Docket No. FMCSA-2005-23151

Federal Motor Carrier Safety Administration
Notice of Proposed Rulemaking, 80 Fed. Reg. 25260

Comments of the American Diabetes Association

The American Diabetes Association (Association) submits these comments in response to the May 4, 2015 Notice of Proposed Rulemaking by the Federal Motor Carrier Safety Administration (FMCSA) regarding its proposal to amend the medical qualifications standards contained in Part 391 of the Federal Motor Carrier Safety Regulations (FMCSRs) to allow the operation of commercial motor vehicles in interstate commerce by drivers with insulin-treated diabetes mellitus. The Association offers these comments on four of the five areas identified by FMCSA for information and response and also addresses additional areas of concern to the Association.

The American Diabetes Association

The Association is a nationwide, nonprofit, voluntary health organization founded in 1940. It consists of people with diabetes, health professionals who treat people with diabetes, research scientists, and other concerned individuals. The Association is the largest non-governmental organization that deals with the treatment and impact of diabetes. The Association establishes, reviews, and maintains the most authoritative and widely followed clinical practice recommendations, guidelines, and standards for the treatment of diabetes.1 The Association also publishes the most authoritative professional journals concerning diabetes research and treatment.2

The mission of the Association is to prevent and cure diabetes and to improve the lives of all people affected by diabetes. This mission requires supporting a system that provides standards to protect commercial drivers with diabetes and the public, while not unduly denying people with diabetes the same rights granted to other Americans.

Background

For many years, the Association has been involved in the development of policies and regulations relating to the assessment and certification of commercial drivers with insulin-treated diabetes. Beginning with the creation of the Diabetes Exemption Program in 2003, FMCSA has made strides to bring its evaluation of drivers with insulin-treated diabetes into harmony with current medicine. Not long after the exemption program was created, however,

2 The Association publishes four professional journals with widespread circulation: (1) Diabetes (original scientific research about diabetes); (2) Diabetes Care (original human studies about diabetes treatment); (3) Clinical Diabetes (information about state-of-the-art care for people with diabetes); and (4) Diabetes Spectrum (review and original articles on clinical diabetes management).
it became clear that the exemption process itself was too cumbersome to effectively provide for a nondiscriminatory means of assessment and, therefore, the process needed to be changed. FMCSA issued its Advanced Notice of Proposed Rulemaking (ANPRM) on March 17, 2006, which indicated the agency’s intent to make a regulatory change to the diabetes standard.\(^3\) The Association submitted substantial comments to the ANPRM, many of which are relevant to this proposed rule.\(^4\)

The Notice of Proposed Rulemaking (NPRM) indicates that the outdated blanket ban currently contained in the FMCSRs will give way to a new process for insulin-treated commercial drivers, one which closely mirrors the general medical assessment program. The Association supports revision to Part 391 of the FMCSRs to provide for individual assessment consistent with efforts made to date, but without the constraints of the unduly burdensome exemption program currently in place. Individual assessment is the cornerstone of the Association’s commitment to commercial drivers with insulin-treated diabetes; it is the only approach supported by current medicine and is required by law.\(^5\)

**Notice of Proposed Rulemaking**

The Association applauds FMCSA; many aspects of the proposed rule will ease the unnecessary burden on commercial drivers with insulin-treated diabetes. First, eliminating the exemption process and allowing commercial drivers with insulin-treated diabetes to apply for and recertify through a treating clinician (TC) and medical examiner (ME) is a critically important change.\(^6\) The delay associated with the agency’s review of the exemption application and publishing applications in the Federal Register rendered the process prohibitive. Many commercial drivers have lost their jobs or were denied employment opportunities as a result of the protracted wait. Many others, unable to afford to wait out the time it takes to receive an exemption, delayed insulin treatment when insulin was the medically advisable way to manage their diabetes. As a result, the exemption program, much like the blanket ban that preceded it, became a deterrent to better health for these drivers. The Association agrees that “the inconvenience and expense for drivers, and the administrative burden of an exemption program are no longer necessary to address concerns of hypoglycemia and meet the statutory requirement that drivers with ITDM maintain a physical condition that ‘is adequate to enable them to operate (CMVs) safely.’”\(^7\)

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7 See id. at 25265.
Additionally, the NPRM appropriately allows individuals to be evaluated by a treating physician or other health care professional, rather than requiring such evaluation by only an endocrinologist. Many individuals with diabetes are treated by an internist or primary care physician and not an endocrinologist, and there are parts of the country where no endocrinologists are available. Physicians who are knowledgeable about current diabetes management, even if they are not board certified or board-eligible in endocrinology, are highly qualified and capable of conducting evaluations of commercial drivers with insulin-treated diabetes. What is most important is for the person with diabetes to be evaluated by a health care professional knowledgeable in the management of diabetes, and for that professional to be familiar with the essential job tasks of person’s particular job. The Association agrees that while an endocrinologist is a valuable asset to an individual’s overall diabetes management and health goals, requiring that the CMV evaluations be performed by such a specialist is unnecessary.

Requests for Information and Comments

FMCSA has identified five areas for public comment. The Association’s comments will address four of those five areas in turn:

(1) Contrary to the MRB recommendations, the Agency is not proposing to prohibit drivers with ITDM from being medically qualified to operate CMVs carrying passengers and hazardous materials...The Agency requests public comment specifically on this point, however.

The Association vigorously agrees with FMCSA’s decision to continue allowing commercial drivers who use insulin to transport passengers and hazardous materials. FMCSA is correct in its statement that there is no evidence to support prohibiting commercial drivers with insulin-treated diabetes from certain operations.\(^8\) FMCSA also correctly notes the risk posed by a driver with stable, well-controlled insulin-treated diabetes is very low in general. All of the diabetes physicians who provided input to the agency communicated their agreement in a letter to FMCSA in 2007:

We see no reason why individuals who use insulin should not be able to drive vehicles transporting hazardous materials or passengers. A person who is qualified to operate a commercial motor vehicle is qualified to operate any commercial motor vehicle. The individual who closely monitors blood glucose levels, regularly sees a physician, does not experience severe hypoglycemia or hypoglycemia without any symptoms, and otherwise properly manages diabetes becomes no less safe when

\(^8\) Id.
he/she is behind the wheel of a vehicle transporting hazardous materials or passengers.¹

Though FMCSA’s appointed Medical Review Board (MRB) proposed this prohibition from transporting hazardous materials and passengers, the proposal was opposed by every diabetes expert that FMCSA has consulted on diabetes. Two separate groups of diabetes experts appointed by FMCSA have studied the issue and both concluded that people with insulin-treated diabetes can be safe commercial drivers. The MRB made this leap to differentiate types of commercial driving without any scientific evidence demonstrating that this population should be so limited or any assessment about how any differences between various types of commercial driving impacts the ability of drivers who use insulin to drive safely. Additionally, the MRB’s recommendation was limited to diabetes; no other medical or physical condition was proposed to adopt such a restriction.

Furthermore, as noted above, individual assessment was required by the Safe, Accountable, Flexible, Efficient Transportation Equity Act (SAFETEA-LU).¹⁰ Prohibiting commercial drivers with insulin-treated diabetes from certain types of operations based on their diagnosis or use of insulin alone is antithetical to the basic premise of individual assessment. Because there is no medical basis for such a restriction and the law requires individual assessment, the Association urges FMCSA to continue permitting qualified CMV drivers with insulin-treated diabetes to transport passengers and hazardous materials without limitation.

(2) FMCSA is not proposing to adopt the MRB recommendation to require annual or more frequent medical recertification for all drivers with diabetes mellitus. The proposed requirements apply only to drivers with ITDM... The Agency seeks comment on these issues.

If a person with diabetes is qualified to operate a CMV, he or she should be issued medical certification equal to what other drivers who do not have diabetes receive without the need for further certification. Drivers with diabetes should be able to hold a medical certificate for up to 24 months, unless their health care provider identifies a diabetes-specific issue or the ME identifies some other specific health condition affecting commercial driving that requires more frequent consultation.

The current Diabetes Exemption Program requires quarterly and annual endocrinologist reports, and provides qualified drivers with a two-year medical certificate. Because the proposed rule requires insulin-treated drivers be free from severe hypoglycemic reactions resulting in a loss of consciousness or seizure, or requiring the assistance of another person, or resulting in impaired cognitive function within the previous 12 months, providing for annual

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¹ Letter from Drs. Brennan, Daly, Grunberger, Horton, Kolodny, Lorber, and Saudek to FMCSA (December 4, 2007) (on file with the Association).

medical certification is a reasonable balance between assessing medical qualification and ensuring safety and ensuring fairness for the CMV driver with diabetes. Annual certification should be limited to only those drivers whose diabetes is treated with insulin.

(3) Although the MRB recommended evaluation by a licensed physician, the Agency believes the TC working in conjunction with the ME, who is certified by the National Registry and working within the regulatory framework under part 391, meets the statutory requirement under 49 U.S.C. 31136(a)(3) for periodic physical examinations of drivers. The Agency seeks comment on these issues.

The Association agrees that a TC knowledgeable in the management of diabetes should be involved in the evaluation process as the evaluator of the applicant’s diabetes. Endocrinologists as well as other physicians and health care professionals regularly care for patients with diabetes. The important qualification is that the TC must have knowledge of the disease and treatment regimens. With that essential experience, a TC is able to assess an individual’s diabetes management and determine whether CMV operation is safe and practicable in accordance with the revised standard and accompanying diabetes guidelines.

(4) The proposed rule would not require drivers with ITDM to be examined or obtain a signed statement from an ophthalmologist or optometrist to meet the vision standard or a separate examination for diabetic retinopathy. The Agency requests comment on the need for a person with ITDM to be examined by an optometrist or ophthalmologist as a condition of passing the physical exam.

The Association’s published Standards of Medical Care do not require annual screenings for retinopathy. The Standards of Care, written by a team of diabetes medical experts and based on a systematic review of other published literature, recommend that patients with type 1 diabetes be screened for retinopathy within 5 years of diagnosis. This is because retinopathy is estimated to take at least 5 years to develop following hyperglycemia. Requiring annual screenings prior to the close of this window would be medically unnecessary and burdensome on applicants. The Standards of Care recommend that patients with type 2 diabetes, who may have had a period of undiagnosed hyperglycemia, should be screened shortly after diagnosis. However, the Standards of Care also state that after one or more normal eye exams, patients with well-controlled type 2 diabetes had essentially no risk of developing significant retinopathy within 3 years of a normal examination.

11 American Diabetes Association: Standards of Medical Care in Diabetes 2015, Diabetes Care 38: Supp. 1, at S6 (2015) (explaining that a coordinated, team-based model of various health care professionals is optimal for treating patients with diabetes).
12 Id. at S60–61.
13 Id. at S60.
14 Id.
15 Id.
Not all individuals with diabetes will develop vision complications, and among those that do, not all will interfere with safe driving ability. As such, only those CMV drivers who pose a high risk – because of the presence of complications that interfere with driving, such as impaired vision – should be further assessed by a specialist to determine if the risk is too high.

Therefore, the Association believes it should be left to the judgment of the TC to refer the patient to an optometrist or ophthalmologist as needed, based on clinical indicators that a screening by an eye specialist is necessary. The Association agrees with the proposed rule that requiring annual screenings by an eye specialist as a condition of passing the physical exam is not necessary, and drivers should need only meet the vision standard all CMV drivers must meet, absent other individualized factors.

(5) FMCSA invites comment from members of the public who believe there will be a significant impact either on small businesses or on governmental jurisdictions with a population of less than 50,000.

The Association does not have expertise in this area but notes the proposed rule would have a positive impact on all employers – including small businesses and governmental jurisdictions – because they would not need to wait for a driver to obtain an exemption in order for business operations to continue.

Other Comments and Information

§ 391.46(b)(1) Evaluation by the Treating Clinician

The Association notes that the proposed rule contains minimal instruction to the TC regarding what clinical indicators to evaluate. Section (i) provides direction on severe hypoglycemia, a critically important point for evaluation. However section (ii) merely requires that the TC determine that the applicant has “properly managed his or her diabetes.” The Association has established positions on the tools used to evaluate diabetes, which we address here, in turn. Additionally, we propose FMCSA adopt a short, clear form for the TC to complete in conducting his or her assessment. A proposed form is included as Appendix A to these comments.

Hemoglobin A1C

The NPRM includes a statement that to apply for an exemption under the current program, a driver must have one measure of glycosylated hemoglobin within a range of ≥7 percent and ≤10 percent.17 This statement is inconsistent with the Exemption Application, which states only that “A CMV driver should not have large fluctuations in blood glucose levels. The determination of a patient’s stable control is left to the treating endocrinologist.” A required A1C range is not specified on either the Exemption Application, or the physician form. It is troubling that FMCSA

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believes this A1C requirement to exist while it does not appear in any exemption documents. The Association hopes that this is merely error and, in any event, there is no intent to import this requirement into the proposed process. However, because this is such an important issue, the Association wants to make clear the rationale behind its opposition to an A1C range in licensing drivers with diabetes.

A1C is never an appropriate measure of a person’s ability to safely perform a job or as a basis upon which to determine the risk for driving mishaps. An A1C test tells a person what his or her average blood glucose level is over the past 2-3 months. It is a useful indicator of diabetes management when used in conjunction with other assessment tools, such as a review of daily blood glucose logs, but cannot be used standing alone to assess an individual’s ability or inability to drive safely. Individuals with an A1C at the low end (below 7%) have very well managed diabetes. These levels are often seen in people with mild diabetes or in people who take very good control of their diabetes, and do not in themselves predict hypoglycemia. High A1C indicates a relatively high blood glucose, the main symptoms of which – excess thirst and urination – do not impair driving.

In fact, the diabetes experts who advised FMCSA on the development of the Diabetes Exemption Program specifically rejected the idea that CMV drivers with diabetes should meet a certain A1C level. When FMCSA published a requirement that A1C be between 7% and 10% in order to qualify for a diabetes exemption, these experts told the agency that “a set A1C range doesn’t best identify those people who can be the safest drivers.” The group further stated:

The new minimum level of 7% that has been established is affirmatively harmful to individuals with diabetes. As endocrinologists, our goal is for our patients to have A1Cs below 7% in order to prevent or delay the devastating long-term complications of diabetes . . . . the goal for the individual patient is an A1C as close to normal for people without diabetes (<6%) as possible, without significant hypoglycemia . . . . It is our expert opinion that, in part because of the many new diabetes management tools that are available, some people can be brought very close to normal levels of blood glucose without significant risk of hypoglycemia. Certainly, most people can reach a goal of <7% without this complication. Such people would make excellent, safe commercial drivers and we can indeed identify these people using other screening criteria in the diabetes exemption program . . . . We cannot over-emphasize that requiring A1C >7% goes contrary to everything we have been trying to accomplish over the last couple of decades. This is simply

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the wrong message for our patients and the wrong message to increase safety on our roads.\textsuperscript{20}

It should be noted that although the goal for many diabetes patients is an A1C below 7%, this is not the case for all patients and taken alone, an A1C above 7% in no way indicates the person cannot safely operate a commercial motor vehicle. FMCSA should not require that individuals with insulin-treated diabetes manage their diabetes in a certain way in order to receive DOT certification. FMCSA’s focus should be on ensuring that the individuals operating CMVs in interstate commerce are physically qualified to do so, and not whether it is medically advisable for a person with diabetes to follow a specific diabetes management regimen or to have a higher or lower A1C level. Rather, that is a decision that, from a medical and legal standpoint, should be made by an individual and his or her physician based on how diabetes affects that person. Simply put, one size does not – and should not – fit all.

The proposed rule specifically includes disqualifying severe hypoglycemic reactions – to include seizure, loss of consciousness, a reaction requiring assistance of another person, or a period of impaired cognitive function that occurred without warning – and thus it is unnecessary to have any further requirement or suggestion of any acceptable range for blood glucose. FMCSA should not use this medically unjustified criterion in any form or for any purpose and should revise its public documents and application materials to remove any reference to what is an acceptable A1C range if such references currently exist. Further, no such range should be included in any revision to the physical qualification standards or implementing physician guidelines.

\textit{Blood Glucose Range}

The current exemption application states that “a CMV driver should not have large fluctuations in blood glucose levels. Drivers should maintain blood glucose levels between 100 to 400 mg/dl prior to and while driving a CMV.” This \textit{operational criterion} was established to ensure that individuals who have received an exemption would not drive if their blood glucose was too low or too high. However, by including this range in its application materials, FMCSA implies an individual must always keep his or her blood glucose within this range in order to be qualified for an exemption. This should be corrected.

There is no legitimate medical reason to automatically disqualify individuals whose blood glucose logs show some readings below 100 mg/dl or above 400 mg/dl. It is appropriate to evaluate blood glucose readings, but not appropriate to use this range as absolute cutoff points. This criterion should not be included in any revisions to the Medical Examiner Handbook or required for eligibility of a medical certificate under the final rule. Rather, significant fluctuations in blood glucose should be considered by the TC when evaluating whether the individual is medically qualified to operate a CMV.

\footnote{\textit{Id.}}
**Urine Glucose**
Since the mid-1970's, urine glucose results have been considered outdated and an inappropriate methodology for assessing diabetes control.\(^{21}\) The urine test is not a reliable or accurate indicator of blood glucose levels and is a poor measure of the individual's current health status. Blood glucose monitoring is a vastly more accurate and timely means to measure glycemic control. Although urine tests are a standard part of the Department of Transportation medical examination, urine glucose tests should not be used in the evaluation of insulin-treated drivers.

§ 391.46(b)(2) Medical Examiner's Evaluation

The proposed rule does not make completely clear the role of the ME in evaluating the applicant's diabetes.\(^{22}\) The most appropriate evaluation process is one in which the TC assesses a driver's diabetes and the ME defers to that assessment in conducting the overall evaluation of the driver's medical qualification. The critical component of any system to certify commercial drivers with diabetes is evaluation by a health care professional knowledgeable about the disease. Such professionals are well-suited to conduct an individual assessment of a person's diabetes, and whether it impacts the ability to safely operate commercial motor vehicles. The Association supports a two-step certification process whereby the TC certifies that the individual with insulin-treated diabetes meets the revised diabetes standard, and the National Registry ME completes the certification process with regard to all other aspects not related to diabetes. If the ME has concerns about a driver's diabetes, the ME should consult the TC or an independent diabetes health care professional for verification.

Unfortunately, during the comment period, the Medical Examiner Handbook (the comprehensive document published by FMCSA, on which MEs rely to perform their examinations) was not available for review and there was a notation it is being revised.\(^{23}\) The Handbook is typically available for viewing online. It is vital this document not be revised to include qualification standards for drivers with diabetes which go beyond those contained in this proposed rule or the final rule and particularly that it not include medically unsupported restrictions like those discussed in this comment. As the agency makes any revisions to the Handbook, it is important the Association and other stakeholders have an opportunity to comment on any provisions pertaining to insulin-treated diabetes.

**Conclusion**

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\(^{22}\) See Qualifications of Drivers; Diabetes Standard, 80 Fed. Reg. 25260, 25272 (proposed May 4, 2015) (to be codified at 49 C.F.R. pt. 391) (§ 391.46(b)(2)(i) seems to suggest that the medical examiner will certify that a person is free of diabetes complications).

The American Diabetes Association agrees with FMCSA “drivers with [insulin-treated diabetes mellitus] are as safe as other drivers when their condition is well-controlled.”\textsuperscript{24} Removing the medical certification process for CMV drivers with insulin-treated diabetes from the cumbersome exemption program and moving it to the regular medical examination process will have an immediate and positive impact on the availability of qualified drivers and on people with diabetes.

The Association appreciates the opportunity to comment on the agency’s proposed changes to the system of medical evaluation for commercial drivers with insulin-treated diabetes and would be happy to provide any additional information or assistance as reexamination of the current process continues and a final rule is adopted.

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khathaway@diabetes.org

APPENDIX A: DIABETES FORM

INSULIN TREATED DIABETES EVALUATION

49 CFR 391.46

INSTRUCTIONS FOR TREATING CLINICIAN: This patient is applying for medical certification to operate a commercial motor vehicle (large truck or bus) in interstate commerce. Federal regulations require drivers with insulin-treated diabetes mellitus to be evaluated prior to a full medical examination. You are asked to determine if this patient has any medical problem related to diabetes that impairs safe driving.

By law, the treating clinician must determine that within the previous 12 months the driver has:

- 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
- Properly managed his or her diabetes.

Patient Information

Name: ____________________________________________

First ___________________________ Last ___________________________

DOB (MM/DD/YYYY): ___________________________

Diabetes Examination

Date of examination (MM/DD/YYYY): ___________________________

1. Is the patient being treated with insulin?
   - YES (Proceed to questions 2-6)
   - NO (This form is not necessary)

2. In the last 12 months, while being treated for diabetes, has the patient had a severe hypoglycemic reaction?
   - YES
   - NO

3. The patient has been asked to test blood glucose _____ times a day.

4. I have reviewed the patient's glucose monitoring records and find them satisfactory for the purpose of operation of a commercial motor vehicle.
   - YES
   - NO
5. I have screened this patient for complications of diabetes with the following results:
   Retinopathy/Other vision condition: ________________________________
   - Not present
   - Under treatment and does not impair safe driving
   - Impairs safe driving
   Cardiovascular Disease: ________________________________
   - Not present
   - Under treatment and does not impair safe driving
   - Impairs safe driving
   Neuropathy: ________________________________
   - Not present
   - Under treatment and does not impair safe driving
   - Impairs safe driving

6. The patient has been educated in diabetes and its management and thoroughly informed of and understands the procedures that must be followed to monitor and manage his/her diabetes and what procedures should be followed if complications arise
   - YES
   - NO

☐ This patient is physically qualified to operate a commercial motor vehicle
☐ This patient is not physically qualified to operate a commercial motor vehicle

Clinic Information

Name: ________________________________________________________________
   First                                      Last

Phone No.: ___________________________ Email: ___________________________

Preferred contact for questions: ________________________________

I am a:

☐ Physician
☐ Physician Assistant
☐ Nurse
☐ Diabetes Educator