Meters have records of up to 1,000 readings, and meter downloads are available with drivers who have hypoglycemia. It must be acknowledged that doctors know certain truck drivers are on the road, and the agency needs to depend on honesty to a degree. Drivers and doctors can always find ways around certain rules.
* Medical examiners are liable when signing medical cards and data are relied upon from the treating doctor. If medical examiners are as aggressive as endocrinologists, can drivers be told they cannot drive unless they are on the meter? Is cost an issue?
	+ [Dr. Lorber, ADA] The ADA will put together a series of instructions for what is adequate. This has been done with firefighters and law enforcement officers (LEOs)**.**
* Does moderate and severe hypoglycemia need to be monitored more closely?
	+ [Dr. Lorber, ADA] The only data ADA is looking for is severe hypoglycemia data, since that is harder to pinpoint. History shows that severe hypoglycemic episodes can predict accidents prior to accidents occurring. No other data can predict an accident.
* [Dr. Lorber, ADA] What is it about hyperglycemia that concerns the board?
	+ Headaches and visual issues.
* The board is concerned that some drivers are not taking care of themselves. Dr. Lorber, ADA, agrees.
* [Dr. Lorber, ADA] There are uncontrollable factors (items sold in “mini-marts” on the highways; cold pills, allergy pills, etc.) that can contribute to risk factors with Type 1 Diabetic drivers.
* Some clinicians do not understand the different effects of diabetes, such as sleep apnea. These effects are often excluded from the medical form.
* [Katie Hathaway, ADA] The degrees of chronic complications of Type 1 Diabetes should be studied.
* The committee is comfortable with creating a checklist form/questionnaire that treating clinicians need to answer. This form can later be fine-tuned to mimic what is being done at the Federal Highway Administration (FHWA).
	+ This form will override the Diabetes Exemption Program.
* Treating clinicians should have a degree of expertise on diabetes. 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.
* [Katie Hathaway, ADA] The ADA can provide a checklist.

**2. Continue Review of Comments from Diabetes NPRM**

The board began creating a questionnaire for ITDM drivers to give to treating clinicians. When creating the questionnaire, the board referred to FMCSA’s safety standards and Canadian Diabetes Exemption Program forms.

Discussion points

* ITDM cases should be as clear as blood pressure cases. Working with the ADA will help.
* Proposition of giving a short-term card to ITDM drivers while other tasks are being completed to satisfaction; could be dependent on clinical knowledge.
* Categories for treating physicians need to be defined.
* A questionnaire for the treating clinician to send to the Certified Medical Examiner (CME) should include the following information:
	+ Statement of the Driver’s Role.
	+ Signature area that requires certification stating that the treating clinician has reviewed the Driver’s Role.
	+ Specifications on when the driver is required to test glucose before/while driving.
	+ ITDM drivers must receive a complete ophthalmology or optometry eye exam at least once every two years.
	+ Evidence that the driver has shown diabetic neuropathy, diabetic cardiovascular disease, or diabetic nephropathy.
	+ Recommendation to use the signature block from the opioid questionnaire.
* Some drivers go on insulin despite not needing to, in fear of losing their jobs.

**3. Continue Review of Comments from Diabetes NPRM (continued from Day 1)**

The board continued its discussion of Task 15-1 from Day 1.

Discussion points

* Potential disqualification factors, including severe hypoglycemia, significant change in insulin regimen, signs of target organ damage, and recent visual impairment; length of disqualification by type of factor was also discussed.
* Clinician liability if truckers have medical related accidents.
* Fabricate of questionnaire answers by truck drivers.
* Deletion of data from patients’ meters.
* There was a vote for A1C to be added to the form to represent uncontrolled ITDM that would order the driver to be disqualified.

Table 1: MRB members discussed if A1C disqualifications should be added to the questionnaire and approved as follows: 3 in favor (Christine Cisneros, Albert Osbahr, and Gina Pervall); 2 against (Michael Kelley and Brian Morris).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Member | Organization | Aye | Nay | Abstain |
| Cisneros, Christine, M.D., Ph.D. M.P.H | USHealthwork Clinics (Goshen and Elkhart, Indiana) | 1 |  |  |
| Kelley, Michael, M.D., M.P.H | Ambulatory Services, OhioHealth Neighborhood Care |  | 1 |  |
| Morris, Brian, M.D., J.D., M.B.A., M.P.H. | AllOne Health, Inc. |  | 1 |  |
| Osbahr, Albert, M.D., M.S. | Occupational Health Services at Catawba Valley Medical Center | 1 |  |  |
| Pervall, Gina, M.D., C.I.M.E. | Johns Hopkins University Applied Physics Laboratory Services; MRB Chairman | 1 |  |  |
|  | TOTALS | 3 | 2 |  |

Table 2: MRB discussed consistency to what has to been established and in place with A1C as 10 and approved as follows: 3 in favor (Christine Cisneros, Albert Osbahr, and Gina Pervall); 2 against (Michael Kelley and Brian Morris).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Member | Organization | Aye | Nay | Abstain |
| Cisneros, Christine, M.D., Ph.D. M.P.H | USHealthwork Clinics (Goshen and Elkhart, Indiana) | 1 |  |  |
| Kelley, Michael, M.D., M.P.H | Ambulatory Services, OhioHealth Neighborhood Care |  | 1 |  |
| Morris, Brian, M.D., J.D., M.B.A., M.P.H. | AllOne Health, Inc. |  | 1 |  |
| Osbahr, Albert, M.D., M.S. | Occupational Health Services at Catawba Valley Medical Center | 1 |  |  |
| Pervall, Gina, M.D., C.I.M.E. | Johns Hopkins University Applied Physics Laboratory Services; MRB Chairman | 1 |  |  |
|  | TOTALS | 3 | 2 |  |

* This will disqualify drivers for as long as it takes to get back on track. The quickest time for glucometers is 30 days.

**4. Finalizing Recommendations on Task 15-1**

Discussion Points

* The title of the questionnaire will be “FMCSA Drivers with Insulin Treated Diabetes Mellitus (ITDM) Form.”
* The introduction to the form was discussed and edited. Further evaluation of the form was completed from earlier discussion.
	+ This questionnaire will be in lieu of the Diabetes Exemption Program.
* Three groups of ITDM will be identified in the questionnaire:
	+ New insulin users, Type 1 users, and old insulin users.
* Blood-glucose logs will be added to the questionnaire:
	+ Finger-stick glucose language will be added. Hand-written glucose logs are not acceptable.
* There will be certain mandates requiring drivers to pull over to test their blood-glucose levels.
	+ The treating clinicians should follow-up with patient’s blood-glucose levels when individuals are not driving. The MRB does not need this information.
* The new form will be easier for treating clinicians to follow.
* CMEs will be required to read and fill out the remainder of the form provided by the treating clinician.
* Treating clinicians do not have the ability to disqualify drivers.
* Drivers must present the form to their insulin prescribing clinician.
* Questions are now formatted so treating clinicians have to fill out the form truthfully.
* All drivers currently receiving an exemption will no longer need one because drivers will not follow this form.
* New drivers must meet the regulations listed in the form to continue to be able to drive.
* Additional information will be added to the form to further explain what it means for a driver’s condition to stay stable.
* At a minimum, there will be public comment on the form.
* MRB will conduct final review of the form.

**5. Drafting of 15-2 Report and Vision Exemption Recommendations**

Task 15-2 was discussed and the board proposed changes to the Vision Exemption.

Discussion Points

* All ITDM patients must undergo eye exams, and eye exam information must be presented to the CME as part of the program. ITDM will not be able to operate unless drivers follow what the board presents in the newly developed forms.
* Diabetes NPRM was issued in May and closed in July. This has not been done for vision.
* Goal is to get rid of the exemption program while maintaining the same level of safety.
* Drivers can be monocular and drive. The good eye must meet the minimum standards and be in stable conditions.
	+ MRB proposed that disease-free monocular drivers should receive eye exams once a year. FMCSA should seek comment from eye specialist (ophthalmologist or optometrist) associations on recommended frequency of examination.
* Some individuals will drive regardless of eye problems because of financial circumstances.
* Data show that drivers who suffer traumatic (eye) loss take a while to acclimate back.
* Diabetes ophthalmologists should look for cataracts, glaucoma, acuity, pressure, field vision, depth, and color.
* MRB recommendations would be in lieu of the current vision exemption program.
* A small percentage of individuals are completely colorblind. However, some drivers who are slightly colorblind still fail traffic signal testing.
	+ Concerned with the distinction of colors at night. It may be hard to differentiate between flashing red and flashing yellow light.
* MEs are still not exempt from their position. The ophthalmologists will complete the eye exam testing, but the MEs will still need to fill out the form. This way, all fields of the form will be completed.
* The title of this form will be “Vision Evaluation Checklist.”

**PRESENTATIONS**

*Federal Advisory Committee Act (FACA) and Ethics Briefing*

 Kirk Foster, Ethics Attorney, FMCSA

**ADJOURNMENT:** The meeting was adjourned at 4:30 p.m. on Wednesday, July 22.

We hereby certify that, to the best of our knowledge, the foregoing minutes are accurate and complete.

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Gina C. Pervall, MD

Chairman, MRB

//signed//

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Larry W. Minor

Designated Federal Officer, MCSAC