

FEDERAL MOTOR CARRIER SAFETY ADMINISTRATION
U.S. DEPARTMENT OF TRANSPORTATION
NOTICE OF PROPOSED RULEMAKING
ON THE
QUALIFICATIONS OF DRIVERS: DIABETES STANDARD
FMCSA-2005-23151
SUBMITTED BY:
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Health and Safety Works, LLC, (H&SW), an occupational and transportation health consulting company, submits the comments below in response to the May 4, 2105 Notice of Proposed Rulemaking (FMCSA-2005-23151-0098) issued by the Federal Motor Carrier Safety Administration (FMCSA). According to the summary of the Notice of Proposed Rulemaking (NPRM) in the Federal Register, "FMCSA proposes to permit drivers with stable, well-controlled insulin-treated diabetes mellitus (ITDM) to be qualified to operate commercial motor vehicles (CMVs) in interstate commerce. Currently, drivers with ITDM are prohibited from driving CMVs in interstate commerce unless they obtain an exemption from FMCSA. This NPRM would enable individuals with ITDM to obtain a Medical Examiner's Certificate (MEC), from a medical examiner (ME) at least annually in order to operate in interstate commerce if the treating clinician (TC) who is the healthcare professional responsible for prescribing insulin for the driver's diabetes, provides documentation to the ME that the condition is stable and well-controlled."

Summary of H&SW concerns about the Proposed Rule

H&SW concurs with FMCSA's proposal to eliminate the Diabetes exemption program which is costly, time-consuming and inefficient for both the driver with ITDM and the Agency. However, in so doing, H&SW believes it is in the best interest of road safety to maintain some of the important provisions built into the Diabetes Exemption Program, such as requiring the driver to:

- 1) Carry rapidly absorbable glucose within reach while operating the CMV,
- 2) test his/her glucose one hour before beginning to operate a CMV and periodically through the driving time (such as every 4-6 hours),
- 3) maintain glucose logs,
- 4) undergo an annual eye examination for retinopathy, a serious eye condition related to diabetes which cannot be detected by the type of eye examination currently required by FMCSA
- 5) undergo hypoglycemic awareness training.

H&SW believes that issues surrounding the provisions above are enforceable and are not impractical as stated by FMCSA in their NPRM. In the comments below we address our rationale for including these provisions and our perspective on the relationship of the provision to:

- 1) the economic burden of the rule, and

2) the impracticability of enforcing the provisions

H&SW agrees with the FMCSA's determination for the "annual or more frequent interval for a new Medical Examiner's certificate (MEC)."

Lastly, H&SW has concerns about relying on the treating clinician's documentation instead of providing provisions in the rule that give the National Registry Certified Medical Examiner (ME) tools for making an evidence-based decisions regarding the driver's physical qualification.

Our comments and rationale are discussed below.

Hypoglycemia Concerns associated with Driving

The American Diabetes Association (ADA) published a Policy Paper in January 2104 entitled Diabetes and Driving. FMCSA referenced this paper in the NRPM but neglected to include information reported about the risk of moderate hypoglycemic events and driving.

As FMCSA noted, hypoglycemia (low blood sugar) is the main concern related to a person who has ITDM and operates a CMV. The concern is the risk of sudden or gradual incapacitation brought on by hypoglycemia associated with insulin use. FMCSA acknowledges that concern about hypoglycemia but only addresses severe hypoglycemic events (defined as one where the driver is unable to treat himself) in the NPRM. The Agency does not address moderate hypoglycemic-events (the driver is able to treat him/herself but can no longer drive safely and loses the ability to make appropriate judgments) despite the issues raised by the ADA regarding moderate hypoglycemic events.

According to the ADA moderate hypoglycemic events also pose a serious concern. The ADA quotes the following statistics.

In a prospective multicenter study of 452 drivers with type 1 diabetes followed monthly for 12 months, 185 participants (41%) reported a total of 503 episodes of moderate hypoglycemia (where the driver could still treat him/ herself but could no longer drive safely) and 23 participants (5%) reported 31 episodes of severe hypoglycemia (where the driver was unable to treat him/herself) while driving (21). Conversely, the Diabetes Control and Complications Trial (DCCT) group reported 11 motor vehicle accidents in 714 episodes of severe hypoglycemia, a rate of 1.5% (23).

The significant impact of moderate hypoglycemia while driving is supported by multiple studies demonstrating that moderate hypoglycemia significantly and consistently impairs driving safety (24–26) and judgment (27,28) as to whether to continue to drive or to self- treat (29,30) under such metabolic conditions. In one study, 25% of respondents thought it was safe to drive even when blood glucose was ≤ 70 mg/dL (3.9 mmol/L) (31). (ADA Diabetes and Driving. Diabetes Care Volume 37, Supplement 1, January 2014, page S 99)

Thus, moderate levels of hypoglycemia causes serious concerns while driving — 41% of those studied (185 people) experienced 503 episodes of moderate hypoglycemia where the driver could still treat himself but could no longer driver safely. That is an average of 2.7 episodes in a 12 month period. This is a significant concern. If drivers with moderate hypoglycemic events operate a CMV, the consequences could be devastating, thus, the concern should be greater. Moderate hypoglycemic events should be addressed in the rulemaking.

The serious consequence of crashes from large bus and trucks is the reason FMCSA exists. The Agency must not forget its mission by generalizing information from the ADA policy of driving a non-commercial vehicle to driving a commercial vehicle. It is imperative that the Agency maintains vigilance for drivers who have a medical condition that increases their risk of unsafe operation of a CMV.

Diabetes exemption program requirements

As mentioned in the summary statement above, H&SW believes it is in the best interest of road safety to maintain some of the important provisions built into the Diabetes Exemption Program, such as requiring the driver to:

- 1) carry rapidly absorbable glucose within reach while operating the CMV,
- 2) test his/her glucose one hour before beginning to operate a CMV and periodically through the driving time (such as very 4-6 hours),
- 3) maintain glucose logs,
- 4) undergoing a eye examination for retinopathy annually
- 5) undergoing hypoglycemic awareness training

We base this on the requirements cited by the American Diabetes Association (ADA) recommendation to physicians and Canada's qualifications for drivers who have ITDM.

1) Carrying Rapidly Absorbable Glucose

As mentioned in the section above, the reason ITDM is treated differently than non-insulin related diabetes is because of the hypoglycemia risk posed by insulin. It is well known that insulin use poses a risk of hypoglycemic reaction which, depending on the severity, may cause mental confusion, loss of consciousness and death, if not treated. Hypoglycemia is treated with rapidly absorbable glucose taken at the onset of symptoms. Thus, the driver should have readily available rapidly absorbable glucose within reach while driving. This mitigates the risk of severe symptoms developing from the hypoglycemic event.

2) Test his/her blood glucose level one hour before driving and periodically thereafter and,

3) Maintain blood glucose logs

To ensure that the driver is safe to operate the CMV, he/she should be required to perform glucose monitoring with either a continuous glucose monitoring device or manual testing and maintenance of a blood glucose log. The driver should also be required to test his/her blood sugar

level one hour prior to driving. Testing the blood sugar level before driving is required by the Canadian Council on Motor Transport Administrators (CCMTA). Their requirements are includ-

ed in a document entitled, “Determining Driver Fitness in Canada.” This document includes a section on Driver Medical Standards with a section devoted to driving with ITDM. (see on-line at ccmta.ca/images/publications/pdf/Determining-Driver-Fitness-In-Canada-Final.pdf pages 163-172). CCMTA also has specific blood sugar levels permitted to operate a CMV.

H&SM believes that FMCSA should site all of the Canadian requirements if they are going to site one section. Canada has a different system and uses the treating clinician as the authority for medical decisions related to driver physical qualifications for driving. Each province implements this slightly differently from others. Canada does not have the model of a National Registry where specific health care practitioners are trained, tested and listed on a registry. Only those examiners are permitted to make physical qualification decisions for CMV drivers. Nevertheless Canada’s rules have very specific requirements for drivers. They do not permit the health care practitioner to make determinations regarding the driver being “well-controlled” without documentation of that control. In addition, the CCMTA places the onus on the CMV driver that differs from a non-CMV driver. CCMTA also requires that drivers comply with specific provisions, such as, not driving if the blood sugar level is below a specific reading. If FMCSA wishes to make comparisons to the CCMTA the Agency should make comparisons on all the CMV driver requirements and not just the requirement for an annual interval for a new medical certificate.

ADA recommends maintaining blood sugar logs and determining the blood sugar before driving a long distance for drivers who may have issues related to hypoglycemia. But, the ADA is addressing the non-commercial driver. Since the consequences of a CMV crash is greater than that of an automobile crash, and since FMCSA is responsible for safety of CMVs, the FMCSA should incorporate a higher level safety measures in its rules to ensure as far as possible public road safety. Drivers should maintain a higher standard of responsibility, too, to maintain their privilege to hold a CMV license.

Keeping records of the blood glucose levels enables the treating clinician and the ME to make a determination regarding whether the diabetes is well-controlled. Blood glucose logs also enable the driver to understand his blood glucose level.

The blood glucose logs should be given to the ME as well as the treating clinician. This provides one of the tools needed to answer the question: is the driver’s diabetes well-controlled and managed appropriately.

The driver has a responsibility to the public to ensure he/she is safe while operating and a responsibility to his/her own health to ensure his/her medical condition is well-controlled. Thus the driver has responsibility for his own and the public’s safety by monitoring his/her blood sugar one hour before getting into the driver’s seat and periodically thereafter as determined by the treating clinician depending on the type of insulin and the treatment regimen.

Incentives to manage medical conditions

FMCSA states that “reasonable persons with ITDM have every incentive to manage their condition so that the disease is stable and well-controlled, because failure to care for themselves would

affect their quality of life.” (NPRM pages 21 of 39) But it is well-known to health care practitioners that people are notorious for not following their doctor’s orders even when managing the condition has an impact on their quality of life. This is particularly true of people who have ITDM. That is why there is such concern among the medical community to educate people and to oversee their treatment. If people managed their diabetes appropriately there would be far fewer cases of retinopathy, neuropathy, amputations of lower extremities and other complications of diabetes. The Agency’s argument is a fallacy. It is well-known that people are frequently non-compliant with their treating clinician’s regimen particularly when it is related to food and eating meals as it is with diabetes.

To summarize, including the provision for maintaining blood glucose logs and testing the blood glucose before getting into the driver’s seat gives the driver responsibility for managing his/her medical condition and acts as an incentive for the driver to comply with the treating clinician’s plan of care. Including these provisions in the rule will provide the Medical Examiner with the tools needed to make an evidence-based decision regarding the individual driver’s ability to safely operate a CMV.

4) Undergoing eye examination for retinopathy annually

Since diabetic retinopathy is a serious condition that leads to blindness and since the development of retinopathy indicates poor management of the ITDM, an annual eye examination should be included as a requirement of the rule. The results of the examination should be given to the ME. This provides another tool for making an evidence-based decision regarding the driver’s management of his diabetes — determining whether the individual driver’s ITDM is well-controlled — and whether the driver has developed a vision condition that would adversely impact his/her ability to safely operate a CMV. H&SW recommends including the eye examination for retinopathy as a requirements of the regulation.

5) Undergoing hypoglycemic awareness training

Many ITDM patients suffer from hypoglycemia unawareness, i.e., they have a sudden hypoglycemic event without being aware of its onset. This is particularly concerning if a driver with ITDM develops a hypoglycemic event while operating a CMV and doesn’t realize it occurred. The ADA recommends Blood Glucose Awareness Training (BGAT) “Four studies have demonstrated that Blood Glucose Awareness Training (BGAT) reduces the occurrence of collisions and moving vehicle violations while improving judgment about whether to drive while hypoglycemic (42–45).” (ADA Diabetes and Driving. Diabetes Care Volume 37, Supplement 1, January 2014, page S 99). H&SW recommends including the BGAT in the requirements of the rule.

Annual Medical Examiner’s certificates

The FMCSA notes that the “annual or more frequent requirement of a new MEC aligns with . . . the interval specified for drivers with ITDM by the Canadian Council of Motor Transport Authority ICCMTA). H&SW agrees with the interval of annual or more frequent requirements for a new Medical Examiner’s certificate (MEC). However, we believe it is disingenuous of FMCSA to cite the Canadian CMT in one provision and not discuss the other provisions required by CCMTA for CMV drivers.

Enforceability and practicality of including Provisions from the Diabetes Exemption Program.

FMCSA stated that the requirements listed above for testing blood sugar, keeping blood sugar logs and keeping rapidly absorbable glucose within reach are not enforceable and are impractical. H&SW disagrees. It is FMCSA's safety mandate to reduce crashes, injuries, and fatalities involving large trucks and buses. Safety is the Agency's mission. Maintaining blood glucose logs, measuring the glucose level an hour before entering the driver's seat, and undergoing an eye examination for retinopathy, are a part of the Diabetes Exemption Program. The Agency enforced the Diabetes Exemption Program for many years. With the elimination of this program, it is still important to maintain the safety components for driving with ITDM.

H&SW believes it is imperative to provide safety measures for ITDM CMV drivers. We assume that the Agency's statement that ". . ." requirements that FMCSA has determined are impractical and unenforceable" (on-line Federal Register, 2015-09993, Qualifications of Drivers, Diabetes Standard, docket number FMCSA -2005-2315 page 21 of 39) refers to the economic burden and the impracticability of the training of inspectors as well as the requirements to keep blood sugar logs.

Enforcement of the Diabetes Exemption Program Provisions

To enforce the provision of blood glucose logs and testing the blood sugar level prior to getting into the driver's seat, the roadside inspector merely needs to compare the blood sugar logs with the hours of service logs. When did the driver begin to drive? When did he/she check the blood sugar level? To determine whether a driver has rapidly absorbable glucose within reach the roadside inspector merely needs to ask to see it.

Follow-up questions may be: What level of blood sugar is acceptable for beginning to operate a CMV? What constitutes rapidly absorbable glucose? Blood sugar level: H&SW believes that a level within the normal blood sugar range 80-140 mg/dL would be appropriate. If the level is below that, the driver must eat and test the blood sugar level again and record it.

However, the Agency should base the level it sets on evidence gathered by an expert panel on diabetes that specifically addresses these issues. The Agency should also convene a Medical Review Board (MRB) meeting to answer the same questions and other questions specific to this rule making such as, how frequently to test blood sugar and what to do with drivers who have insulin pumps.

Modifying the Medical Examiner Certificate to include blood sugar logs and carrying rapidly absorbable glucose

There may be another argument: How does the inspector know the driver has ITDM when he/she stops an ITDM driver? H&SW believes that the best way is to 1) modify the medical examiner certificate to include a checkbox that states the driver is physically qualified to operate "when carrying rapidly absorbable glucose and maintaining blood glucose logs or monitoring." This

follows the precedent of the check box for drivers who must “wear corrective lenses” or who must have “an SPE certificate.” Once the inspector notes the medical certificate, then he/she should ask the driver to produce the rapidly absorbable glucose and the blood sugar logs

Roadside inspector training

How does the inspector recognize what he/she sees on the logs? The FMCSA should provide a page of written instruction and training for the inspectors. To minimize the economic burden of this inspector training, the diabetes rule training should be included in the mandatory biannual training the enforcement officers have to undergo every year. Inspectors are not clinicians and should not be determining if the blood glucose level is appropriate other than to comply with the requirements in the rule. These requirements would set the blood glucose limit under which a driver should not operate, similar to those provisions in the Canadian rules.

Impracticability and economic burden

Now, the question of impracticability arises. Is the inspector training and blood glucose logs maintenance considered too economically burdensome? If so why? If these measures constitute the safest way for a CMV driver with ITDM to operate a CMV, why would an Agency responsible for bus and truck safety not consider this imperative? Inspectors have a mandated training biannually regardless of the new regulation. Would adding the diabetes rule information to the biannual training still mean including it in the rule’s economic burden?

All regulatory agencies must consider the economic burden of the rule making. However, there is a difference of opinion on what should be included in the calculations of economic burden. Some believe that anything written in the regulation must be calculated. Others state that if the provision is required by another entity then it doesn’t need to be included in the calculations of the rule’s economic burden. Having worked for the Occupational Safety and Health Administration for 13 years and having served on many rule making teams, I have seen differences in how economic burden is calculated, yet, accepted by the Office of Management and Budget.

The Treating Clinician’s role

If the Agency gives the authority to the MEs listed on the National Registry to make a decision about the driver’s physical qualification for operating a CMV, the Agency should give the ME the tools by which to gather the evidence for the decision-making. One of the tools should be documentation by the treating clinician.

H&SW disagrees with FMCSA relying solely on the treating clinician for information about the driver’s management of his/her diabetes and compliance with the insulin regimen. We believe that FMCSA should require the collection of documentation by the treating clinician as one piece of the data gathered by the Medical Examiner (ME) listed on the National Registry of Certified Medical Examiners. In addition to that documentation, the ME should be required to obtain a laboratory test to check for compliance by the driver, a Hemaglobin A1c (which gives the average blood glucose for the prior three months), or other appropriate laboratory tests, review the

driver's blood glucose logs, ensure the driver has had hypoglycemic awareness training and check the results of an annual eye examination for retinopathy.

Documentation from a treating clinician of the driver's compliance with treatment should not be the only tool or the Agency is subtly permitting the treating clinician the medical certificate decision-making even though he/she is not listed on the National Registry. The ME needs to see the blood sugar logs, needs to see the results of the eye examination for retinopathy, needs documentation from the treating clinician, needs to be able to check the blood levels for glucose to make an evidence-based decision re: whether the driver is physically qualified to operate a CMV in interstate commerce.

After all, the Agency has no authority over the treating clinician. What if all the treating clinician does is to write a one sentence stating the driver's diabetes is well-controlled? What does the ME do — base his decision on one sentence when he/she is the party authorized to make the decision which affects peoples' lives?

In addition to the argument above The ADA noted a few studies conducted in other countries that noted that many health care providers are unfamiliar with diabetes and driving issues and concerns.

In this rulemaking, FMCSA gives the ME the authority for granting the medical certificate and the responsibility but not the tools. Denying the MEs the tools to make an evidence-based decision is inappropriate.

Treating clinicians and knowledge of CMV Driving

H&SW believes that most treating clinicians do not understand the CMV driver's challenges.

Indeed many clinicians may not understand the relationship between diabetes and driving non-commercial vehicles, as noted by the ADA policy paper.

”In a recent Scottish study, only 62% of health care professionals suggested that insulin-treated drivers should test their blood glucose before driving; 13% of health care professionals thought it safe to drive with blood glucose ≥ 72 mg/dL (4 mmol/L), and 8% did not know that impaired awareness of hypoglycemia might be a contraindication to driving (5). It is important that health care professionals be knowledgeable and take the lead in discussing risk reduction for their patients at risk for hypoglycemia. In a large international study, nearly half of drivers with type 1 diabetes and three-quarters of those with type 2 diabetes had never discussed driving guidelines with their physician (8). (ADA Diabetes and Driving. Diabetes Care Volume 37, Supplement 1, January 2014, page S 98)

Although the study was international the results are startling and may be reflect the status of health care providers in the US as well. ADA publishes their Policy papers to educate their clinicians as well as the public.

If the treating clinician knows about the concerns related to diabetes and driving, he/she may think of driving in the context of an automobile. Most automobile trips are short and automobile drivers do not have the challenges faced by many CMV drivers. A few of these challenges are driving long distance across many states, being far from home and their treating clinician's erratic schedules. These are the major influences that may impact their ability to eat meals as scheduled and thus impact their insulin control. Drivers who operate motor-coaches also have additional stresses with meeting the needs of passengers. Treating clinicians who are not trained in CMV driving may be unaware of the differences between CMV and automobile driving and how those differences impact the CMV driver's ability to properly and effectively manage his/her insulin-dependent diabetes.

One of the reasons the FMCSA established the National Registry of Certified Medical Examiners (National Registry) is that few health care providers' understand CMV driving and its challenges. The National Registry regulation requires anyone who conducts a medical examination on CMV drivers to undergo training, testing and then become listed on the National Registry. To obtain a medical certificate, drivers must go to a health care provider who appears on the National Registry for their medical examination. Thus, the ME listed on the National Registry is responsible for determining the driver's fitness for duty.

The National Registry ME's authority and responsibility is undermined by FMCSA taking the decision-making out of the his/her hands and relying on someone who is unschooled and untested in CMV driver roles and responsibilities and FMCSA regulations. According to the proposal, the ME may only issue a medical certificate "if the treating clinician (TC) who is the healthcare professional responsible for prescribing insulin for the driver's diabetes, provides documentation to the ME that the condition is stable and well-controlled." The type of documentation is not prescribed. This is problematic. A treating clinician may write "driver manages his diabetes and it is well controlled." This may not be enough information for the Medical Examiner but the proposed rule does not permit further information gathering.

Studies from the past have shown that treating clinicians, because of their close relationship with their patients, will often deceive insurance companies and other authorities so their patients will not lose benefits. (Alexander, G.C., Werner, R.A., et al. for Physician Deception of Insurance Companies among a Sample of Philadelphia Residents. *Ann Intern Med.* 2003;138:472-475; Sade, R.M. (2001). *Insurance Companies: New Expression of an Ancient Tradition.* *Ann Thorac Surg* 2001;72:1449-1453; Freeman, C. V, Rathore, S.S., Weinforth, K.P. , et el. (1999). *Lying for Patients, Physician Deception of Third Party Payors.* *Arch Inter Med.* 1999;159:2263-2270). "The practice of lying to insurance companies appears to be widespread among physicians." (Sade, R.M. (2001). *Insurance Companies: New Expression of an Ancient Tradition.* *Ann Thorac Surg* 2001;72:1449-1453.) The treating clinician often faces a patient who is pleading with him/her to say the diabetes is managed appropriately and well-controlled, so the driver won't lose their livelihood.

The treating clinician may feel a responsibility to help the patient maintain his/her medical certificate and may not provide any substantive information to the ME. If clinicians are known to deceive insurance companies to obtain benefits for their patients, it is feasible they would do the same to help them maintain the CMV driver's livelihood.

It is important for road safety to have an independent objective health care provider gather additional information to make the final decision of the CMV driver's physical qualification for operating in interstate commerce.

Obtaining Insulin without a prescription

FMCSA did not address drivers who obtain insulin without a prescription. Several states permit the sale of insulin without prescription and therefore no treating clinician oversight. Insulin may also be obtained over the internet without a prescription.

This poses an additional problem for the MEs. H&SW believes that FMCSA should include language in the rule stating that anyone without a prescription or a treating clinician may not be qualified to operate a CMV in interstate commerce.

Gathering more evidence for rulemaking

To make true evidence based decisions for rulemaking, FMCSA should conduct more thorough data gathering by convening a meetings of the MRB and special Medical Expert Panel to pose issues raised here. This will ensure the regulation is truly be evidence-based and include the best and latest information for medical professionals. Relying on the 2011 and 2006 MRB information and evidence reports does not provide the best information for rulemaking, especially when the rules are in effect for many years.

Successful management of ITDM to minimize complications require extensive individual commitment, following the treating clinician's regimen of diet, exercise, rest, blood glucose monitoring and insulin administration. Safe driving requires successful management of ITDM.

Health and Safety Works appreciates the opportunity to comment on this very crucial important rulemaking. We welcome your response to our comments and concerns.