Qualification of Drivers; Diabetes Standard

Medically Significant Comments

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FMCSA-2005-23151-0127-Dusty Lewis

I think this maybe the step in the right direction, however unless ALL CME's are infact doing their jobs as demanded by the FMCSA this can in fact directly put the public at risk for safety no question about it. The initial startup of the NRCME is still relatively new. Although all CME's now are trained, certified and active on the NRCME does not necessarily mean that all these CME's are competently screening CMV Drivers using at least the federal stands and the guidelines ,let alone a physical more than 10 mins long. I do feel there are drivers , good drivers, who do have their diabetic conditions well controlled and the industry would benefit the utilization of their skills of a CMV driver. I do not feel that all CME's are whiling to do their parts in the process that it will take to safely screen monitor and certify a driver who is taking insulin in a manor that will insure the publics safety! I have very little faith in the process right that is in place monitoring CME's.Just because a licansned proffessional has completed minatory training , achieving certafication and who are maintaining registration on the NRCME ,does not mean that they are implementing and assuring that They are in fact following federal standards, guidlines(best practice) resulting in driver determination that will help fight the process of keeping the public safe from injury directly involving a CVM. So in conclusion until we have a system that assures that the CME is providing commecial motor vehicle driver fitness determination exams at the quality that the public demands for safely screening diabetics on insulin ,NO please do not at this time pass this rule there is just to much at stake here.

FMCSA-2005-23151-0138 - Philip McAndrew

I have the honor to provide Certified Medical Examinations to drivers. I have provided DOT exams for 20 years and have taught residents the intricacies of the DOT exam and evaluations of function for drivers.

I disagree whole-heartedly in the opening of DOT driving to those currently on insulin for IDDM. The proposal again and again states that the reasonable IDDM driver will want to assure that his illness will be closely followed. The current regulations assure that the IDDM driver is reasonable and safe. I perform physicals on many drivers that are NOT reasonable around their chronic disease states.

The proposal seems to state that the IDDM driver would no longer need the eye exam or the endocrinologist visit and would somehow ave money. AS a CDME I would make that a requirement each year anyway. We ask the endocrinologist to sign off as a way of assuring that the IDDM is well-controlled, compliant and the endocrinologist takes on the responsibility that this remains the case not just once a year but throughout the year.

Why would you improve the DOT physicals by training, educating, testing and certifying us and then take a step back by tying our hands behind our backs with loosening the regulations on IDDM drivers?

Bad Move.

Sincerely,,

Philip E. McAndrew, MD
Occupational Medicine Specialist
Assistant Professor Family Medicine
Loyola University Medical Center

FMCSA-2005-23151-0145-Anonymous

I am currently a Safety Manager & 19-A C.E. for a Paratransit Company in Brooklyn, NY & have a full understanding of the necessity unto which individuals with diabetes that take insulin should not have issued a FMSCA DOT Medical on form 649-F. However, if the rule is going to change, they should make it a mandatory 3 month renewal with no exceptions. Too many doctors commit malfeasance to allow any grey area or extended period of time.

FMCSA-2005-23151-0149-Joseph Mignogna, MD

I am a medical doctor board certified in occupational medicine, family medicine, and emergency medicine, with 35 years of clinical practice and medical management experience involving both regulated and non-regulated environments. I can speak from both sides of the fence, having practiced in both a private setting providing primary care and more recently solely dedicated to occupational medicine supporting employers and their employees. My comments are in response to Proposed Rule docket number FMCSA-2005-23151, Qualification of Drivers; Diabetes Standard, regarding the medical certification of commercial drivers with insulin-treated diabetes and reliance by the commercial driver medical examiner (CDME) on the drivers personal healthcare provider managing the drivers diabetes. I am opposed to this practice. Occupational medicine professionals (including medical doctors [doctor of medicine or doctor of osteopathy], physician assistants, and nurse practitioners) are trained and experienced in supporting our nations workforce and public safety. We are charged with complying with federal regulations and following published guidelines in the context of best medical practices, professional ethics, and sound clinical judgement. The science of medicine dictates a mindset and methodology based on validated objective evidence. Using clinical judgment, the art of medicine requires the ability to incorporate the science with a variety of additional resources and best medical practices, and in this case make an informed medical decision to determine if the drivers condition is in fact stable and well-controlled. When evaluating a commercial driver with insulin-treated diabetes, one cannot solely rely on limited or potentially biased clinical opinions from medical providers, regardless of the quality of the care being provided, if those providers are not astutely aware of their patients unique and challenging demands of commercial driving. Acting in a private patients best interest, diabetic or otherwise, may not objectively account for all the critical factors affecting the drivers risk to themselves or to the public and may in fact be a potential for an unintended conflict of interest. The opinion and perspective of a drivers personal healthcare provider is but one critical factor that should be considered when determining a diabetic commercial drivers medical fitness, and must be taken in context by the CDME using additional objective validated data, published medical guidance, and unbiased sound clinical judgment. The current FMCSA insulin exemption program effectively and objectively addresses the insulin-treated commercial drivers ability to safely operate a commercial motor vehicle

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June 5, 2015

Docket Services (M-30)

U.S. Department of Transportation

West Building Ground Floor

Room W12-140

1200 New Jersey Avenue SE

Washington, DC 20590-0001

Attention: Records Officer

Subject: Docket No. FMCSA – 2005-23151

49 CFR Part 391

RIN 2126-AA95

Proposed Rule Change: Qualifications of Drivers; Diabetes Standard

To Whom it May Concern:

My name is Tanisha K. Taylor, MD, MPH, and I am a certified Medical Review Officer and a certified Commercial Driver Medical Examiner, an ACOEM member and secretary of the Transportation Section of ACOEM.

My comment focuses specifically on the proposed rule change found in the Executive Summary I. A. where FMCSA proposed to allow individuals with well-controlled Insulin-Treated Diabetes Mellitus to drive commercial motor vehicles in interstate commerce if they are examined at least annually by a Medical Examiner who is listed in the National Registry of Certified Medical Examiners.

I do not support this proposed change in any form or any deviation from the current driver's exemption program that we are presently using for ITDM.

Insulin dependent diabetes is a very significant medical problem and requires intense management and control. As an Internist and a specialist in the field of Occupational Medicine, I would require that my diabetics consult with an Endocrinologist at least annually for management of their diabetes as well as consult with Cardiology, Ophthalmology and Podiatry annually to help manage the potential complications of the disease. This is the standard of care for managing diabetics.

The determination of a diabetic driver's condition and determination of their status as a "well-controlled diabetic" is not a simple matter. For these reasons I feel that the current exemption program is the safest approach and the correct way to continue.

The FMCSA has already moved in reverse by now permitting the latest medical evaluation by a certified medical examiner to take precedence over a prior failure, even if the latest evaluation was done by an examiner that is less qualified medically. The National Registry of Certified Medical Examiners was intended to prevent "doctor shopping" which could now be encouraged with this situation.

FMCSA asks certified medical examiners to use their best medical judgement yet they have pulled the handbook from the website leaving many practitioners with no guidance. Now they wish to shorten the clearance process for insulin dependent diabetics which is extremely risky.

Medical examiners should ask themselves the question when certifying: "Would I feel safe with this examine driving an eighteen wheeler on our nation's highways?". If you can say yes to this question then certify.

I also have concerns that the results of this proposed ruling could influence future rulings on waivers such as regarding seizures.

Thank you for the opportunity to comment on this proposed ruling.

Tanisha K. Taylor, MD, MPH, MRO, FACP, FACOEM

MD, MPH, MRO, FACP, FACOEM

Senior Medical Director

Barnabas Health Corporate Care

Monmouth Medical Center – Southern Campus

Barnabas Health

FMCSA-2005-23151-0457-Ronald Musto

I have read the proposed revisions to the rule regarding medical qualifications of drivers with insulin treated diabetes mellitus. The rule would require the person with diabetes mellitus currently requiring insulin for control to have an evaluation by his or her TC who would determine that the driver had not experienced a recent severe hypoglycemic reaction and was properly managing the disease. The rule requires that the examinee maintain his or her blood glucose records per the guidance of the TC for the period of certification and submit those records to the TC at the time of the evaluation. The certified medical examiner ME must obtain and review written notification from the TC that the person is properly managing the diabetes mellitus.

The certified medical examiner should not be required by statute to obtain the examinees medical records, but only to review them. Obtaining the records requires that the examinee provide the ME with a HIPAA compliant release of information to forward to the TC who may take days or longer to act upon it. The examinee should be responsible for providing the ME with the necessary statement from the TC as well as any other medical documentation that the ME requires.

The ME should not be required to accept at face value a blanket statement from the TC that the examinees diabetes is stable and well controlled. This statement by a TC should be necessary but not sufficient for the ME to certify a driver with ITDM who is otherwise medically qualified. Examinations by treating clinicians may vary widely with regard to the criteria by which they form an opinion regarding whether diabetes is well controlled or whether reactions were severe.

It is the Medical Examiner, not the Treating Clinician, who has the statutory responsibility to medically qualify the driver with ITDM. MEs are not able to substitute the judgment of a Treating Clinician by relying solely upon a broadly worded statement that a driver with ITDM has stable, well controlled diabetes. MEs should have at least the same information as does the Treating Clinician in order to form their own opinion with regard to a drivers medical qualification.

Sincerely,

Ronald V. Musto MD, MPH, MBA, CIME

FMCSA-2005-23151-0498-Anonymous

As a RN, CDE, I would urge you to, please, consider allowing people who self administer insulin to drive trucks. However, I think that they should be subject to every three month A1C level (a lab test that tests the average Blood Glucose over a three month period) tests; just as airline pilots have to pass certain aspects of a physical. They should be required to have a primary care physician and be able to provide documentation that they are followed by a Primary Care Physician. They should be required to provide documentation that they have attended an ADA, American Diabetes Association certified Comprehensive Diabetes Self Management series of classes, and an ADA class on Insulin. They should be held accountable, if asked, to present a log of all of their BG levels. They should be required to present, if asked, that they are checking their Blood Glucose levels before each meal or at least every 5 to 5 1/2 hours when driving on the road.

Thank you.

FMCSA-2005-23151-0517-Jeff Unger

Although this is a very important step to allow patients with T1DM to operate commercial vehicles, I am concerned about several aspects of the rule change. First, how is "well-controlled" diabetes defined? Is this based on A1C, frequency of hypoglycemia, incidence of severe hypoglycemia, use of an insulin pump and sensor, glycemic or A1C variability? Secondly, I feel that patients should be evaluated for safety not by an endocrinologist but by a diabetologist. Not all endos manage patients with diabetes intensively whereas diabetologists are better equipped to determine whether or not a patient with type 1 diabetes might be a low-risk driver. In addition, diabetologists receive their board certification from other specialties besides endocrinology including primary care and family medicine.

Finally, to ensure safety for the other drivers on the road, I feel that patients who have had T1DM for over 5 years should use continuous glucose sensors to minimize their risk of driving while hypoglycemic.

FMCSA-2005-23151-0558 - WorkNet Occupational Medicine

I am an Adult Acute Care CRNP who is part of a midlevel and physical occupational medicine group. We do numerous DOT physicals. At our June 2015 staff meeting proposed changes to FMCSA regulations were discussed, including changing the diabetes extension process. It is my understanding that this would entail eliminating the medical review board portion and placing the decision solely on the certifying provider and the patients primary care provider. While this would potentially expedite the process and reduce workload for FMCSA it would be extremely detrimental to safety of drivers to use insulin to treat diabetes. This process was put in place because diabetes is a complex disease which requires multiple levels of assessment, more medications to treat, and has impairing symptoms. As correctly pointed out in FM CSA regulations and examiner guidance there is a regimen of insulin injection and the possibility for rapid or immediate incapacitation. As diabetes also affects the internal organs including the eyes specialty examination and evaluation will always be necessary. That is why ophthalmology was originally included in the process. Primary care offices and occupational medicine facilities are extremely unlikely to have a slit lamp or other complicated specialized optometric testing equipment that is necessary to fully assess the effects of diabetes on the eyes. In addition primary care providers are not endocrinologists and neither are we. Endocrinology is necessary to help manage diabetes as type I DM is a complex disease with multiple facets. Removing endocrinology from the process significantly limits objective, specialized medical assessment of this complex disease. Lastly, primary care providers are in our experience a very lenient or in some cases lax and readily agree that someone is okay to drive due to fear of loss business or unwillingness to engage in some type of perceived hostile or confrontational action with a CDL driver. Primary care providers and others who are involved in the physical process now also must be concerned about having a bad reputation as there is a website specifically listing examiners and allowing drivers to rate or comment on them. All in all it would be detrimental to drive or safety to change the current process of finding CDL drivers with type I DM. The result in some cases would be individuals on the road who are not safe to be on the road due to a variety of examiner problems including the unwillingness of some examiners to fully examine problems, inability to order diagnostic tests for a non-work related medical issue (the CDL examiner is often an occupational medicine facility and has no business relationship with the drivers primary insurance), and inability to perform the necessary complex ophthalmologic testing due to lack of equipment. In many cases there are simply not enough CDL drivers with type I DM for an occupational medicine practice to be able to justify spending over $4000 per unit for a slit lamp, and even if familiar with its operation would not be familiar with the operation or use of more complex extremely expensive equipment for perimetry. The other result would be that because of the inability to perform certain tests or fully interpret them in conjunction with the assistance of specialists such as ophthalmologists and endocrinologists-as currently required-more drivers with type I DM would be excluded from commercial driving as the CDL examiner would not have sufficient information, time, or backup to certify someone within the bounds of reasonable medical liability.

National Transportation Safety Board
Washington, DC 20594

Office of the Chairman

June 26, 2015

US Department of Transportation
Docket Management Facility (M–30)
West Building, Ground Floor, Room W12–140
1200 New Jersey Avenue, SE
Washington, DC 20590-0001

Attention: Docket No. FMCSA-2005-23151

Dear Sir or Madam:

The National Transportation Safety Board (NTSB) has reviewed the Federal Motor Carrier Safety Administration's (FMCSA) notice of proposed rulemaking (NPRM) and request for public comments titled "Qualifications of Drivers; Diabetes Standard," published at 80 *Federal Register* 25260 on May 4, 2015. The request solicits comments on a proposed FMCSA rule change to permit drivers with stable, well-controlled, insulin-treated diabetes mellitus (ITDM) to be qualified to operate commercial motor vehicles (CMV) in interstate commerce. The NTSB has considered the proposed waiver requirements and provides the following comments.

The NTSB agrees that the current waiver review process is burdensome to both the ITDM CMV driver and the FMCSA. Currently, the process requires that the ITDM CMV driver submit a formal exemption request to the FMCSA, which must include information from a treating endocrinologist and other subspecialists. In addition, the process requires that the FMCSA post personal medical information in the *Federal Register* for each potential waiver applicant. With more than 800 waiver requests for ITDM in a recent year, the NTSB agrees that this process is not sustainable. However, the NTSB is concerned that the proposed changes to the medical certification of CMV drivers with ITDM will significantly degrade the current level of highway safety.

The NTSB is concerned that the justification to support the rule change is flawed. The justification states that "CMV drivers with diabetes whose condition is stable and well-controlled do not pose an unreasonable risk to their health or to public safety," as stated in the NPRM. This statement is primarily based on an American Diabetes Association (ADA) report assessing the safety risks of non-commercial diabetic drivers, including those who do not require medications and those treated with medications other than insulin.[1] However, as the FMCSA acknowledged, the ADA report does not address the risks to public safety of CMV drivers with ITDM. Although a driver's risk of becoming acutely impaired or incapacitated from stable, well-controlled ITDM may not be higher among CMV drivers, the potential consequences of such an event are

[1] ADA, ''Diabetes and Driving,'' *Diabetes Care*, vol. 35, supplement 1, January 2012.

significantly greater. Just one acute medical event related to ITDM in the driver of a motor coach carrying dozens of passengers or the driver of a tractor-trailer carrying hazardous materials could result in catastrophic consequences for the public. Thus, CMV drivers with ITDM pose risks to public safety far beyond those of non-commercial drivers with the same condition. Therefore, the NTSB believes that the FMCSA has not provided adequate justification that CMV drivers with ITDM do not pose an unreasonable risk to public safety. Additionally, the NTSB is concerned that, contrary to the FMCSA's medical review board (MRB) recommendations, the FMCSA is not proposing to prohibit drivers with ITDM from being medically qualified to operate CMVs carrying passengers and hazardous materials.

The NTSB is also concerned that the proposed FMCSA rules do not include specific criteria for certification of ITDM drivers. The proposed rule would essentially delegate the decision about medical certification of these CMV drivers to their treating clinician (TC). The training and experience of TCs may vary widely – from Board Certified, subspecialty-trained endocrinologists specializing in diabetes care to general practice physicians without specialty certification. Partly as a result, TCs may differ widely in their interpretation of what constitutes "proper management" of ITDM. In addition, it is unlikely that many TCs will have had any training regarding the operational environment and additional public safety risks associated with commercial driving. TCs should be appropriately focused on the well-being of their specific patients; for a TC, the need to advocate for an individual may eclipse public safety concerns. Although medical examiners (ME) have been certified to understand the operational and safety concerns of commercial driving, many do not have experience treating ITDM and may have limited knowledge of what "proper management" should include or what additional risks may be posed by various treatments.

In addition to acute risks posed by incapacitation from hypoglycemia, hyperglycemia from inadequate diabetes management may cause subtle cognitive deficits and degrade visual acuity, also increasing the risk of a crash involving a CMV driver. Further, ITDM patients may develop long-term complications, including kidney disease, retinopathy, neuropathy, cardiovascular disease, and peripheral vascular disease. The NTSB is concerned that the NPRM requires only that the TC determine that a driver has had no "severe hypoglycemic episodes" and that the diabetes is "properly managed," rather than providing clinical information to demonstrate that the driver meets specified criteria. Such criteria might include defining acceptable ranges for hemoglobin A1C (measures glucose control over previous 6 weeks), glucose, and creatinine (measure of kidney function) measurements, as well as requiring a report regarding the presence or absence of hyperglycemic episodes and any diabetic complications in addition to hypoglycemic episodes. Many of these ITDM complications cannot be identified by a routine physical exam.

The NTSB is also concerned that the NPRM does not provide MEs with any criteria to assess the adequacy of ITDM management. The NTSB notes that the FMCSA allows healthcare providers who are not licensed to prescribe medication to medically certify CMV drivers. These healthcare providers have no experience prescribing medications, including insulin, and therefore no experience managing the effects of insulin or other diabetic medications. Without adequate training, experience, or any criteria provided by the FMCSA, these MEs will simply have to accept a TC's assurance of "proper management" without further evaluation. As mentioned above, a TC's interpretation of that term as well as the driver's compliance with

recommendations may vary considerably. The NTSB suggests that the FMCSA consider emulating the best practices of the Federal Aviation Administration and the United States Coast Guard, which require operators with ITDM to be evaluated using published/scientifically based standards.[2]

Finally, the NTSB is concerned that the NPRM proposes to do away with the review of annual ophthalmological evaluations and rely on evaluating vision health in drivers with ITDM solely based on a test of visual acuity and an ME eye exam. Because of the risk of diabetic retinopathy, a condition that can cause loss of areas of vision without affecting acuity, a dilated retinal eye exam is an annual standard of care for most ITDM patients.[3] The NTSB believes that the FMCSA should require a copy of this routine evaluation and develop criteria for defining acceptable findings for CMV drivers with ITDM. The NTSB further believes that eliminating the requirement for an annual ophthalmological examination will increase the likelihood of ITDM CMV drivers with significant diabetic retinopathy and degraded visual performance that will pose a hazard to public safety.

The NTSB appreciates the opportunity to comment on this notice.

Sincerely,

[2] Guide for Aviation Medical Examiners, Decision Considerations Disease Protocols - Diabetes Mellitus Type I and Type II - Insulin Treated https://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/dec_cons/disease_prot/diabetes_insulin/ US Coast Guard Navigation And Vessel Inspection Circular NO. 04-08, CH-1 Enclosure 3: Medical Conditions Subject To Further Review, June 7, 2013.

[3] National Committee for Quality Assurance (NCQA) Managing Diabetes Complications Quality Profiles http://www.ncqa.org/PublicationsProducts/OtherProducts/QualityProfiles/FocusonDiabetes/ManagingDiabetesComplications.aspx. Accessed May 8, 2015.

FMCSA-2005-23151-0709-Douglas M. Wendland, MD, MPH

49 CFR Part 391

Qualifications of Drivers; Diabetes Standard

I am a certified examiner for FMCSA medical certification. I am also residency trained in family medicine; and trained and board certified in occupational medicine. I have had over 20 years of experience providing diabetic care and performing FMCSA medical certification evaluations. I agree that a "driver with stable, well-controlled insulin-treated diabetes mellitus (ITDM)" may be qualified to safely operate a commercial motor vehicle in interstate commerce. I also believe that there is general consensus that drivers with stable, well controlled ITDM who are without significant disease complications should qualify to operate a commercial vehicle in interstate commerce. I believe that the current insulin exemption program adequately protects public safety. I question some of the assumptions made in the proposed rule change.

First, there is the assumption that commercial drivers are motivated primarily by minimizing their health risks. Many of the drivers that I evaluate do not go beyond the minimum demands that I place on them to control and monitor their various chronic medical conditions. Without the motivation to get their DOT medical certificate I am certain that many drivers would not adhere to medical recommendations for treatment and follow-up of hypertension, diabetes mellitus, coronary artery disease and many other chronic conditions.

Second, is the assumption that treating providers have knowledge of the demands placed on a commercial driver and can balance the needs of their patient with the needs of public safety. When I was in medical school and primary care training I don't recall any training directed at linking medical conditions with occupational function. I suspect that this has not changed much and I don't see in the proposal any evidence that treating providers as a group are better qualified than certified examiners to make this decision. I also understand the conflict between the treating provider role as patient advocate and the public good; and the pressure that drivers may put on the treating provider to "not take away my job". Yet, it appears that as an examiner I am expected to adhere to the recommendation of the treating provider. This is unique when considering all of the medical conditions that may affect driving. I thought that a large part of the reason for expending resources on training and certifying examiners was to improve the system by raising the knowledge base relative to the relationship of medical conditions to the safe operation of commercial motor vehicles and the obligation to consider public safety in certification decisions. Why have certified examiners if for drivers with ITDM we simply defer to the treating provider.

I agree that ending the insulin exemption program would be more time efficient and save the FMCSA money. If as an examiner I am to take on the function and responsibilities of the exemption program I will continue to expect at least annual assessment and input from an ophthalmologist and endocrinologist. To compensate for the increased time and risk involved in certifying ITDM drivers I will be making adjustments to my charges. Overall, I expect that the cost savings to the FMCSA will be transferred to the drivers and examiners and not be a real savings. If, as an examiner, I will not be permitted to demand anything from the driver other than a statement from the treating provider I will no longer agree to provide certification evaluations for ITDM drivers.

I would agree to the ending of the insulin exemption program as long as it is clear that examiners can request whatever medical information is necessary to make a sound certification decision and that drivers understand that the increased cost and responsibility placed on the examiner will likely be reflected in higher charges for the DOT certification evaluations.

Sincerely,

Douglas M. Wendland, MD, MPH

Medical Director

St. Luke's Occupational Medicine

Duluth, Minnesota

AAPA-OM
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FMCSA-2005-23151-0778-American_Academy_of_Physician_Assistants_in_Occupational_Medicine

July 1, 2015

Docket Services (M-30)
U.S. Department of Transportation
West Building Ground Floor
Room W12-140
1200 New Jersey Avenue, S.E.
Washington, D.C. 20590-0001

RE: Docket No. FMCSA-2005-23151

On behalf of the more than 2,000 nationally certified physician assistants (PAs) represented by the American Academy of Physician Assistants in Occupational Medicine (AAPA-OM), I wish to thank the Federal Motor Carrier Safety Administration, U.S. Department of Transportation (FMCSA/DOT) for the opportunity to submit comments on the proposed rule to permit drivers with stable, well-controlled insulin-treated diabetes mellitus (ITDM) to be qualified to operate commercial motor vehicles in interstate commerce. Although the AAPA-OM does not have a policy on the proposal to replace the current FMCSA commercial driver medical certification for drivers with controlled ITDM with an annual certification, AAPA-OM does support the proposed rule's affirmation of the role of all National Registered Commercial Medical Examiners (NRCME) in the medical evaluation of all Commercial Drivers (CD), specifically the physician assistant.

AAPA-OM has always believed and supported the idea that healthcare professionals other than physicians, specifically Physician Assistants, (PAs), can provide quality medical care, prescribing insulin for all patients including drivers with ITDM. We strongly recommend that PAs should be listed as providers who can manage the driver's condition through the use of the term, Treating Clinician (TC).

AAPA-OM strongly believes that there should be direct contact with the TC and the NRCME before the CD is certified to hold an unlimited Medical Examiners Card even for a year.

AAPA-OM agrees with some of the guidelines recommended by the American Diabetes Association (ADA) paper, but disagrees that the only providers that should be able to perform these reviews should be physicians or diabetic specialists. PAs have been treating complicated medical patients for over 40 years and should be allowed to continue the examinations and reviews of CD with ITDM. PAs are trained in primary care and are boarded every ten years in primary care.

In reviewing what was placed on the Federal Register for the proposed rulemaking dated 5-4-215 states:

> ***"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."***

This does not say that they need to be physicians or diabetic specialists, just healthcare professionals who are responsible for prescribing insulin for their patients including drivers with that require insulin to control their diabetes. It is for this reason that AAPA-OM feels strongly that PAs should be considered providers who can review their patients for stability and also NRCME providers who can approve a CD.

AAPA-OM believes that for an ITDM, the CD must comply with the following:

All CD to be certified need to have records that proves that the CD has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years.

CD must have been on insulin for at least 2 years prior to this certification.

Also for new certification a 6 month card should be issued and if stable a recertification card will be good for one year.

AAPA-OM also wholeheartedly supports the FMCSA decision to not recommend past proposals offered by the FMSCA Medical Review Board to restrict exemptions for a commercial driver with ITDM to a physician or endocrinologist.

As AAPA has stated, the AAPA-OM also believes that physician assistants, by virtue of their medical educational process, ongoing certification of competency, well-established scope and quality of practice, and team-based practice model, are qualified to examine and certify by their signature any commercial driver. The NRCME does not need to be an endocrinologist, a sleep specialist, orthopedist, or neurologist to perform an appropriate CD examination – rather, the NRCME needs to understand what medical information is needed and how it relates to commercial driver's safety and health risks. An integral part of the CD medical examination process, particularly for drivers with multiple medical

problems, is for the NRCME to obtain medical records, consultations, and recommendations from attending medical providers and specialists according to the circumstances of the case. PAs routinely request and assimilate such records and consultations into medical decision-making for patients they treat. Since PAs are capable of routinely performing this medical function in treating patients, PAs are also capable of performing this function for CD medical certifications.

AAPA-OM also believes that in *Section 391.46 (b)(1)* with the proposed rule's use of the term, "treating clinician," acknowledging that the healthcare professional who is responsible for managing the driver's ITDM may NOT be a clinician other than a physician. AAPA and AAAP-OM recommends that the definition of TC be more clearly stated through the following definition, "For purposes of this paragraph, 'treating clinician' means a physician, physician assistant, or nurse practitioner who manages and prescribes insulin for the treatment of individuals with diabetes mellitus."

Physicians, PAs, and nurse practitioners (NPs) represent the three healthcare professionals in the U.S. who provide primary medical care. All three healthcare professionals diagnose illness, develop and manage treatment plans for their patients, manage patient panels, and serve as patients' principal healthcare professional.

In rural and other medically-underserved communities, a PA may be the only healthcare professional in the community. Chronic care management, including management of diabetes, is a key component of a typical PA's practice. AAPA's 2013 Annual Survey revealed that 64% of PAs provide chronic disease management – and most of these PAs see patients with multiple chronic conditions. Furthermore, PAs provide an important access point in medically underserved areas of the nation.

Just as AAPA utilizes best practices established by the American Diabetes Association (ADA) in its continuing medical education offered to PAs, AAPA believes that the FMCSA should make available to NRCME ADA guidelines for the management of diabetes mellitus. AAPA applauds the FMCSA rule's embrace of all NRCME in determining whether the driver may receive the medical certificate, in consultation with the driver's TC. AAPA recommends that the rule's definition of TC be clarified to state that a physician, PA, or NP who manages and prescribes insulin for the treatment of individuals with diabetes mellitus may serve as the TC.

AAPA-OM appreciates the FMCSA's continued outreach to the AAPA-OM throughout the development of the National Registry of Certified Medical Examiners (NRCME) and for its attention to AAPA-OM's comments. AAPA-OM looks forward to a continued partnership with the FMCSA throughout the continued implementation of the NRCME that best serves the needs of interstate commercial carriers, drivers, and the public's safety. Should you have any questions regarding the PA profession or the Academy's

comments, please do not hesitate to contact Regina White, PA-C, President of AAPA-OM, at regleepac@yahoo.com.

Sincerely,

Regina White, PA-C

Regina White, PA-C
President AAPA-OM

FMCSA-2005-23151-0780-Concentra

Concentra
treated right

2015 JUL -6 A 11:56

July 2, 2015

TO: U.S. Department of Transportation
Federal Motor Carrier Safety Administration
Fax: 202-493-2251

FROM: Ellison Wittels, MD; FACP
10909 East Freeway
Houston, Texas 77029
ellison.wittels@concentra.com

RE: Qualifications of Drivers; Diabetes Standard
A Proposed Rule by the Federal Motor Carrier Safety Administration on 05/04/2015
Docket number FMCSA-2005-23151

Ending the current diabetes exemption program for insulin treated CMV drivers is an excellent idea. Previous experience has shown that proper evaluation and monitoring allows ITDM drivers to be certified without sacrificing public safety or their health. With an increasing number of adult onset diabetics needing insulin treatment, FMCSA needs to develop a pathway for certification that does not require the current exemption program. The prolonged period between applying for and receiving an exemption will increase with increasing demand for insulin exemptions.

The proposed rule does not incorporate current medical recommendations. While guidelines are no longer emphasized, an examiner needs boundaries by which to decide certification. The safety risks from acute hypoglycemia and long term microvascular and macrovascular disease are too great for medical requirements for certification not to be defined.

Examples of areas for discussion include time on insulin before becoming eligible to drive a CMV, criteria for severe hypoglycemia, re-certification criteria after severe hypoglycemia, criteria for monitoring blood sugar and required supplies to prevent hypoglycemia while driving, and vison and vascular disease monitoring . Also, blood sugar requirements need to be provided to promote consistency among examiners.

If FMCSA is to achieve the best medical program for insulin taking CMV drivers, the criteria need to be reviewed with leading endocrinologists who specialize in diabetes.

Thank you.

FMCSA-2005-23151-0798-Truckers for A Cause

Comments NRPM Insulin Treated Diabetes

These comments are submitted on behalf of Truckers for A Cause which is a patient support group for drivers with sleep apnea. Many of our members also deal with managing diabetes.

GENERAL: These comments are in support of removing the current ITDM waiver program as we agree with the position that it is overly cumbersome and is not warranted given the improvements in treatment options available. We feel that the proposed rule does go too far in removing requirements and a compromise group of requirements would be appropriate.

We understand FMCSA's reluctance to make very specific requirements in medical requirements as the science of treatment options changes. Yet, there is a need to specificity in medical requirements to ensure there is consistency in how individual medical examiners handle situations. The recent issues with sleep apnea and the need for FMCSA to issue the Bulletin to Medical Examiners on sleep apnea would be an example of this kind of problem.

Unless FMCSA issues clear and precise requirements the medical examiner community, medical examiner employer groups, individual medical examiners, and litigator will establish normal practice parameters rather than FMCSA through a rulemaking process that allows input from all stakeholders, has a proper regulatory balance of requirements, and reviews cost effectiveness.

The lack of specificity in the sleep apnea bulletin is something than can be corrected on ITDM management.

BENEFITS AND COSTS: An area of cost savings FMCSA has failed to address in its economic impact is cost savings to the existing driver population currently under treatment for Type II diabetes.

Under the current waiver program, the preservation of pancreatic function is of greater concern than in a regular non-CMVdriver patient. If pancreatic function is lost a CMV driver patient would have to go on insulin resulting in the probable loss of career and insurance coverage. For treating clinicians the choice of drugs used then mandates ones that preserve pancreatic function over cost.

An example of this is the use of Victoza over less expensive Sulfonylureas. Victoza costs $ 397 per month. It is not available as a generic. As there are less expensive generic alternatives insurance will only cover 50% of the costs. Sulfonylureas are available as generic equivalents and cost $ 4 per month.

Removing the requirement for ITDM waivers will allow medical professionals treating drivers with Type II diabetes to better treat these patients in a cost effective manner where preservation of pancreatic function to avoid insulin at all costs is not a major treatment issue.

TREATING CLINICIAN: We agree with FMCSA's position that requiring quarterly reports or an annual exam by a board-certified endocrinologist places an undue burden on driver due to the lack of these specialists nationwide.

We disagree that '"treating clinician" means a physician or health care professional who manages and prescribes insulin for the treatment of individuals with diabetes mellitus' is sufficient specificity and requires enough medical training and certification to properly evaluate a CMV operator with ITDM.

We propose that “treating clinician” be modified to an MD, DO, Nurse Practitioner, or Physicians Assistant who manages and prescribes insulin for the treatment of individuals with diabetes mellitus who has completed appropriate additional training and experience to hold a certification in Advanced Diabetes Care and Management.

We feel that this strikes a reasonable compromise between little or no specific medical qualifications in the care and treatment of diabetes needed and the overly cumbersome board certified endocrinologist requirements in the current waiver program.

We feel that this additional medical certification and training requirement is appropriate given that not all medical examiners under the NRCME have similar levels of base medical certification and training. Examiners who are Doctors of Chiropractic will not have the medical expertise to evaluate the information from a TC on a condition they are not licensed to treat in their normal practice. In fact in some states (Illinois for example) a DC even rendering an expert medical opinion on a driver meeting diabetes treatment requirement would be a violation of Illinois State law in the DC scope of practice statute.((225 ILCS 60/) Medical Practice Act of 1987.)

If the medical certification requirements of a TC as suggested are not adopted, we suggest FMCSA require ITDM drivers to get their Medical Certificates from an NRCME examiner who is an MD, DO, NP or PA. That driver not be allowed to seek certificates from DC’s when under treatment for ITDM. We feel strongly that the lack of base medical knowledge or certification of DC’s does not provide sufficient medical expertise to properly evaluate some complicated medical conditions such as ITDM.

391.46

Current proposal reads. “(ii) The medical examiner must obtain written notification from the person's treating clinician that the person's diabetes is being properly managed and must evaluate whether the person is physically qualified to operate a commercial motor vehicle.”

This does not contain enough specificity for the medical examiner to make a reasonable determination. The medical examiner is still required to certify “free of complications…” while the written notification gives the medical examiner no information about how the treating clinician made their determination. It also does not allow for the medical examiner to ask for additional tests or test results to confirm the assertion by the treating clinician on being physically qualified to operate a commercial motor vehicle.

The proposed rule also does not address the issue found in creation of the NRCME program that treating clinicians are often reluctant to not certify their patients even when they should not be certified.

We suggest that a form or statement to be completed and signed by the treating be developed. The form should require that the treating clinician acknowledge:

- They are familiar with the appropriate sections of 49 CFR regarding driver qualifications.
- They are familiar with the physical demands and duties of a CMV operator.
- They outline the methods of treatment used
- Provide test results of an A1C done within 30 days of the certification. We disagree with other commenters on not requiring this test result be used. Due to the need to evaluate long term control this test provides the best information available on long term control and cannot be falsified as a daily BG log can.
- Either provide a copy of BG logs or a statement summarizing the review of the logs by the TC.

- Provide contact information for the treating clinician to allow the medical examiner to verify the validity of the certification. A notarized signature of the TC is overly burdensome. Requiring a contact phone number to allow the medical examiner to call to verify is adequate. This standard of verification has been used for roadside enforcement to verify medical certificates.
- Include a statement that the TC in their expert medical opinion concludes that the driver patient meets the regulatory requirements regarding their diabetes management and should be certified.

Medical examiners have voiced concerns that the proposed rule puts them in an inappropriate situation of being asked render an expert medical opinion and certifiy a driver is "safe" while not giving them information to base this decision on.

We propose that the statement required from the TC make it clear in the area of diabetes management it is the TC who is rendering the expert medical opinion that the driver is "safe" therefore relieving the medical examiner from concerns about potential liability.

DIABETES SELF MANAGEMENT EDUCATION: We agree with comments submitted by the American Diabetes Association that education on self-management of diabetes is an important component of proper care. We feel that a requirement for completion of a minimum of 3 contact hours of education on diabetes self-management and care delivered by a Certified Diabetic Educator or other appropriately trained and certified health care professional should be a requirement. This education must be completed prior to certification by a medical examiner at the first exam performed after beginning insulin treatment.

Further we feel that one contact hour of refresher education should be required every 2 years.

Medical examiners should be given authority to issue one (and only one) 90 day conditional certification pending completion of the education required.

ANNUAL EXAM BY EYE SPECIALIST: The proposed rule removes annual eye exam requirements. We disagree with this proposal.

There are several complications affecting vision such as cataracts and diabetic retinopathy that would severely impact a driver's ability to safely operate a CMV especially at night. The current NRCME vision testing requirements for in office vision testing during a DOT medical exam would not pick up on vision problems of this type. The risk of these undetected vision issues with ITDM drivers is large enough to warrant requiring vision exams by a qualified eye specialist.

We suggest that a vision exam by a qualified eye specialist be required when first going on insulin treatment and every 2 years thereafter. We also suggest that medical examiners be given authority to issue one (and only one) 90 day conditional certification pending completion of the eye exam. We further suggest that the qualified eye specialist complete a form similar to that of the TC for insulin treatment acknowledging familiarity with the requirements of 49 CFR and the physical demands of a CMV operator.

REQUIREMENT TO CARRY FAST ACTING GLOCUSE: Other commenters have suggested that the requirement in the current waiver program to require drivers to carry fast acting glucose be retained. This is a requirement we feel would be overly burdensome and not improve safety.

Before this type of requirement be included FMCSA should at least undertake research on any incidents where fast acting glucose was needed in any drivers currently under the ITDM waiver program or that at any time have applied for a waiver.

A major problem with doing this type of research would be that no driver with a waiver or seeking a waiver would willingly admit to a hypoglycemic episode. Efforts to have the research done by an entity with a reputation for protecting driver's privacy rights would be needed.

The Owners Operator Independent Drivers Association (OOIDA) Research Foundation (Contact Thomas Weakley) would be a group able to get reasonably accurate responses from drivers. If not The University of Alabama School Of Nursing (Contact Dr. Karen Heaton) has a reputation from previous research collecting data from drivers. Dr. Heaton is an NRCME certified examiner and the UAB is a training organization for the NRCME program. If Dr. Heaton is not available she has many PhD and MS students needing dissertation topics she might be able to suggest.

NOTING ITDM ON MEDICAL CERTIFICATE – ROADSIDE ENFORCEMENT TO CHECK LOGS AND GLUCOSE:
Commenters have also suggested that the driver's medical certificate be amended to note ITDM just as corrective lenses and SPE are currently noted. These same commenters suggest that the BG logging and fast acting glucose requirements of the current exemption program be retained. They suggest that roadside enforcement check if the driver has BG logs and fast acting glucose as part of random roadside inspections.

We strongly oppose any requirements or rule changes that potentially involve making information on a driver's ITDM status available to roadside enforcement.

There is an unfortunate history with roadside enforcement becoming involved with asking medically related questions during roadside inspections in the State of Minnesota's Fatigue Enforcement program. This program was litigated under OOIDA V STATE OF MINNESOTA.

We thank you for this opportunity to comment and hope FMCSA can strike an appropriate balance in this rulemaking.

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,

[1] American Diabetes Association: Standards of Medical Care in Diabetes 2015, *Diabetes Care* 38: Supp. 1 (2015).
[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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[3] Qualifications of Drivers; Diabetes Standard, 71 Fed. Reg. 13801 (proposed March 17, 2006) (to be codified at 49 C.F.R. pt. 391).

[4] American Diabetes Association, Comment Letter on Proposed Rule to Change Qualifications of Drivers; Diabetes Standard (March 17, 2006) (available at: http://www.diabetes.org/living-with-diabetes/know-your-rights/discrimination/drivers-licenses/commercial-drivers-and-diabetes-discrimination/legislation-and-rulemaking.html).

[5] Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU), Pub. L. No. 109-59, § 4129, 119 Stat. 1144, 1742 (2005) (directing FMCSA to provide individual assessment to commercial drivers with insulin-treated diabetes).

[6] *See* Qualifications of Drivers; Diabetes Standard, 80 Fed. Reg. 25260, 25264 (proposed May 4, 2015) (to be codified at 49 C.F.R. pt. 391).

[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.[9]

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

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

[10] Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU), Pub. L. No. 109-59, § 4129, 119 Stat. 1144, 1742 (2005).

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) [A]lthough 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.[11] 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.[12] 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.[13] This is because retinopathy is estimated to take at least 5 years to develop following hyperglycemia.[14] 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.[15] 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.[16]

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[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.*
[16] Agardh E, Tababat-Khani P. Adopting 3-year Screening Intervals for Sight-Threatening Retinal Vascular Lesions in type 2 Diabetic Subjects without Retinopathy. *Diabetes Care* 34:1318–19 (2011).

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

[17] Qualifications of Drivers; Diabetes Standard, 80 Fed. Reg. 25260, 25264 (proposed May 4, 2015) (to be codified at 49 C.F.R. pt. 391).

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.[18] 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."[19] 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

[18] American Diabetes Association: Diabetes and Employment, *Diabetes Care* 37: Supp. 1, at S115 (2014). *See also* American Diabetes Association: Diabetes and Driving, *Diabetes Care* 37: Supp. 1, at S100 (2014).

[19] Letter from Michael Brennan, George Grunberger, Edward Horton and Christopher Saudek, members of the Expert Medical Advisory Panel, to Annette Sandberg, Administrator, Federal Motor Carrier Safety Administration (Dec. 20, 2005) (available at docket no. FMCSA-2001-9800).

> the wrong message for our patients and the wrong message to increase safety on our roads.[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.

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 *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.

[20] *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

[21] American Diabetes Association: Diabetes and Employment, *Diabetes Care* 37: Supp. 1, at S115 (2014).

[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).

[23] Federal Motor Carrier Safety Administration, http://nrcme.fmcsa.dot.gov/documents/FMCSAMedicalExaminerHandbook-2014MAR18.pdf (last visited June 4, 2015) ("Please Note: This document is in the process of being updated. A revised version will be published shortly").

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."[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.

Contact Information: Katie Hathaway
(703) 253-4821
khathaway@diabetes.org

[24] Qualifications of Drivers; Diabetes Standard, 80 Fed. Reg. 25260, 25261 (proposed May 4, 2015) (to be codified at 49 C.F.R. pt. 391).

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 <u>is not</u> physically qualified to operate a commercial motor vehicle

Clinician Information

Name: _____
First Last

Phone No.: _____ Email: _____

Preferred contact for questions: _____

I am a:

☐ Physician
☐ Physician Assistant
☐ Nurse
☐ Diabetes Educator

FMCSA-2005-23151-0850-International_Brotherhood_of_Teamsters

The International Brotherhood of Teamsters

Comments on

Qualifications of Drivers; Diabetes Standard

Notice of Proposed Rulemaking (NPRM)
80 Federal Register 25260 (May 4, 2015)

Department of Transportation
Federal Motor Carrier Safety Administration

Docket No. FMCSA-2005-23151

July 6, 2015

Azita Mashayekhi, MHS
Staff Industrial Hygienist
Safety and Health Department

INTRODUCTION

On May 4, 2015, the Department of Transportation, Federal Motor Carrier Safety Administration ("FMCSA" or "the Agency") published a Notice of Rulemaking (NPRM), request concerning amendments to the medical qualifications for operators of commercial motor vehicles (CMVs), in interstate commerce, to permit drivers with "stable, well-controlled insulin-treated diabetes mellitus (ITDM)" to be qualified to operate CMVs. By becoming a final rule, "CMV drivers with ITDM could meet physical qualification standards under the new rule without applying for or receiving exemptions."

The "proposed rule would amend 49 CFR part 391 by revising §391.41 and §391.45 and by adding new §391.46 to address driver health and public safety concerns associated with hypoglycemia related to diabetes and its control through insulin."

The International Brotherhood of Teamsters (IBT) is a 1.4 million member labor organization that represents hundreds of thousands of commercial motor vehicle drivers and other workers in the transportation trades, who would be directly or indirectly affected by the proposed amendment. These members are employed within 21 industry sectors including transporting freight, cars, durable and nondurable goods, passengers (motor coaches, vans), and hazardous materials, both locally or short-haul, and long-haul.

The IBT is encouraged by this effort to revise the current medical qualification regulation that only allows drivers who have successfully applied for and received an exemption to drive in interstate commerce and submits these comments in support of the Notice. We concur with the NPRM assertion that "CMV drivers with diabetes whose condition is stable and well-controlled do not pose an unreasonable risk to their health or to public safety." As the regulatory record amply points out, the conclusions of this NPRM and the resulting proposal have been in the making for years and are long expected by the IBT, and

other stakeholders, who have participated actively in this process.

COSTS AND BENEFITS

The health issues of interstate CMV drivers mirror those of the aging U.S. population and the increasing number of adult onset diabetics is an example of that. As acknowledged in the NPRM, there has been a continuing growth trend in the diabetes exemption applications received by the FMCSA in the 6 years prior to 2012.

Although the FMCSA now allows certain individuals to drive in interstate commerce through a program that exempts them from the medical regulation governing commercial drivers who have ITDM, a number of our members are unable to work as commercial drivers due to the regulation. Consequently, these workers are forced to either take lower-paying intrastate or non-driving jobs, or not work at all. The revised rule would also afford dock workers, package handlers and other non-driver workers in the transportation industry, some of whom are aspiring drivers, with a greater incentive to seek such employment. The proposal would also provide the drivers and aspiring drivers with additional incentives to properly manage their medical condition. Therefore, the IBT as the designated bargaining representative for these workers has had a vested interest in this rulemaking since its inception in 2006. Moreover, modifying the rule may improve the driver shortage being experienced by man industries that operate in interstate commerce.

In the NPRM, FMCSA asserts that this protocol "would ensure a level of safety equal to or greater than that achieved with the current prohibition on individuals with insulin treated diabetes mellitus driving such vehicles." As stated and documented in the NPRM, "evidence reports, ADA studies, and MRB [Medical Review Board] conclusions and recommendations indicate that drivers with ITDM are as safe as other drivers when their condition is well-controlled." Alongside accomplishing this, the NPRM also asserts that "The proposed rule is less onerous for both drivers with ITDM and for the Agency." "The Agency would no

longer review applications for exemptions, further reducing administrative costs for FMCSA."

APPLICATION PROCESS

Under the current rule, the FMCSA must either grant or deny an exemption within 180 days of receiving a complete application. This is a prolonged period between applying for and receiving an exemption; this time will increase with increasing demand, as noted earlier. As stated in the NPRM, "A driver with stable, well-controlled ITDM who meets the requirements of the proposed rule could obtain a MEC and continue to earn income operating CMVs in interstate commerce without the additional expense and delay of applying for an exemption."

The IBT driver/members who have applied for the exemption express concerns that the six-month processing period is extremely burdensome to the drivers in that they may be forced to work in non-driving jobs during application processing period. It should be noted that many of these individuals are high-seniority drivers and who may be physically challenged by the non-driving jobs due to many of these jobs involving manual materials handling and similar non- driving tasks associated with the transportation industry. Despite the physical challenges, however, the coverage of these drivers by collective bargaining agreements enables them to work in non-driving jobs and to avoid significant financial loss and cancellation of medical benefits. It is likely that many non-union drivers do not have such alternate work options and, therefore, face loss of employment and medical benefits that may them to forego medical treatment during the waiting period.

EXPERT GUIDANCE AND STUDIES

The medical advances in treating and managing diabetes allow many experienced commercial drivers to be productive and safe transportation workers. Based on the

common finding of these reports regarding hypoglycemia as the chief safety concern for ITDM drivers, the FMCSA has proposed to "eliminate the prohibition on physically qualifying drivers" and replacing it with a regulatory protocol to ensure proper disease monitoring and management for drivers using insulin."

The FMCSA "uses an evidence-based systematic review process and consultation with the MRB and the Chief Medical Officer to revise or develop medical standards and guidelines for commercial drivers." The NPRM "discusses data reflected in evidence reports and American Diabetes Association (ADA) studies examining risks associated with diabetes and driving in general, and the association between hypoglycemia and ITDM in particular, as well as "MRB findings and conclusions based on evidence reports."

The NPRM's discussion of published literature and FMCSA's own data "indicate that the safety performance for CMV drivers with ITDM who hold exemptions is as good as that of the general population of CMV drivers" (see Table 4). "On a per-driver, per-year basis, the crash rate for drivers with ITDM in the exemption program was 0.013"; in comparison, regarding crashes reported to MCMIS for all FMCSA-regulated CMV drivers from 2005 to 2011, "the average number of crashes per year per active CMV driver is about 0.038."

MEDICAL EXAMINATION AND CERTIFICATION PROCESS

In 1998, per section 4018 of TEA-21, the DOT was tasked to "determine the feasibility of developing "a practicable and cost-effective screening, operating and monitoring protocol" for allowing drivers with ITDM to operate CMVs in interstate commerce.

FMCSA's 2000 "Report to Congress concluded that it was feasible to establish a safe and practicable protocol containing three components allowing some drivers with ITDM to operate CMVs. The three components were: (1) Screening of qualified ITDM commercial drivers, (2) establishing operational requirements to ensure proper disease management by

such drivers, and (3) monitoring safe driving behavior and proper disease management."

In its 2006 comments submitted to this docket, the IBT recommended "that the FMCSA make the necessary regulatory revisions to allow commercial drivers with ITDM to operate CMVs in interstate commerce providing that such drivers have been individually assessed by a qualified medical provider who utilizes scientifically valid, medically acceptable criteria to make the determination." We, therefore, welcome the proposal to allow a treating clinician (TC) to evaluate a driver with ITDM at least annually, followed by an annual, or more frequent, evaluation by a Medical Examiner (ME) listed in the National Registry of Certified Medical Examiners (National Registry).

The MRB recommended that all drivers diagnosed with diabetes mellitus be required to obtain at least annual recertification by a ME who is a licensed physician, regardless of whether they are insulin- treated, and also recommended to require annual or more frequent medical recertification for all drivers with diabetes mellitus. The NPRM explains that "Current regulations do not prohibit any drivers with non-insulin treated diabetes mellitus from being qualified medically to operate CMVs. Finding no medical necessity for such a prohibition, the Agency is not proposing such a change." We wholly support FMCSA's decision in not proposing to adopt the MRB recommendation to require annual or more frequent medical recertification for all drivers with diabetes mellitus on the grounds that it is in accordance with existing evidence and FMCSA's "evidence-based systematic review process."

Furthermore, 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.

We support the Agency's position on this issue. The TC will be most knowledgeable regarding the driver's current health status, medical history and compliance with treatment regimen, etc. The TC may not, however, be on the registry and may not be thoroughly familiar with the FMCSA regulations or with the job tasks performed by a commercial driver. Subsequent evaluation by an ME, annually or more frequently, would complement the role of the TC in the certification process.

Furthermore, the FMCSA removes the requirement to see an endocrinologist. As noted in the NPRM, "although the ADA, the U.S. National Institutes of Health, and other organizations urge yearly assessments for individuals with diabetes by a physician or health care professional knowledgeable about the disease, none of these groups calls for yearly evaluations by endocrinologists." Moreover, "a requirement to be evaluated by an endocrinologist now seems impracticable for most drivers with ITDM. According to the American Board of Internal Medicine, there are only about 5,300 board-certified endocrinologists in the United States, approximately 1,300 of which do not provide clinical care."

It is our view that the TC, rather than an endocrinologist, would be a more suitable medical provider to monitor for any of the progressive conditions associated with diabetes (e.g., nerve damage to the extremities, diabetic retinopathy, cataracts and hypoglycemia unawareness). This action would also reduce the burden of quarterly reports submitted by an endocrinologist to FMCSA including blood glucose logs, insulin regimen changes and hypoglycemic events, if any, that the driver has experienced.

Furthermore, the IBT supports the revision of the current rule which would remove the requirement that driver 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. We agree with the FMCSA "that meeting the vision acuity standard as part of the annual exam by an ME listed in the National Registry of Certified Medical

Examiners provides reasonable certainty of discovering and mitigating risks associated with any safety-related condition that would interfere with meeting the standard, including diabetic retinopathy."

As noted in the NPRM as well, such drivers have every incentive to manage their condition, including its potential effects on their vision, so that the disease is stable and well-controlled, because the failure to care for themselves would affect their quality of life, including their immediate and long-term health and their ability to maintain a job.

A chief purpose of establishing the National Registry was "to improve safety by achieving high-quality medical exams that are consistent with Federal regulations and guidelines" and to "help commercial motor vehicle drivers, and employees, find trained and qualified medical examiners to perform physical qualification examinations." Healthcare professionals must complete training and testing on the Federal Motor Carrier Safety Administration's (FMCSA) physical qualifications standards and advisory criteria.

While the proposed rule in § 391.46, Physical qualification standards for a person with insulin-treated diabetes mellitus, sets clinical criteria for the TC and ME, given the proposal to not require seeing an endocrinologist or ophthalmologist, the FMCSA should consider what additional guidance may be helpful to the TC and ME to attain a superior and consistent level of clinical practice in the certification process. This could be done, for example, through an appendix, checklists, and/or additional language or references within the rule, including information about state-of-the-art medical monitoring devices, tests, etc. The current Federal Diabetes Exemption Program provides program eligibility criteria, including checklists, such as the *Endocrinologist Evaluation Checklist* and the *Vision Evaluation Checklist.*

Given the safety risks from acute hypoglycemia and long term problems from microvascular and macrovascular disease, clarification on certain issues may be helpful. For example, how

long insulin must be used before a driver can be certified to drive. Under the existing rule, individuals who have type 1diabetes will need to have been on insulin for two months before they are eligible to apply for an exemption, and individuals with type 2 diabetes will have had to have been on insulin for one month. The NPRM does not address this issue and needs to state if these criteria will continue to govern § 391.46 as proposed by the NPRM or would be irrelevant.

PRIVACY

The ME may obtain information from the TC to demonstrate the driver's condition is stable and well-controlled. As we also stated in our 2006 submission, although the medical examiner should be afforded the opportunity to request additional, relevant supporting documentation from the TC, it must be emphasized that the information that is provided to the medical examiner must be limited to that which supports the treating physician's determination. This Union is very concerned about privacy issues as they relate to releasing medical information. It has been our experience that in many instances, the medical examiner is a "company doctor" who may request the entire medical file for drivers as a prerequisite to performing the examination. To obtain this information, the medical examiners require the drivers to sign a "blanket authorization" which also allows the medical examiner to release the driver's medical file to insurance companies, the employer and various other entities. We feel that the motor carriers should not be allowed to, in our opinion, improperly utilize the regulations as promulgated in 49 CFR Part 391 as justification to obtain and release to third parties, information that not relevant to determining whether a driver is qualified to operate a commercial motor vehicle in commerce.

PASSENGER CARRYING AND HAZARDOUS MATERIALS TRANSPORTATION

"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 IBT represents thousands of interstate drivers who transport passengers and hazardous materials. We full support FMCSA's assertions in this NPRM that "The risk posed by a driver with stable, well-controlled ITDM is very low in general. Further, there is no available evidence to support such a prohibition, and, as noted, under section 4129 of SAFETEA-LU, FMCSA may not hold drivers with ITDM "to a higher standard of physical qualification . . . than other individuals . . . except to the extent that limited operating, monitoring, and medical requirements are deemed medically necessary under regulations." In addition, the current exemption program permits these drivers to qualify for passenger carrying and hazardous materials transportation." For these reasons, we urge the Agency to proceed with the proposal as written.

MEXICAN AND CANDAIAN DRIVERS

The proposed rule would not allow drivers with ITDM with licenses issued in Canada or Mexico to operate a CMV in the United States. As the NPRM explains:

> Drivers from Mexico with a Licencia Federal de Conductor (LFC) generally may operate in the United States. 49 CFR 383.23(b), n. 1 and 391.41(a)(1)(i). But Mexico does not issue an LFC to any driver with diabetes. Under the terms of the 1998 reciprocity agreement with Canada, a Canadian driver with ITDM holding a license issued by a Canadian province is not authorized to operate a CMV in the United States.

The IBT has long and actively opposed the entry of Mexico-domiciled commercial drivers into the United States due to concerns about their safety performance. We applaud the FMCSA for continuing the current policy on drivers with ITDM domiciled in Canada and Mexico.

CONCLUSION

There have been significant advances in the treatment and management of ITDM. We are

very pleased that the FMCSA is proposing to amend the current medical qualification standards to allow individuals with ITDM to operate commercial motor vehicles in interstate commerce, without having to receive an exemption. Further, the medical screening criteria as set forth in the NPRM are reasonable and protective of both the safety of the motoring public and the health of the drivers.

The IBT urges the Agency to aggressively move forward with this rulemaking. The IBT concurs with the FMCSA that the proposed procedures "will ensure that drivers with ITDM manage the condition so that it is stable and well-controlled, and that such a regulatory provision creates a clearer, equally effective and more consistent framework than a program based entirely on exemptions under 49 U.S.C. 31315(b). The FMCSA needs to develop "a practicable and cost-effective screening, operating and monitoring protocol" for allowing drivers with ITDM to operate CMVs in interstate commerce that does not require a driver to choose between his/her health and career.

Thank you for the opportunity to comment on this important rulemaking for our membership and we look forward to the promulgation of a new and improved rule.

AMERICAN OPTOMETRIC ASSOCIATION
1505 PRINCE ST., STE. 300, ALEXANDRIA, VA 22314 | 800.365.2219

FMCSA-2005-23151-0852-American_Optometric_Association

July 6, 2015

T.F. Scott Darling, III, Chief Counsel
Federal Motor Carrier Safety Administration
United States Department of Transportation
1200 New Jersey Avenue SE
Washington, DC 20590

Mr. Darling,

The American Optometric Association represents 33,000 doctors of optometry and optometry students. Optometrists serve patients in nearly 6,500 communities across the country, and in 3,500 of those communities are the only eye doctors. Doctors of optometry play a key role in the care of patients with diabetes and over the past several years, many drivers have relied on our members to evaluate them for the Federal Motor Carrier Safety Administration's (FMSCA's) diabetes exemption program. Optometrists are pleased to assist the Department of Transportation (DOT) to ensure applicants are physically qualified to drive commercial motor vehicles. Doctors of optometry understand the great responsibility and importance of ensuring that these drivers are able operate commercial vehicles safely.

The AOA appreciates that the DOT has required drivers with diabetes to have an eye examination from an optometrist or ophthalmologist to qualify for the diabetes exemption program since 2005. However, since the program's most recent major modification in 2005, the AOA has disagreed with the requirement for drivers with diabetic retinopathy to be evaluated only by an ophthalmologist. This restriction is not in alignment with clinical care guidelines related to diabetes care, and the AOA strongly believes that the program requirements have created an unnecessary burden for applicants. Essentially, the program has needlessly mandated that those individuals who are examined by an optometrist and who are found to have diabetic retinopathy must seek additional evaluation by another practitioner, even though the doctor of optometry is well trained to appropriately stage and evaluate effects on vision and driving safety of patients with diabetic retinopathy.

While the AOA is pleased that the FMSCA is moving forward to improve the diabetes exemption program, we have serious concerns regarding the proposed modifications. Taking into account the need to balance safety and reduce burden, the AOA offers these timely comments on the "Qualifications of Drivers; Diabetes Standard" Proposed Rule.

Overall, the FMSCA proposal seems to reverse many of the current regulations. This drastic change appears to be without scientific merit as there is no medical justification to require less rigorous eye and vision health monitoring for patients with diabetes in 2015 than when the present regulations were established. Diabetic retinopathy (DR) and Diabetic Macular Edema (DME) are still the most common microvascular complication of diabetes mellitus type 2 (DM2) and type 1 (DM1), and the leading cause of blindness among adults age 20-74. DR and DME evolve over time from a non-proliferative stage (NPDR), associated with microaneurysms, hemorrhages, cotton-wool spots, hard exudates, intraretinal microvascular abnormalities (shunt

vessels) and venous beading through a proliferative phase (PDR) associated with neovascularization, retinal detachment and blindness. DME refers to intra-retinal swelling within the center of the retina, may occur at any stage of DR and is, in fact, the leading cause of visual impairment in patients with diabetes. Separately, diabetic macula edema (DME) may occur anytime during the disease process. Importantly in the last decade, technology advances, such as OCT (optical coherence tomography) and other technologies, have enabled optometrists and ophthalmologists to better predict vision risk to the central macula, making monitoring even more important and valuable than ever. Furthermore, other common ocular signs and symptoms found in high prevalence among Insulin-Treated Diabetes Mellitus (ITDM) patients require close monitoring, and include; fluctuating vision and refractive changes, binocular vision anomalies (double vision), recurrent corneal erosion, neurologic lid and pupil anomalies, accommodative insufficiency, early cataract development, greater prevalence of glaucoma, dry eye, Kruckenberg spindle, optic nerve disease and recurrent eye infections, all of which pose safety concerns for commercial motor vehicle drivers.

Incidence or progression of these eye and vision complications for drivers with diabetes can be greatly reduced, but not eliminated by adequate well-controlled blood glucose and blood pressure levels. Since good systemic control cannot entirely remove the risk of diabetic retinopathy and DME, regular ophthalmic exams by doctors of optometry or ophthalmologists are necessary for detecting ocular complications and initiating treatments (e.g. laser photocoagulation and intravitreal medication in case of clinical significant diabetic macular edema or early proliferative diabetic retinopathy).[1] In this way, the risk of vision impairment and blindness can considerably be reduced and potential impacts on driving can be fully assessed, mitigated and or resolved.[2] Furthermore, timely treatment will benefit drivers by allowing them to maintain their vision and their livelihoods.

It is because of the serious impacts of diabetic retinopathy on visual function that the AOA cannot entirely support the FMCSA proposal to eliminate the requirement for drivers with diabetes to have a vision examination by an ophthalmologist or optometrist. The FMSCA proposal would rely only on a cursory visual acuity examination that may be provided by a non-eye care professional to evaluate a driver's eye health. This type of monitoring would not meet the acceptable clinical care standards. According to evidenced based care guidelines of the American Diabetes Association, the Centers for Disease Control and Prevention, the National Eye Institute of the National Institutes of Health, the American Association of Clinical Endocrinologists and the AOA, monitoring patients with diabetes requires a dilated eye examination from a doctor of optometry or ophthalmologist. Testing only for visual acuity and relying on glycemic control is simply insufficient from an evidence-based perspective as many patients with sight-threatening diabetic eye disease have normal visual acuity at the time of diagnosis, and impacts on driving safety may occur subsequent to meeting minimal visual acuity requirements.

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[1] Nentwich MM, Diabetic retinopathy - ocular complications of diabetes mellitus. World J Diabetes. 2015 Apr 15;6 (3):489-99
[2] Nentwich MM, Diabetic retinopathy - ocular complications of diabetes mellitus. World J Diabetes. 2015 Apr 15;6 (3):489-99.

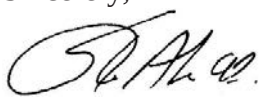
The AOA is also concerned that certain qualified medical examiners lack the instrumentation or expertise to assess visual function and ocular health beyond evaluating visual acuity with a Snellen eye chart. It is important to understand that the entire range of diabetic retinopathy complications are predominantly asymptomatic, and can occur without any deterioration in visual acuity. The central retinal area can be without clinically significant compromise during any DR stages.[3] Research has demonstrated that even with central retinal changes (e.g. maculopathy), the majority of patients may be asymptomatic.[4] Additionally, visual function tests performed by doctors of optometry and ophthalmologists (e.g. contrast sensitivity, color perception, frequency doubling technology (FDT) perimetry and other perimetric procedures) often reveal an expanded range of diabetes induced retinal damage, including significantly impaired dark-adapted visual sensitivity, even in patients with good visual acuity.

The AOA understands the need to reduce burden on driver applicants, however, the proposal to only require visual acuity measurement by the medical examiner is not appropriate for accurately monitoring potential visual problems related to ITDM commercial drivers. A visual acuity test is not a substitute for a dilated eye examination which is the only appropriate method for evaluating the eye health of these drivers and for predicting with high confidence which patients will retain adequate visual function in the interim between eye examinations. The desire to reduce applicant burden must be balanced with maintaining health and safety.

The AOA is concerned that the current proposal could put drivers and the public at serious risk. If FMCSA would like to reduce applicant burden, then a prudent step would include eliminating the current requirement that indicates applicants who have diabetic retinopathy must be evaluated by an ophthalmologist. Allowing those applicants to be evaluated by a doctor of optometry would reduce cost and burden to drivers and maintain quality, all of which would serve as a positive step. If FMSCA is unwilling to make this change and return to the eye exam requirement, then the administration should require that for commercial drivers with ITDM the vision component of the medical examination be performed by a doctor of optometry or an ophthalmologist because patients on insulin therapy have the highest risk for sight-threatening eye disease. This would ensure that a trained eye care professional has evaluated the applicant with ITDM before they are deemed fit to drive a commercial vehicle.

Thank you for the opportunity to comment on these proposals. If you have questions, please contact Rodney Peele, JD, Associate General Counsel for Public Policy at rpeele@aoa.org.

Sincerely,



Steven A. Loomis, O.D.
AOA President

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[3] Hernández OH, Optical coherence tomography and visual evoked potentials in patients with type 2 diabetes with and without retinopathy: preliminary report, Rev Invest Clin. 2014 Jul-Aug; 66 (4):330-8.
[4] Jackson GR, Inner retinal visual dysfunction is a sensitive marker of non-proliferative diabetic retinopathy. Br J Ophthalmol. 2012 May;96 (5):699-703

FMCSA-2005-23151-0881 – Jeffrey Liva MD, MPH, MS

Benefits and Costs

FMCSA believes that this rule making would not have a significant economic impact. The total impact focuses only on the cost of an additional medical exam and the risk of hypoglycemia in the ITDM CMV driver (ITCMVD).

FMCSA leaves out all type of costs involve in the elimination of the exemption program.

Hypoglycemia is not the only complication in Insulin treated diabetics. In 20052008, of adults with diabetes aged 40 years or older, 4.2 million (28.5%) people had diabetic retinopathy. It is a well-known fact, that tighter control slows down the progression of the complications of diabetes and for the ITCMVD to avoid hypoglycemia, the CMV driver will not be able to maintain tight control which will accelerate the progression for the ITCMVD to develop eye, nerve, and kidney complications.

FMCSA has not addressed the increased cost incurred on the medical system because of the unintended consequence of avoiding hypoglycemia in this population. FMSCA looks at the short term of driving and not the impact that the rule will have on the organ systems and lifespan of the ITCMVD.

In 2011, about 282,000 emergency room visits for adults aged 18 years or older had hypoglycemia as the first-listed diagnosis and diabetes as another diagnosis. Hyperglycemic crisis

In 2011, about 175,000 emergency room visits for people of all ages had hyperglycemic crisis, e.g., diabetic ketoacidosis and hyperglycemic hyperosmolar state, as the first-listed diagnosis.

What information must the TC provide to the ME?

FMCSA has not issued guidelines to inform the Treating Clinician (TC) what information he/she must provide to the ME. How is FMCSA going to educate the TC in the rigors of driving and the necessity for the TC to modify the treatment plan of his patient in order for the driver avoid hypoglycemia.

Will the TC need to provide informed consent to the driver that will not be optimally managed and that risk of the complications of their disease will be increased?

How will FMCSA educate the TC that they cannot recommend any restrictions like avoiding shiftwork?

What criteria has FMCSA issued to guide the ME to determine the ITCMVD is effectively managing his/her diabetes in a way that ensures he/she is able to safely operate a CMV.

The FMCSA in there instruction to ME does not require a retina exam to meet the vision standard. In order to do a proper retina exam, the CMV driver would need to have drops instilled to dilate the pupil.

Most clinicians are not skilled in performing a retinal exam especially on a non-dilated pupil.

The FMCSA has determined that non physicians can issues a Medical Card.

Would Chiropractors be prohibited in determining certification in ITCMVD since diseases of the retina are beyond their scope of practice?

Who indemnifies the TC and the ME when ITDM is involved in a fatal accident?

The TC duty is to his patient and not to the public.

Has the FMCSA considered the position the agency is putting on the TC. The TC who determines their patient, the ITCMVD is unqualified to drive risks losing their patient who will doctor shop until he finds a TC to sign off on their condition.

How will the ME protect themselves from a lawsuit for discrimination when they dont approve every ITCMVD when recommended by the TC who is not well informed on the rigors of driving?

I have first-hand experience with a lawsuit for Discrimination for a CMV driver who had a HA1C that was 14.9%. The lawsuit was funded by the American Diabetic Association. Their experts didnt have a problem for a driver with this level to drive. I was surprised the ADA even felt the guidelines issued by the NQF to be restrictive. Lucky that the company covered me, the legal fees were over 1M. Part of the settlement is now a driver with a HA1C of 12% can drive.

Does the FMCSA agree a HA1C of 12% is adequate to enable them to operate (CMVs) safely?

If not, then what is the standard for the evaluation of the ITCMVD. The FMCSA will need to come up with a table like they have with blood pressure.

Will the TC have to accept a HA1C of 12% as satisfactory for managing their patients disease even though the TC will receive a reduction in reimbursement for ignoring the NQF (National Quality Forum)standard?.

The FMCSA need to answers these question before proceeding. The FMCSA needs to be specific in there guidance. If not, the TC and the ME will avoid the risk of an ADA lawsuit which malpractice does not cover by allowing ITCMVD who should not drive get a MEC.

If the rule as written is adopted, we will make our roads less safe and especially for passengers and other drivers on the road. The current exemption process seems to be working and I would highly recommend the process remain unchanged unless there is very specific criteria to

determine the ITCMVD is adequate to operate safely and that the drive not subject the public to unnecessary risk.

COMMENTS FOR CONSIDERATION

RESPECTFULLY SUBMITTED BY THE

UNITED MOTORCOACH ASSOCIATION

REQUEST FOR COMMENT:

Qualifications of Drivers; Diabetes Standard

BEFORE THE

UNITED STATES DEPARTMENT OF TRANSPORTATION

FEDERAL MOTOR CARRIER SAFETY ADMINISTRATION

Docket No. FMCSA-2005-23151

Submission Date – July 6, 2015

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The United Motorcoach Association (UMA) is grateful for the opportunity to respond to the Notice of Public Rulemaking (NPRM)– Qualifications of Drivers; Diabetes Standard, Docket No. FMCSA-2005-23151.

The Federal Motor Carrier Safety Administration (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. The proposed rule 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.

In preparing our comments, UMA recognizes the industry's increasing demand for bus and motorcoach drivers, individuals who desire to pursue a career as a commercial motor vehicle driver, and the industry's prevailing responsibility to protect passengers and the traveling public.

The NPRM states:

> *"Of particular concern for drivers, however, are the immediate symptoms of severe hypoglycemia—a condition where insulin treatment may cause blood glucose to drop to a dangerously low concentration. A person experiencing hypoglycemia may have one or more of the following symptoms: Double vision or blurry vision; shaking or trembling; tiredness or weakness; unclear thinking; fainting; seizures; or coma. If any of these symptoms of severe hypoglycemia occurs while someone is driving, there is the potential for a crash."*

UMA shares these specific concerns.

The over-the-road bus environment

Unlike the solitude of a truck, an over-the-road bus driver is in constant view of the customer. Passengers routinely observe driver behaviors as evidenced by very publicly viewed cell-phone videos of drivers' texting or talking on a cell phone.

Insulin dependence

Insulin dependents diabetes requires optimum discipline to manage glucose levels; including monitoring blood glucose levels requiring, proper diet, and insulin injections. Failure to comply with these disciplines can result in hypoglycemia. The earliest stages of hypoglycemia include: confusion, dizziness, feeling shaky, hunger, headaches, irritability, pounding heart; racing pulse, pale skin, sweating, trembling, weakness, and anxiety. Without treatment, more severe symptoms include poor coordination, poor concentration, numbness in mouth and tongue, passing out, and coma.

Diet and Hypoglycemia

Low blood sugar (hypoglycemia) generally occurs when an individual takes too much insulin in ratio to the amount of carbohydrates they eat or drink or may occur after and individual consumes a meal that has considerable simple sugars, misses a snack or fails to eat a full meal, eats later than usual or skips meals when taking diabetes medications.

OVER-THE-ROAD BUS OPERATIONS

There are two basic types of over-the-road bus operations; scheduled service and charter. Approximately 57% of the over-the-road bus service mileage is attributed to charter, tour, and sightseeing services and 43% accounts for fixed-route services (airport shuttle, commuter, scheduled, and special operations)[1] .

[1] John Dunham & Associates for the American Bus Association Foundation, A Study of the Size and Activity of the Motorcoach Industry in the United States and Canada in 2013, March 12, 2015.

Scheduled service

Scheduled service operates on fixed schedules and routes. While the driver remains in constant view of passengers, an insulin dependent driver may have some limited opportunities to plan appropriate times to test blood glucose levels, obtain a snack/meal, or administer insulin injections. It is also critical to understand that an OTRB driver must remain on schedule as passengers have time constraints and may be making other travel mode connections.

Charter service

Drivers of OTRB charters in most cases have less opportunity to plan appropriate times to test blood glucose levels, obtain a snack/meal, or administer insulin injections as group objectives are often time and destination driven. Besides driving duties, drivers are often compelled to spend non-driving and/or off-duty time with groups including mealtimes and hotel stays.

Concerns

UMA has four primary reservations if a final rule emerges that allow CDL holders to obtain a passenger endorsement.

1. The current system of vetting drivers appears effective. What we do not know is the number of drivers that currently begin the process to apply for an exemption but for medical reasons, never complete the required submissions.

2. Over-the-road bus operations environment may not be conducive to maintaining proper blood-glucose levels sufficient to avoid a crash. Considering a typical motorcoach can hold 57 passengers; and, increasingly up to 81, even one incident of hypoglycemia could have tragic results.

3. The day-to-day over-the-road bus operations environment may not be in the best interest of the driver's health if compromises in monitoring blood glucose levels, snacking/eating, and insulin ejections are delayed or missed. Will drivers test blood-glucose levels or use insulin considering the ever-present cell-phone cameras?

4. Passengers may have concerns or become alarmed when visually observing a driver using blood glucose monitoring devices and injecting insulin. In charter service, groups chartering motorcoaches may demand another driver.

Under current regulations, a driver with ITDM may not operate a CMV in interstate commerce unless the driver obtains an exemption from FMCSA, which must be renewed at least every 2 years. FMCSA may revoke an exemption immediately under standards set out in §381.330.

UMA believes it is likely most drivers currently seeking an ITDM exemption were CMV drivers prior to developing insulin dependency and may be in the earliest stages of ITDM. These drivers are likely accustomed to the rigors of commercial motor vehicle operations. If the proposed rule becomes final, a much broader population will likely obtain Commercial Drivers Licenses and endorsements; including new entrant drivers.

The Medical Review Board recommended FMCSA maintain a restriction on medical qualification of drivers with ITDM from passenger transportation. UMA supports the recommendation of the Medical Review Board.

UMA recommends retaining the current standards for those CMV drivers seeking a CDL with a passenger endorsement. UMA further recommends FMCSA monitor and study the crash rates of CMV drivers obtaining a CDL with ITDM under the NPRM for a period of not less than five years before further considering allowing insulin-dependent CMV drivers obtain a passenger endorsement under a similar future proposed rule.

Again, UMA appreciates this opportunity to comment on this proposed rule and seeks only the best possible solution for the passengers and industry.

Respectfully submitted,

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Founded in 1971, United Motorcoach Association (UMA) is a thriving association of bus and motorcoach company owners and industry suppliers with over 1200 members located across North America. UMA Members represent the full spectrum of passenger carrier operations, from small family-owned companies to nationwide operations. UMA operator members typically afford passenger transportation services such as charters, tours, fixed route scheduled service, airport shuttle and commuter services.

FMCSA-2005-23151-0960-American_Trucking_Associations

FEDERAL MOTOR CARRIER SAFETY ADMINISTRATION
U.S. DEPARTMENT OF TRANSPORTATION
DOCKETS # FMCSA-2005-23151

Qualification of Driver; Diabetes Standard

SUBMITTED BY:
American Trucking Associations, Inc.
950 North Glebe Road
Suite 210
Arlington, VA 22203

July 6, 2015

Contacts:
P. Sean Garney
Director, Safety Policy
703-838-8804

I. Introduction

American Trucking Associations, Inc., (ATA) submits these comments to the Federal Motor Carrier Safety Administration (FMCSA) in response to the agency's May 4, 2015 Notice of Proposed Rulemaking titled "Qualifications of Driver; Diabetes Standard."[1] ATA is the national trade association representing the American trucking industry.[2] As such, ATA is vitally interested in matters affecting the medical qualifications of truck drivers as they can have a direct impact on the safe operation of commercial motor vehicles.

II. Summary of ATA's position

ATA is pleased that FMCSA is using the rulemaking process to adjust the physical qualifications of drivers diabetes standard. Recent history has indicated that FMCSA no longer feels that the diabetes standards are appropriate as evidenced by the 1,000 exemptions it granted last year. ATA is supportive of FMCSA's proposal to once again rely on the expertise and judgment of the certified medical examiner rather than that of government employees who may lack a full understanding of the circumstances and medical histories of the drivers they are reviewing. ATA support however, is contingent on the elimination of all exemptions for the diabetes standard, which place motor carriers in a precarious predicament.

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[1] Qualifications of Driver; Diabetes Standard, 80 FR 85, 25260 (May 4, 2015) (hereinafter "the Notice").

[2] ATA is a united federation of motor carriers, state trucking associations, and national trucking conferences created to promote and protect the interests of the trucking industry. Directly and through its affiliated organizations, ATA encompasses over 34,000 motor carriers and suppliers of every type and class of operation in the United States, Canada, and Mexico.

III. The volume of exemption applications suggest a concerning emerging trend.

ATA and many of its members have observed a concerning trend. An alarming number of drivers have begun using the exemption process[3] to apply for exemptions from 49 C.F.R. §391.41, *Physical qualifications of drivers*. Specifically, over 1,000 drivers are requesting exemptions from the physical qualification of drivers diabetes mellitus standard annually.[4] The Federal Motor Carrier Safety Regulations consider this standard to be absolute, meaning that any driver who has an "established medical history or clinical diagnosis of diabetes mellitus currently requiring insulin control" cannot be medically certified to drive a commercial motor vehicle.[5] Despite this, FMCSA has consistently granted exemptions to drivers with insulin treated diabetes mellitus (ITDM). Indeed, in 2014, FMCSA granted exemptions to 1000 of 1003 (>99%) drivers who asked for them.[6] ATA has detailed this concern in previous comments.[7]

IV. Eliminating exemptions would clarify confusion among motor carriers about which drivers are medically fit to operate a CMV.

The granting of exemptions to large classes of drivers undermines the physical qualifications standards and places motor carriers in a challenging conundrum. Of course, hiring managers cannot employ drivers who do not meet the absolute standard for insulin treated diabetes. When presented with an exemption approval, though, motor carriers must consider these drivers qualified. Yet, in the event of an accident involving one of these drivers, motor carriers can still be considered culpable of allowing a driver known to have a potentially troublesome medical condition, as outlined in the FMCSRs, to operate a CMV. By adjusting the diabetes standard to allow drivers with ITDM to operate and eliminating these exemptions, motor carriers will no longer be forced to knowingly allow a driver who does not meet the minimum standards to drive, thereby reducing post-crash liability.

V. Medical examiners, in consultation with the treating clinician, should be given final authority to determine driver fitness for duty.

ATA supports FMCSA's proposal to allow Medical Examiners (MEs), in consultation with the Treating Clinician (TC), to make the final determination as to whether or not a driver's ITDM is "stable and well-controlled" and can therefore be medically certified. MEs are far better positioned to make these determinations than FMCSA because they conduct the physical exams and can make direct observations of the driver regarding the individual's health and wellbeing. They can also engage in candid conversations regarding the driver health and how

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[3] 49 C.F.R. §381 Subpart C
[4] 49 C.F.R. §391.41(b)(3)
[5] 49 C.F.R. §391.41 Guidance question #3
[6] Tabulation performed by ATA via daily monitoring of the Federal Register
[7] ATA comments to Qualifications of Driver; Exemption Applications; Diabetes Mellitus, 80 FR 15, 3724 (January 23, 2015). Docket ID: FMCSA-2014-0312-0004

well they control their ITDM. Under the current exemption-based process, FMCSA makes decisions based not on direct observations but on the paperwork provided to them in the exemption application. This is clearly less informative.

ATA also supports allowing the ME to consult with the TC instead of requiring approval from an endocrinologist. With only approximately 4,000 board-certified endocrinologists who provide clinical care in the United States, driver access is severely limited.[8] In fact, in most cases, it is not the actually endocrinologist who prescribes insulin and monitors its usage. Allowing treating clinicians to provide recommendations to the ME will greatly facilitate access for ITDM drivers. ATA does however, request that FMCSA further define the term Treating Clinician to reduce ambiguity and ensure the person making the recommendation is properly certified and knowledgeable about ITDM.

VI. The monitoring of insulin usage should be the responsibility of the driver, treating clinician and ME.

ATA believes that any monitoring and compliance requirements developed by FMCSA should be the sole responsibility of the driver, medical examiner and treating clinician. Once a driver is verified as medically certified, as indicated on the driver MVR or the presentation of a medical examination certification (med card), responsibility for monitoring and submitting compliance information should not fall to the motor carrier. Motor carriers and their safety managers are not medical experts and cannot be reasonably expected to have the knowledge and understanding of the intricacies of ITDM and its many gradations. This is especially true given the frequency with which some drivers change employers, which makes monitoring each driver's specific condition much more challenging. This responsibility most appropriately resides with the medical examiners, treating clinicians and the drivers.

While carriers should not be responsible for any specific compliance requirements FMCSA may place on an ITDM driver, motor carriers should retain access to important health information available on the medical long form and other sources. Ultimately, motor carriers can be found in violation for not ensuring the driver is medically prepared for duty prior to being dispatched.[9] As such, many motor carrier use driver medical information to monitor compliance with part 392.3 and should not be precluded from doing so.

Under the proposal, the medical examiner must attest that the driver has "stable and well-controlled" ITDM. A determination of "stable and well-controlled" presumes that the driver is fully capable, and has a history of, successfully monitoring his or her glucose levels and treating his condition and is considered safe to operate a CMV. If FMCSA is convinced that drivers need additional oversight to be sure their ITDM is properly monitored to prevent

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[8] The notice at 25266.

[9] 49 C.F.R. §392.3 requires that "a motor carrier shall not require or permit a driver to operate a commercial motor vehicle, while the driver's ability or alertness is so impaired, or so likely to become impaired, through fatigue, illness, or any other cause, as to make it unsafe for him/her to begin or continue to operate the commercial motor vehicle."

against possible complications which may compromise safety, ATA encourages them to consider a graduated oversight model. Here, FMCSA could advise MEs to issue shorter term medical certifications initially. Once the driver has demonstrated his or her ITDM is "stable and well controlled," they can be issued longer term certifications up to a maximum of one year.

VII. FMCSA should provide guidance to medical examiners as to the threshold above which ITDM can be considered "stable and well-controlled."

While ATA supports allowing a ME a degree of flexibility in making a medical qualification determination in his or her best judgment, some minimum thresholds may be appropriate here. At a minimum, MEs should be instructed that in order to certify a driver with ITDM, he or she must be certain the driver has had no episodes of hypoglycemia in the past year. Additionally, the ME or TC should evaluate whether or not the driver has experienced any episodes of hypoglycemia unawareness and be sure the driver has no progressive conditions associated with diabetes including diabetic retinopathy, cataracts or nerve damage to the extremities. Finally, drivers with ITDM should be certified for a maximum period of one year, providing the ME and TC adequate opportunity for continuous monitoring.

VIII. Conclusion

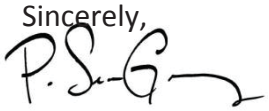
ATA thanks FMCSA for pursuing this rulemaking rather than continuing to issue exemptions to drivers with ITDM. ITDM is a serious medical ailment with the potential to result in hypoglycemia which can cause disorientation or even loss of consciousness. This can result from either not taking insulin when it is needed, or from taking too much. FMCSA should proceed with caution as the stakes are high. ATA supports FMCSA decision to allow a driver with ITDM to operate a CMV provided:

- FMCSA no longer issues exemptions to drivers who have been declared unfit to drive by a certified medical examiner;
- Motor carriers are not held responsible for monitoring driver compliance with ITDM treatment;
- Drivers are issued MECs that are valid for no longer than one year;
- FMCSA succinctly defines Treating Clinician; and
- FMCSA issues guidance defining to medical examiners on what constitutes "stable and well-controlled."

ATA believes that these changes will ensure only safe drivers are certified as medical qualified. Eliminating the exemption process will create a more efficient solution, eliminate the need for drivers to file pro forma requests, limit wasted agency resources, will broaden the pool of eligible, safe truck drivers, and will create more job opportunities for individuals suffering from ITDM.

Finally, ATA implores FMCSA to also conduct rulemakings on its other "absolute" medical standards for which it is currently issuing exemptions en masse including the vision and hearing standards. Exemptions from these medical standards only create confusion in the industry as to what constitutes a medically safe driver and what does not. It also creates an unnecessary, but easily solvable, predicament for motor carriers.

Sincerely,



P. Sean Garney
Director, Safety Policy

Response of Southern Company Entities to the Department of Transportation's Request for Comments Concerning its Proposed Rulemaking Regarding Individuals with Insulin-Treated Diabetes Mellitus Who Operate Commercial Motor Vehicles in Interstate Commerce

I. Introduction

On May 4, 2015, the Department of Transportation's Federal Motor Carrier Safety Administration ("FMCSA") issued a Notice of Proposed Rulemaking ("NPRM") related to individuals with diabetes who operate commercial motor vehicles ("CMV"). Specifically, FMCSA proposes to lessen the requirements under which drivers with insulin-treated diabetes mellitus ("ITDM") can be qualified to operate CMVs in interstate commerce. Currently, drivers with ITDM are prohibited from driving CMVs in interstate commerce unless they obtain an exemption from FMCSA. The Proposed Rule 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, provides documentation to the ME that the ITDM is stable and well-controlled. This process would replace the existing exemption system.

This response is being submitted on behalf of the subsidiaries of The Southern Company, which include Alabama Power Company, Georgia Power Company, Gulf Power Company, Mississippi Power Company, Southern Communications, Inc. d/b/a SouthernLINC, Southern Company Services, Inc. and Southern Nuclear Operating Company, Inc. These subsidiaries employ thousands of individuals who operate CMVs as part of their essential job duties. These employees regularly interact with other employees, contractors, and the general public.

II. Background Information

Diabetes mellitus ("DM") affects approximately 8.7% of the world population and approximately 9% of US population. According to the Behavior Risk Factors Surveillance System 2013, the prevalence of DM in the deep south (Alabama, Mississippi & Georgia) is higher than the national prevalence (AL 13.8% of adults over 18 years of age or approximately 510,000, MS 12.9% of adults over 18 years of age or 291,000, GA 10.8% of adults over 18 years of age or 819,000 studied).

90% of these individuals are so called Type II "non-insulin requiring" diabetics. In general, Type II diabetes:

1. Often occurs later in life(there has been an increase in younger Type II DM);
2. May have less numerous and less severe complications (but these are increasing);
3. Generally has less tendency for low blood sugar events but more so if insulin is added;
4. Is thought to be caused when individuals are insensitive to their own insulin; and
5. Requires medication to cause the individual's own insulin to work better (some Type II individuals may require insulin shots also).

10% of these individuals are so called Type I "insulin requiring" diabetics. In general, Type I diabetes:

1. Occurs more frequently in youth(although more older individuals are being diagnosed as Type I);
2. Generally has more frequent and severe complications;
3. Has a greater tendency to have low blood sugars;
4. Is thought to be caused by the body not making enough insulin; and
5. Requires insulin shots.

III. Comments to the Proposed Rule

Of the range of potential complications of ITDM, the most problematic for CDL drivers is the occurrence of hypoglycemia (low blood sugars) which can cause intense hunger, shaking, nervousness, seizures, stroke-like symptoms, and sudden loss of consciousness. These symptoms may come on with or without warning. These symptoms are more likely to happen if the insulin dose is changed or if meals are changed or missed. Stress and coexisting illness may change insulin requirements also. Because individuals with ITDM must proactively manage their behavior to decrease the chance of hypoglycemia, ongoing diabetes education is critical.

While hypoglycemia is the most common complication for individuals with ITDM (and is the focus of the Proposed Rule), there are other serious potential complications that must be considered in the context of CMVs. For example, individuals with ITDM are at an increased risk for:

1. Hyperglycemia (high blood sugars), which can cause dehydration, changes in vision, and altered mental state;
2. Heart attack, stroke, heart rhythm disorders, and similar conditions which can result in loss of consciousness or the ability to drive;
3. Vision problems, such as cataract, retinopathy, and vision loss due to vascular disease; and
4. Numbness and pain in the extremities from nerve degeneration, which commonly causes a progressive loss in sensation in the legs and which can cause tingling, burning, and aching pain in the extremities (all of which can impact the ability to feel brakes, pedals, etc.).

Recognizing these potential risks and complications, the DOT/FMCSA has traditionally restricted individuals with ITDM from operating CMVs. While some CDL holders were "grandfathered," individuals with ITDM generally must apply for and receive a special exemption (waiver) from FMCSA. In order to qualify for the exemption, the individual should:

1. Be followed by an endocrinologist knowledgeable about CMV driving issues;
2. Have yearly eye exams by an ophthalmologist/optometrist;

3. Provide a blood sugar (glucose) log of his/her finger stick glucose determinations (daily glucose log);
4. Participate in a diabetes education program at least annually; and
5. Be rechecked by a ME yearly.

The Proposed Rule eliminates many of these important safeguards. For example, the Proposed Rule does not require (1) an endocrinologist or other physician with specific knowledge of CMV/CDL issues, (2) an examination(s) designed to detect DM related visual, cardiovascular, neurological, or similar problems, or (3) ongoing diabetes education. We find the Proposed Rule to be a step backwards in the process of safely accommodating commercial drivers who require insulin as treatment for diabetes.

Instead, we recommend that the establishment of any new program (or amendment to the current exemption program) include, at a minimum, the following requirements:

1. Note from the treating physician (with specialty in diabetes, such as endocrinologist), who is familiar with unique requirements of a commercial driver (essential job functions), that his/her patient is stable on current therapy and is not experiencing hypoglycemic episodes;
2. Note from Ophthalmologist/Optometrist that the individual is free of diabetic related retinal disease, vision impairing cataracts, and has good field of vision and acceptable vision in both eyes;
3. Required attendance annually at a diabetic education program;
4. Required maintenance of a glucose log for review by the treating doctor;
5. Required evaluation and documentation that evidence of coronary atherosclerosis, peripheral or cerebral vascular disease is or is not present;
6. Required evaluation and documentation that evidence of diabetic neuropathy, paresthesia, and proprioception has been evaluated and noted by the examining doctor;
7. These requirements should be noted by the treating physician at least annually;
8. Recertification should be at least annually; and
9. Immediate reporting to the ME and the treating doctor of new and/or recurring hypoglycemia.

IV. Conclusion

The mutual goal of all parties is to ensure the safe operation of commercial vehicles in interstate commerce. The Proposed Rule will not help achieve this goal. Due to the myriad of potential and existing ailments associated with diabetes, special vigilance and care needs to be undertaken by the authorizing ME as well as the treating physician. While it is recognized that some drivers with ITDM can be certified to drive in interstate commerce, others with ITDM cannot. The risk

for the sudden loss of capacity to drive is of major concern and the approval of a driver who may experience this potentially catastrophic event must be assessed very carefully.

We appreciate the opportunity to provide these comments. Due to the serious safety concerns associated with this proposed change, we hope that these comments will be carefully reviewed and considered.

If you have any questions regarding these comments, feel free to contact Charles A. Shaw Corporate Safety & Health Manager, Southern Company Safety & Health Council Chairman.

FMCSA-2005-23151-0975-Randolph_Rosarion

U.S. Department of Transportation
Federal Motor Carrier Safety Administration
Notice of Proposed Rulemaking
Qualification of Drivers; Diabetes Standard
[Docket No. FMCSA-2005-23151]

Submitted by:
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Randolph Rosarion M.D. a certified DOT Medical Examiner listed in the National Registry of Certified Medical Examiners (NRCME) is a Board Certified physician in Physical Medicine & Rehabilitation for 20 years, who also practices Occupational Medicine. My practice Sands Point Medical Rehab is located in College Point, Queens New York and my full contact information can be found at www.usdotmedicalexaminer.com. I would like to submit my comments here as an individual in response to the Federal Motor Carrier Safety Administration (FMCSA) Notice of Proposed Rulemaking (NPRM) docket number [FMCSA-2005-23151-0098] issued on May 4, 2015. The NPRM proposes to permit on an annual basis drivers with well controlled insulin treated diabetes mellitus to operate a commercial vehicle in interstate commerce if a Treating Physician (TC) certifies that the driver is stable and well controlled on his insulin, and a Medical Examiner (ME) listed in the National Registry of Certified Medical Examiners (NRCME), working in conjunction with that TC certifies that the driver meets all other qualification requirements otherwise. Currently a driver using insulin is prohibited from driving a commercial vehicle in interstate commerce unless he or she is granted an exemption from the FMCSA. If the NPRM is passed and 49CFR part 391 is amended as the FMCSA is proposing, the current Diabetes Exemption program would no longer exist.

My viewpoints as a physician and a Certified Medical Examiner (ME)

I agree with FMCSA's proposal to eliminate the current Diabetes Exemption Program, and I believe that from reading many of the other comments already posted, and from talking to others in the industry that this is a view point shared by most commercial drivers, motor carriers and driver advocates alike. For the most part the current exemption program is costly and burdensome and likely discourages many qualified and experienced drivers from pursuing their goals.

I started performing commercial driver medical examinations 7 years ago, prior to the compliance date of the NRCME on May 21, 2014. I continue to see many drivers today in addition to the patients I care for in my regular medical practice. When it comes to the evaluation of drivers using insulin, I find that these drivers quickly become discouraged once I start discussing the exemption process and provide them a copy of the Diabetes Exemption Package. In fact, many would claim that they were not even aware of the existence of an exemption program. Those that do move forward and apply, (and in my experience they have been few and far), often become lost to follow up. This is especially true with the CDL Self Certification requirements now in place in all the states. I have seen drivers contemplating returning to the trucking profession, but because they are on insulin and do not wish to bother

submitting a lengthy application, decide to give up their CDL altogether. So removing the Diabetes Exemption Program, an apparent barrier to many drivers makes sense, and seemingly will help bring more qualified drivers to a much needed industry.

However, I do have reservations on how the NPR seeks to replace the current exemption program. This is what I would like to discuss here, and would like to thank the Agency ahead of time for the opportunity to do so. Before I start though, I would like to comment on how I came about discovering this NPR in the first place. It came about while looking through the FMCSA website and looking at regulations.gov. It did not come as a memo or a letter to MEs as was the case in previous bulletins regarding obstructive sleep apnea (OSA), or technical instructions on how to complete the Medical Examiner's Certificate (MEC), or how to add a Medical Examiner Administrative Assistant. Although it is clear to me that the Agency is not required to notify MEs or others in any fashion other than what is required by law, as was done in this current public comment period for this NPR, I do feel that at minimum a concurrent letter to all MEs listed in the Registry would have been appropriate. After all the NRCME which was mandated by Congress and created by the Agency places a significant onus on the ME. A NPR such as this one on the Diabetes Standard if passed will completely change the way MEs are required to certify commercial drivers using insulin. It will also increase the responsibilities placed on the ME, since the Diabetes Exemption Program will no longer exist, and the FMCSA will no longer play a central role in the the insulin driver certification process. That role will now be that of the ME. Therefore, it is my opinion that all MEs should have been made aware of this particular NPR directly.

Concerns I have with the Notice of Proposed Rule (NPR) and suggestions made

1. **Treating Clinician (TC)**: I will begin by addressing FMCSA's definition of TC and the role they will play in the certification process of commercial drivers using insulin. The last page of the NPRM describes how the FMCSA intends to revise 391.41 (Qualification of Drivers and Longer Combination Vehicles), and 391.45 (Persons who must be medically certified) and the addition of the new regulation 391.46 (Physical qualification standards for a person with insulin treated diabetes mellitus). The definition of TC is found in the text of 391.46 and the FMCSA describes the TC as "a physician or healthcare professional who manages and prescribes insulin for the treatment of individuals with diabetes mellitus". The TC is to evaluate the driver using insulin prior to the annual or more frequent examination that is required by 391.45 with the ME . The TC is to determine that within the previous 12 months that the driver has had no severe hypoglycemic episodes, and has properly managed the diabetes. The driver on insulin is required to monitor and maintain blood glucose records as determined by their TC, and submit those blood glucose records to the TC at the time of their evaluation. The ME who will ultimately certify such driver is responsible for obtaining written notification from the driver's TC that the driver's diabetes is being properly managed.

   I a concerned that there lacks a clear definition from the FMCSA as to what the written notification from the TC to the ME should entail. Since the monitoring for driver compliance will now be left to the TC, and since the FMCSA has no jurisdiction over the TC, how will the ME know that proper care and preventive measures were taken to ensure driver health and compliance. If I were to imagine a best case scenario in this TC and ME interaction, I would give the following as an example. Ideally the ME should receive a complete report as to what the blood glucose logs actually showed or any particular trends

that would be helpful in determining the driver's ability to manage the diabetes properly and show compliance. The TC might also note in his or her report whether or not any hypoglycemic episodes (moderate or severe) was experienced by the driver, and that the driver knows to carry a rapidly absorbable glucose while operating a commercial motor vehicle (CMV) and checks his or her blood sugar one hour prior to operating a CMV, after eating a meal and periodically every 4-6 hrs while driving. Also, that the driver has been educated and trained in hypoglycemia awareness and understands what corrective measures to take to remedy a potentially life threatening or hazardous situation. Finally, that the driver has been educated in the possible systemic side effect of diabetes, that can occur, especially when the diabetes is not well controlled, and is screened annually for conditions such as diabetic retinopathy. Given such a report from a TC it would be quite straight forward for most ME to safely certify "an otherwise qualified driver" who is using insulin. However, what was presented here is the best possible scenario, which in my experience both in treating patients and certifying commercial drivers is the exception rather than the rule. Even if the TC were to perform his duty in a responsible manner, he or she is usually busy, and may have more pressing issues at hand. Also, TCs tend to be somewhat partial or sympathetic to their patients needs (genuine or not), to expedite an encounter and may even "fudge" or do whatever it takes so that he or she is able to attend to the next patient and save face. Also, because they have not been trained in the examination of commercial drivers they usually are not familiar or sensitive to the whole driver certification process and it's importance. They often equate commercial driving with regular passenger car driving or with driving a taxi or some other vehicle such as a van or "box truck" with livery or commercial plates as is often the case in New York City where I reside. So then, how is the TC able to seriously and earnestly evaluate the driver on insulin and present the ME with a note that includes most if not all the items detailed here in the best case scenario, when they do not necessarily even know what the FMCSA is and why this doctor or chiropractor, PA or nurse who is not involved in the care of their patient keeps bothering them about "Driver John or Jane" who just wants to work and make a living? Obviously this relationship between TC and ME needs to be better defined and improved upon within the text of the NPR or there will be confusion, further delay for the driver, and the NPR will not be a means for improved driver health and public safety.

Some suggestions on how to improve the TC and ME interaction

(a) As mentioned in the best case scenario above, the TC should provide ME with supporting documentation of properly maintained glucose logs, proof of proper diabetes management and compliance, driver hypoglycemia awareness and preparedness by carrying rapidly absorbing glucose at all times and proof of yearly preventive care to screen for the long term side effects of diabetes such as retinopathy. In other words most of the provisions currently in the exemption program remain necessary. The only way to assure that the driver is being properly certified is for the FMCSA to require the ME to obtain such documentation from the TC. In my opinion the FMCSA failed to address this pivotal point by not specifying in detail the documentation that MEs should require from the TCs. The NPR literally leaves the ME unable to properly certify a driver on insulin if ME simply receives a note from TC that says, "driver manages his insulin and diabetes properly and is fit to drive commercially". Also, the FMCSA has no jurisdiction on the TC, but can audit, sanction, and remove MEs who certify drivers improperly on a repeated basis. The purpose of the NRCME was to create a group of examiners trained and knowledgeable with the demands of commercial driving,

FMCSA regulations and how CMV drivers physical examination and medical conditions affect safe driving and public safety. The FMCSA needs to give MEs the tools they need to properly evaluate the CMV driver on insulin so that the ME will not have to rely on the "hearsay" of the TC. This is a **key** and critical point for me as a ME and probably for others who have read this NPR carefully. In my opinion it requires modification by the FMCSA and that modification alone if made, would make the NPR that much more acceptable, and will allow for a safer certification process. Also, that will allow the ME to meet FMCSA expectations. These expectations from MEs were stated in the NPR by the FMCSA and I quote: " Essentially, in issuing a MEC under FMCSA regulations, the ME will reflect his or her evaluation that such drivers are free of complications that might impair the ability to operate a CMV safely in interstate commerce".

(b) The FMCSA can help educate the TC on the importance of their role as diabetes care specialist by designing digital and printed information that the ME can share with the TC, or the FMCSA can provide the ME the tools to do so and the ability to use the FMCSA logo or emblem in such educational documents. However it's done, apparent FMCSA involvement would probably carry greater weight than if these materials were conveyed solely from the ME to the TC.

(c) The ME with or without suggestions from the FMCSA can design or write a certification letter or "clearance" letter that includes the description of the duties and requirements placed on the commercial driver, as we currently have in the current Medical Examination Report Form (MER) that is used by all MEs. This will further help educate the TC as to the demands of commercial motor vehicle driving. It might emphasize to the TC of the importance of answering all questions truthfully and completely, and thank them for their participation, and remind them that their contribution will help their patients live healthier lives and stay active longer in the work force, and that their involvement will also help improve public safety. As discussed earlier, such document should contain at minimum all the provisions that currently exists in the Diabetes Exemption Program. A list or series of checkboxes that the TC can use to certify that driver manages his or her diabetes properly, such as blood glucose testing, HgA1C results, hypoglycemia awareness and prevention might facilitate the process for the TC. Once the form is completed, the TC would have to complete and sign it and provide the ME with all supporting laboratory and diagnostic tests performed on the driver with regards to their diabetes. The ME would reserve the right to request additional testing such as formal visual field perimetry screening and testing and others, if the ME believes it is necessary for proper certification of a driver using insulin.

2. **Hypoglycemia-The need to undergo hypoglycemia awareness training**

On the subject of hypoglycemia and hypoglycemia awareness the FMCSA has stated that the proposed rule has no requirement for hypoglycemia awareness training because the annual or more frequent ME certification exam and TC's evaluations provide sufficient time to intervene should it be deemed necessary. The importance of hypoglycemia awareness training is well accepted in the medical literature. I will refer the FMCSA to the American Diabetes Association (ADA) website, the ADA studies cited by Health and Safety Works, LLC on this NPR. I agree with Health and Safety Works that the omission of moderate hypoglycemia by the FMCSA in the NPR is not only erroneous but presents a significant safety concern. The studies which were cited from the American Diabetes Association (ADA) clearly show that in moderate hypoglycemia, although the driver

is able to treat his or herself, both judgement and safe driving are impaired. The ADA studies regarding moderate hypoglycemia are important despite the emphasis placed by the FMCSA in this NPR on the risks of severe hypoglycemia, as reported by the 2006 and 2010 Medical Review Board(MRB) reports. if the full statement of the MRB report is read carefully, after indicating to the FMCSA that they allow insulin treated diabetes mellitus drivers to drive CMVs if they are free of severe hypoglycemic reactions, the MRB also said that such driver should have no altered mental status or unawareness of hypoglycemia, and manage their diabetes mellitus properly to keep blood sugar levels in the appropriate ranges. Although one of the main distinction between moderate and severe hypoglycemia rests in the fact that in moderate hypoglycemia the driver tends to be able to treat his or herself but is unable to do so in severe hypoglycemia, the fact remains that the driver's mental status and judgement is affected, albeit to varying degrees but nevertheless possibly enough to still interfere with safe driving. Therefore, the need for the TC to submit to the ME documentation and proof of proper hypoglycemia awareness training by the driver is critical and should not be undermined.

3. **The operation of CMVs with hazardous materials or carrying passengers and 391.64**

Hazardous materials and passenger carrying CMVs

As far as the ability of ITDM drivers to operate CMVs involved in carrying passengers or hazardous materials the 2012 ADA study "Diabetes and Driving" reference by the FMCSA in the NPR was done primarily on non-CMV drivers, and as such I do not believe can be used in assessing safety in this specific types of driving. However, I concur with the FMCSA that the risk posed by a driver with stable well controlled insulin treated diabetes are low, that there is no evidence to support restricting the type of driving they are able to do. Furthermore, as stated by the FMCSA the current exemption program allows insulin treated drivers to qualify for passenger and hazardous material transport. From my point of view as a ME, I see no reason for that to change, and support continuing to allow the insulin treated driver to operate all types of CMVs, unless new studies performed on CMV drivers state to the contrary. I will defer further comment on this matter to the motor carriers involved in hazardous material transportation and the motor coach companies involved in passenger transportation.

391.64

As far as the remaining drivers involved in the grandfathering program after the termination of the 1994 ITDM waiver program, they should be held to the same standards as all ITDM drivers and I concur with the FMCSA that 391.64 would be redundant if the NPR is passed. With the withdrawal of the Diabetes Exemption Program, so too should 391.64 be eliminated. The remaining drivers from this program (and I am not sure of the number and how many are still active) would first see the TC and then be certified by the ME in the usual manner if the NPR is adopted. I do not see how they would be affected adversely, if certified like all other ITDM drivers.

4. **The role of the annual diabetes eye examination with opthalmologist/ optometrist**

The FMCSA asked for comments specifically on the need to be assessed by an ophthalmologist or optometrist as a condition of passing the physical exam. Unfortunately, I can not answer this question with a simple yes or no. However, in my opinion not

having an exemption program should not mean a driver using insulin does not ever need to see an opthalmologist /optometrist. Depending on driver health and how well the diabetes is managed, it may be necessary more frequently in some than others.
What would be eliminated though is the burdensome process, the automatic signed statements and quarterly reports found in the current exemption program.

A dilated eye exam is generally recommended to properly assess the retina or back of the eye, especially in diabetics. Most ME probably do not routinely perform dilated eye exams with their opthalmoscopes and generally do not have specialized equipment such as digital photography in their office. This is the speciality of eye specialists such as optometrists and opthalmologists. On the other hand, a driver who presents to the ME for an examination (whether he or she has ITDM or not) can pass the DOT physical if his or her visual acuity, peripheral field of vision and color vision perception meet the standards, and receive a MEC providing no other conditions are present that would impair his or her ability to operate a CMV. However, I don't think that this is the relevant question to ask here in an individual with ITDM.

The ADA states that people with diabetes are more likely to develop problems that can lead to blindness than people who do not have diabetes. Of the two types, non-proliferative and proliferative, non-proliferative is less likely to cause blindness but can still progress to fluid leakage into the macula, macular edema, and blurry vision that lead to blindness. With the more serious proliferative retinopathy, neo-vascularization, and scarring that occurs can lead to retinal detachment and blindness. Good glycemic control and regular eye examinations are recommended by the ADA as a standard of care for diabetics. The frequency of screening is yearly, and the ADA states that evidence for less frequent screening every two years in diabetics with no retinopathy at the outset is not yet supported by current research. So, given the recommendations of the ADA, and from the Clinical Practice Guidelines (CPG) used by medical centers (CPG can be found at sites such as **www.guideline.gov** , a national guidelines clearing house, and **www.Pubmed.org** , yearly retinopathy screening is generally accepted as a best practice recommendation and standard of care for diabetics. The FMCSA should require the TC to perform yearly eye examinations for the ITDM driver or send him or her to an eye specialist to perform such examination and provide the results to the ME.

Diabetic retinopathy study
A recent study cited by the ADA at their website : Progression of diabetes retinal status within community screening programs and potential implications for screening intervals, by Leese and colleagues. Diabetes Care 2015;38:488–494 - **http://care.diabetesjournals.org/content/38/3/488** will be referenced here.
The study was done in 354,000 patients who had exams in one of seven eye screening programs in the U. K. between 2005 and 2012. It was done to watch the progression from no retinopathy to various degrees of retinopathy in people with diabetes and to determine how often they should have an eye exam. Patients with no retinopathy or background retinopathy (defined as mild non-proliferative retinopathy) were followed for four years to see if they progressed to what was termed "referable retinopathy" (moderate or worse non-proliferative disease) and or macular edema or "treatable retinopathy" (which is the more serious aforementioned proliferative retinopathy). The results showed that 16,196 out of the 354,00 studied progressed to referable retinopathy or the moderate or worse non-proliferative type of retinopathy. In the patients with no retinopathy in either eye 0.3-1.3 % progressed

to referable retinopathy and less than 0.3% progressed to treatable retinopathy (or proliferative retinopathy) after 2 years. Those with mild background retinopathy in both eyes 13-29% progressed to referable retinopathy and 4% to treatable retinopathy.
The results of the study indicate that diabetics can be screened into various risk categories based on the degree of retinopathy they have to assess the need for eye screening. Those with low risk can be screened every 2 years, moderate risk every year and high risk two times per year. Limitations of the study is that it was a retrospective chart review looking back at the records of patients who already had eye exams and not a prospective study that could look at the effects of changing the intervals of the eye examination with the occurrence of retinopathy.

To return again to the question posed by the FMCSA regarding the need for an ophthalmologist or optometrist evaluation as a condition to pass the DOT physical, I think that the recommended standard of care as described by the ADA, the research supported in the literature, and the CPG used in medical training that I and other physicians have received all concur that diabetics are more at risk than the general population and should be screened, and at the minimum once every year. The ADA and the current CPG and research do not yet fully support less frequent screening. I would therefore strongly recommend the continuation of the yearly eye examination of the driver with diabetes by an optometrist or opthalmologist regardless of whether or not the CMV driver passes their commercial driver medical examination.

5. **Enforcement for compliance of driver with insulin ITDM versus economic burden**

The FMCSA has stated that “FMCSA has determined 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. This is the reason given to eliminate the Diabetes Exemption program, and as previously stated I concur with the FMCSA. However, with regards to continued monitoring of the ITDM driver, and enforcement of compliance I believe that such provisions should be maintained even without the current exemption program, and that they are practical, and do not present an undue economic burden for the driver. Whether we are discussing truck drivers, police officers, fireman or any other persons with ITDM, the overall health and well being of that person rests in their desire and ability to properly monitor and treat their condition. The ADA supports glucose monitoring, glucose logs, hypoglycemia awareness and carrying a rapidly absorbable form of glucose in case of emergencies. The provisions of the current Diabetes Exemption Program require that. Those provisions should not be eliminated in the NPR. Relying on the driver alone to honestly report his condition without any enforcement measures in place is not a guarantee of compliance and does not improve public safety. That is the reason it is necessary for the TC to provide the ME with more than just an “OK to drive” note. As a physician who also actively treats patients, I can never accept such a note from another physician. Why would it be any different for me as a ME?

What needs to be done to enforce ITDM driver compliance with TC recommendations?

There are many ways to go about it but ultimately I do believe that a modification of sorts needs to be made to the Medical Examiner's Certificate (MEC). I have discussed some of these ideas with Health and Safety Works and I reference to you their contribution to this NPR with regards to the training of roadside inspectors to check for glucose logs and verifying that driver has a rapidly absorbable form of glucose, as well as indicating the requirement for these items on the MEC, as is currently done for corrective lenses or the SPE certificate. Without the exemption program the FMCSA will not directly oversee the driver with ITDM. The driver in turn may only see the TC and ME once a year, unless there has been a roadside event or driver's health changes and he or she goes to the TC and is referred back to the ME. Even then, the ME may remain in the dark unless TC or motor carrier refers driver back to ME. This is again the reason why it should be a requirement for the ME to obtain complete documentation from the TC. The TC should be made aware by ME at the time of the initial evaluation of the driver that any changes in the driver's health status should be reported back to the ME.

The FMCSA contends that reasonable persons like those with ITDM have every incentive to manage their condition well, because failure to do so will lead to adverse events like a hypoglycemic episode that can potentially cause them to lose their CDLs. I disagree. I believe that this argument is likely posed to make the case that there is no real need for enforcement once the driver is cleared by the TC and certified by the ME. From my experience treating patients (not just those with ITDM), most do not follow their physician's instructions. Patients, if they do take their medications at all, will vary dosage, frequency and generally report what they want, unless they were frightened or worried about some adverse event. They may alter or embellish their treatment regimen with the use of over the counter supplements or perhaps obtain medications from friends and families or the world wide web. Interestingly enough, after evaluating commercial drivers over many years it one day dawned upon me that not only are they like my regular medical patients, but that a majority of my medical patients drive professionally for a living. I just never placed much emphasis on their job description as truck drivers until I started evaluating them as a ME. So apparently, they are one of the same for the most part, whether they are truck drivers, police officers, office workers or medical or law professionals. To say that CMV drivers or others would behave a certain way because of the fear of losing their jobs, would be like assuming that most reasonable people would not take the chance and use illicit drugs at times, so therefore there is no need for a drug and alcohol testing program.

I wish to thank the FMCSA for the opportunity to comment on this very important rulemaking. Please contact me with any questions or concerns.

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FMCSA-2005-23151-1140-Health and Safety Works, LLC

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:

Health and Safety Works, LLC
Primary Contact:
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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 very 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 included 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 diver 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 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 ~~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 regiment 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 site 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 the 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.

<u>Enforcement of the Diabetes Exemption Program Provisions</u>

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.

<u>Modifying the Medical Examiner Certificate to include blood sugar logs and carrying rapidly absorbable glucose</u>

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 F~~N~~MCSA 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 de-

ceive 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.

FMCSA-2005-23151-1143-The First Five MRB Members

**[Part 1 of this comments was posted as docket item 1143
and part 2 was posted as docket item 1102. Both are in this file.]**

We appreciate the FMCSAs statements over the years on eliminating the Diabetes/Insulin and Vision Exemption programs to save the costs of over $5M/year. Still driver, employer, coworker and public safety need to be properly factored into a proposed rule change.

These are part 1 of our comments (Please either see PDF or equest the references as the website is challenging to submit a referenced document).

Epidemiological studies 1,2,3,4,5 and the FMCSAs contracted systematic review 6. show that DM drivers have approx. 20% increased risk of crash,7 with some estimates substantially higher. Those taking insulin have an approx.. 40-130% increased risk of crash. Parsing data down to insulin use and US-based studies in FMCSAs 2010 Evid. Report yields a concerning finding of an estimate of 2.3, suggesting risk is likely more than doubled, though it currently lacks statistical sig. (OR=2.32, 95% CI 0.6-9.7). 8 Clinicians efforts to tighten glucose control to drive hemoglobin A1cs below 7% is a substantial concern for further increasing crash risk. 9

Thus, the FR statement that, FMCSA evidence reports, ADA studies, and MRB is well-controlled was, and remains, false. 10 A 40-130% increased crash risk is critically important. A brief literature search we conducted (June 2015) to ascertain whether recent data change the conclusions instead provided additional evidence that DM and insulin are risks for crash. 11,12,13

Thus, the best available scientific evidence on crash risk among diabetics contradicts at least 2 FR statements:

The risk posed very low in general, [sic] and
The ADAs summary of findings also reflects FMCSAs conclusion based on the available evidence.

The implied purpose of this FMCSA proposal to eliminate the insulin exemption program includes a desire to enlarge the pool of DM drivers. As such, the prior experiences with (1) DM Waivers, (2) DM Exemptions, or (3) Lg. Truck Causation Study are unusable to infer what would happen to a larger driver pool. This is because of a number of factors that include inclusion of (1) currently ineligible drivers, and (2) likely less well-controlled diabetics the proposal is likely to enroll due to its largely unstructured requirements. Use of those 3 datasets to infer what would happen to others could be considered an example of an ecological fallacy, and those same ecological fallacy problems were previously pointed out to FMCSA, e.g., by the

Vision Medical Expert Panel. 14

The following FR text ignores the cohort of DM drivers who do not adhere to therapy: Reasonable persons with ITDM have every incentive but also would significantly increase the risk of a hypoglycemic event. Instead, a surprising number engage in safety sensitive work, truck driving, etc., and their examiners sign off that they are in good control when they are not.

The MRB specified that for public safety, the medical examiner (ME) evaluating drivers with DM should be an MD/DO, 15 but this specification was neglected, further it states without specificity: At least annually, an ME, listed on the National Registry for annual or more frequent recertification. [sic]

In contrast with MRB recommendations to limit the overall pool of examiners to MD, DO, NP and PAs, 16 there are now thousands of CDME MEs with no significant medical training (including chiropracters, naturopaths). Thus, the following intent of the proposed rule cannot be met: The practice of medical certification make an individualized assessment of a particular drivers health status and ability to operate a CMV, [sic] as there cannot be an expectation for an individualized assessment of risk of hypoglycemia, medications, interactions with various medical conditions, etc. by naturopaths, DCs, high school trained nurses and any other group that is now allowed by state laws to be in the NRCME that lacks in-depth education and clinical experience with all these issues.

An added challenge is that the primary and tertiary treaters for DM drivers often lack sufficient understanding of safety sensitive work. More specifically, they often do not understand the specific demands on truck drivers.

Based on the above considerations, the FMCSA cannot meet the intent of its following proposed rule change: Furthermore, although the MRB recommended(a)(3) for periodic physical examinations of drivers. [sic]

The current proposal could yield a common combination of an inexperienced HCP plus a chiropractor with perhaps a dozen hours or less of combined clinical training in diabetes deciding whether someone meets safety sensitive work requirements. This is inadequate.

See part 2 for a proposed solution.

We trust these potential solutions are helpful.

Sincerely,
The first five FMCSA Medical Review Board Members (titles on other comment submission):

Kurt T. Hegmann, MD, MPH
Gunnar Andersson,
Michael Greenberg, MD, MPH
Matthew Rizzo, MD
Barbara Phillips, MD, MSPH

July 3, 2015

Docket Services (M–30), U.S.
Department of Transportation, West
Building Ground Floor, Room W12–140,
1200 New Jersey Avenue SE.,
Washington, DC 20590–0001.

Re: Federal Motor Carrier Safety Administration
49 CFR Part 391
[Docket No. FMCSA–2005–23151]
RIN 2126–AA95

To Whom It May Concern:

We appreciate the FMCSA's statements over the years on eliminating the Diabetes/Insulin Exemption and Vision Exemption programs to save the costs of over $5M/year. Still driver, employer, coworker and public safety need to be properly factored into a proposed rule change.

Epidemiological studies[1],[2],[3],[4],[5] and the FMCSA's own contracted systematic review,[6] show that diabetic drivers have about a 20% increased risk of crash,[7] with some estimates substantially higher. Those taking insulin have an approximately 40-130% increased risk of crash. Parsing the data down to insulin use and US-based studies in the FMCSA's 2010 Evidence Report yields a concerning finding of a point estimate of 2.3, which suggests the risk is likely more than doubled risk, even though it currently lacks statistical significance (OR=2.32, 95% CI 0.6-9.7).[8] Further, continuing efforts to tighten glucose control to drive hemoglobin A1c's below 7% is a substantial concern for further increasing crash risk.[9]

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[1] Songer TJ, Lave LB, LaPorte RE. Risk Anal. 1993 Jun;13(3):319-26.
[2] Songer TJ, Dorsey RR. Annu Proc Assoc Adv Automot Med. 2006;50:335-351.
[3] Redelmeier DA, Kenshole AB, Ray JG. PLoS Med. 2009 Dec;6(12):e1000192.
[4] Kilpatrick ES, Rigby AS, Warren RE, Atkin SL. Diabet Med. 2013 May;30(5):616-9.
[5] Orriols L, et al. Accid Anal Prev. 2014 Oct;71:137-43.
[6] Diabetes and Commercial Motor Vehicle Drive Safety. 2006.
http://ntl.bts.gov/lib/30000/30100/30117/Final_Diabetes_Evidence_Report.pdf
[7] Diabetes and Commercial Motor Vehicle Drive Safety. 2006.
http://ntl.bts.gov/lib/30000/30100/30117/Final_Diabetes_Evidence_Report.pdf
[8] Evidence Report. 2010 Update: Diabetes and Commercial Motor Vehicle Driver Safety.
http://ntl.bts.gov/lib/39000/39400/39416/2010_Diabetes_Update_Final_May_27_2011.pdf
[9] Kilpatrick ES, Rigby AS, Warren RE, Atkin SL. Diabet Med. 2013 May;30(5):616-9.

Thus, the Federal Register statement that, "FMCSA evidence reports, ADA studies, and MRB conclusions and recommendations indicate that drivers with ITDM are as safe as other drivers when their condition is well-controlled" was, and remains, false.[10]

A 40-130% increased crash risk is critically important, especially in a population with a considerable disease prevalence rate. Perhaps more importantly, a brief literature search we conducted (June 2015) to ascertain whether recent data could change the conclusions regarding risk instead provided additional evidence that diabetes and especially insulin use are risks for crash.[11],[12],[13]

Thus, the best available scientific evidence on crash risk among diabetics contradicts at least two Federal Register statements:

"The risk posed by a driver with stable, well-controlled ITDM is very low in general," [sic] and "The ADA's summary of findings concerning the risks of driving and diabetes concludes that, "[M]ost people with diabetes safely operate motor vehicles without creating any meaningful risk of injury to themselves or others." [sic] This statement also reflects FMCSA's conclusion based on the available evidence."

The implied purpose of this FMCSA proposal to eliminate the insulin exemption program includes a desire to enlarge the pool of diabetic drivers. As such, the prior experiences with (1) the Diabetes Waiver program, (2) the recent Diabetes Exemption program, or (3) the Large Truck Causation Study are unusable to infer what would happen to a larger driver pool. This is because of a number of factors that include inclusion of (1) currently ineligible drivers, and (2) likely less well-controlled diabetics the proposal is likely to enroll due to its largely unstructured requirements. Use of those 3 datasets to infer what would happen to others could be considered an example of an ecological fallacy. These exact same ecological fallacy problems were previously pointed out to the FMCSA, e.g., by the Vision Medical Expert Panel.[14]

The following Federal Register text ignores the cohort of drivers with diabetes who do not adhere to therapy:

"Reasonable persons with ITDM have every incentive to manage their condition so that the disease is stable and well-controlled, because the failure to take care of themselves not only would affect the quality of life, but also would significantly increase the risk of a hypoglycemic event."

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[10] "FMCSA evidence reports, ADA studies, and MRB conclusions and recommendations indicate that drivers with ITDM are as safe as other drivers when their condition is well-controlled."
[11] Kilpatrick ES, Rigby AS, Warren RE, Atkin SL. Diabet Med. 2013 May;30(5):616-9.
[12] Redelmeier DA, Kenshole AB, Ray JG. PLoS Med. 2009 Dec;6(12):e1000192.
[13] Orriols L, et al. Accid Anal Prev. 2014 Oct;71:137-43.
[14] Vision and commercial Motor Vehicle Driver Safety. Medical Expert Panel.. 2008 http://www.fmcsa.dot.gov/sites/fmcsa.dot.gov/files/docs/MEP-Recommendations-Vision-v2-prot.pdf

Instead, a surprising number engage in safety sensitive work, truck driving, etc., and their examiners sign off that they are in good control when they are not.

The MRB specified that for public safety, the medical examiner (ME) evaluating drivers with DM should be an MD/DO,[15] but this specification was neglected by the FMCSA recommendation, which states without further specificity:
"At least annually, an ME, listed on the National Registry, must examine and certify that the driver is free of complications that would impair the driver's ability to operate a CMV safely and only renew the medical certificate for up to 1 year. This proposed requirement is consistent with the MRB recommendation for annual or more frequent recertification." [sic]

In contrast with MRB recommendations to limit the overall pool of examiners to MD, DO, NP and PAs,[16] there are now thousands of Commercial Driver MEs who have no significant medical training (including chiropracters, naturopaths). Thus, the following intent of the proposed rule cannot be met:
"The practice of medical certification through MEs is more efficient and is reflective of congressional intent to have MEs on the National Registry make an individualized assessment of a particular driver's health status and ability to operate a CMV," [sic] as there cannot be an expectation for an individualized assessment of risk of hypoglycemia, medications, interactions with various medical conditions, etc. by naturopaths, chiropracters, high school trained nurses and any other group that is now allowed by state laws to be in the NRCME that lacks in-depth education and clinical experience with all these issues.

An added challenge is that the primary care and tertiary treaters for the diabetic drivers often lack sufficient understanding of safety sensitive work. More specifically, they often do not understand the specific demands on truck drivers.

Based on the above considerations, the FMCSA cannot meet the intent of its following proposed rule change:
"Furthermore, 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." [sic]

The current proposal could yield a common combination of an inexperienced health care provider plus a chiropractor with perhaps a dozen hours or less of combined clinical training in diabetes deciding whether someone meets safety sensitive work requirements. This is inadequate.

As providing sufficient required training for all of these personnel (chiropracters, naturopaths, nurse practitioners, physician assistants, primary care physicians,

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[15] MRB meeting July 26, 2007. http://www.mrb.fmcsa.dot.gov/072607_meeting.aspx

[16] MRB meeting January 12, 2009. http://www.mrb.fmcsa.dot.gov/documents/FinalJan122009_MRB_Meeting_Sum_Certified4-22-09.pdf

endocrinologists, etc.) is likely impractical and insurmountable, that means that the best solution is either to maintain the current program or to provide unequivocally clear criteria. After careful consideration, if a change in the current Diabetes Exemption program is to be enacted, then we recommend that the requirements be:

- Development of a 3-step form ("Diabetic Annual Form") that the driver would need to get completed. This could be an approximately 1-2 page form. Parts would include sections completed by the driver, the healthcare provider, and an ophthalmologist/optometrist. Some details follow.
- Drivers should attest to no severe hypoglycemic reactions in the prior year on the Diabetic Annual Form.
- Drivers should be required to check fingerstick glucose levels prior to and every 4 hours while driving. Glucose levels should be maintained at at least 100mg/dL while driving.[17] They should attest to having performed fingerstick testing on this schedule on the Diabetic Annual Form.
- Healthcare providers should attest to no severe hypoglycemic reactions in the prior year on the Diabetic Annual Form.
- No hemoglobin A1c over 10%.[18] When, as currently the case that some providers are signing off that control is "satisfactory" and "good" at 12-13-14%, the proposed rule is insufficiently clear on this point.[19] Without clarifications of both A1cs and severe hypoglycemia reactions, the suppositions of the rule[20],[21] are unlikely to prove correct. Resumption of driving is recommended to be considered allowable when the HgbA1c is below 10%. This is recommended to be on the healthcare provider part of the Diabetic Annual Form.
- Requires at least annual examinations by an ophthalmologist or optometrist to evaluate and certify that there is no proliferative diabetic retinopathy, and to score the retinas. (The rationale in the proposed rule to not require eye exams[22] is directly in opposition to efforts to reduce what is the leading cause of blindness in the US. The rule's supposition that reasonable persons will avoid that complication implies that most adults with acquired blindness are thus, in essence, reckless. By the time

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[17] Endocrinologist Annual Evaluation Checklist. http://www.fmcsa.dot.gov/sites/fmcsa.dot.gov/files/docs/Diabetes-Annual-Endo-Vision-Evaluation-Checklist-508.pdf

[18] Diabetes Waiver Program.

[19] must obtain and review written notification from the TC that the person is properly managing the diabetes mellitus.

[20] The sharing of information between the ME on the National Registry and the TC would ensure that only drivers who are controlling their ITDM would receive a 1-year medical certificate.

[21] The Agency would change the requirement from an annual evaluation by a board-certified endocrinologist to one with a TC because the treating licensed healthcare professional is capable of determining whether the driver's condition is well-controlled.

[22] The rule would eliminate an annual eye exam, because a qualified ME on the Agency's National Registry could determine whether the driver meets the vision standard.

the driver may experience a reduction in visual acuity that is captured by the relatively crude CDME (i.e., fails ability to correct to at least 20/40), it is often too late. Note also that because the examiners in the NRCME are (1) so often without any significant medical training as noted above, (2) not required in the CDME to perform direct ophthalmoscopy, (3) cannot reasonably be expected to perform direct ophthalmoscopy when so many are untrained examiners in that examination performance, let alone in the ascertainment of retinopathy via direct ophthalmoscopy even if that was now changed to a CDME examination requirement, thus there is further need for mandatory, annual eye examinations for retinopathy by ophthalmologists/optometrists.[23]

- No diabetic retinopathy above Stage 1 is acceptable. The risks of progression, which may occur very suddenly, are too high. Disease staging should be on the Diabetic Annual Form.
- No laser treatments for retinopathy. This should be included on the Diabetic Annual Form
- No intraocular injections for retinopathy. This should be included on the Diabetic Annual Form
- Vision exemptions should not be acceptable in this context in contrast with the proposed rule language.
- No hypoglycemia unawareness. This should be included on the healthcare provider part of the Diabetic Annual Form
- No severe hypoglycemia episodes (i.e., no hypoglycemia with seizure, loss of consciousness, needing help of another to recover or impaired cognitive function without warning). The proposed rule is not clear regarding number of episodes nor times between them.[24] It must be, and prior published FMCSA criteria would form the basis for those aspects of a rule change (simple rules could be included on the Diabetic Annual Form, similar to those for hypertension on the current CDME):
    - The driver is required to report any severe hypoglycemia episodes to their healthcare provider who is treating them for the diabetes mellitus. These and other elements should be included on the Diabetic Annual Form
    - If there is a severe hypoglycemia episode within any one year period, then there is at least a 1-year period of removal from work.
    - If there is a third severe hypoglycemic episode in any 5-year period, then the worker is removed from driving for a 5-year period during

[23] The cost assumptions of this proposed rule appear to need a more vigorous approach. Based on usual guidelines and recommendations, the diabetic driver should already have an annual eye exam. Thus the cost of a mandatory requirement should be net zero. Eliminating the requirement for an eye exam could considerably increase costs if diabetic drivers forego eye exams, develop retinopathy that is naturally first discovered on visual acuity testing, and then is placed on Social Security and other Disability insurance mechanisms, thus increasing aggregate costs.

[24] Paragraph (b) would require the person with diabetes mellitus currently requiring insulin for control to have an evaluation by his or her TC who would determine that the driver had not experienced a recent severe hypoglycemic reaction and was properly managing the disease.

which they must demonstrate control without severe hypoglycemia before resuming truck driving.

- Continue to follow prudent guidance against transporting passengers or hazardous materials while using insulin.[25]
- Those using high-risk medications such as insulin for hypoglycemia should be examined at least every 6 months.
- To address sufficient training in diabetes, complications of diabetes, interactions among diabetic medications, etc., the proposal should state that there should be an MD/DO who at minimum oversees a mid-level provider and counter-signs the form approving the individual with insulin use as safe to drive.

We trust these potential solutions are helpful.

Sincerely,
The first five FMCSA Medical Review Board Members:

Kurt T. Hegmann, MD, MPH (MRB Chair 2006-2010). Professor and Center Director of the Rocky Mountain Center for Occupational and Environmental Health, University of Utah

Gunnar Andersson, MD. Emeritus Professor, Orthopaedics Chair Emeritus and Past Vice President, Rush University

Michael Greenberg, MD, MPH. Professor of Emergency Medicine and Chief Division of Medical Toxicology, Drexel University

Matthew Rizzo, MD Professor and Chair of Neurology, University of Nebraska

Barbara Phillips, MD, MSPH. Professor and Sleep Center Director, University of Kentucky.

[25] MRB meeting July 26, 2007. http://www.mrb.fmcsa.dot.gov/072607_meeting.aspx

FMCSA-2005-23151-1102-The First Five MRB Members

This is part 2 of our comments.

After careful consideration, if a change in the current Diabetes program is to be enacted, we recommend:

Development of a 3-step, approx. 1-2pp form (Diabetic Annual Form (DAF)) that the driver would get completed, including sections completed by the driver, the HCP, and an ophthalmologist/optometrist. Some details follow.

Drivers should attest to no severe hypoglycemic reactions in the prior year on DAF.

Drivers should check fingerstick glucose levels prior to and Q4 hrs while driving. Glucose levels should be at least 100mg/dL while driving. 17 Should attest to having performed fingerstick testing on this schedule on the DAF.

HCPs should attest to no severe hypoglycemic reactions in the prior year on the DAF.

No hemoglobin A1c over 10%. 18 When, as currently the case that some providers are signing off that control is satisfactory and good at 12-13-14%, the proposed rule is insufficiently clear. 19 Without clarifications of both A1cs and severe hypoglycemia reactions, the rule's suppositions 20,21 are unlikely to prove correct. Resumption of driving is recommended to be considered when HgbA1c is <10%. This is recommended to be on the HCP part of DAF.

Requires at least annual examinations by an ophthalmologist or OD to eval. and certify there is no proliferative diabetic retinopathy, and to score retinas. (Proposed rule's rationale to not require eye exams 22 is directly in opposition to efforts to reduce what is the leading cause of blindness in the US. The rules supposition that reasonable persons will avoid that complication implies that most adults with acquired blindness are thus, in essence, reckless. By the time the driver may experience a reduced visual acuity that is captured by the relatively crude CDME (i.e., fails correcting to 20/40), it is often too late. Note also that because the examiners in the NRCME are (1) so often without any significant medical training as noted above, (2) not required in the CDME to perform direct ophthalmoscopy, (3) cannot reasonably be expected to perform direct ophthalmoscopy when so many are untrained examiners in that exam performance, let alone in the ascertainment of retinopathy via direct ophthalmoscopy even if that was now changed to a CDME exam requirement, thus there is further need for mandatory, annual eye examinations for retinopathy by ophthalmologists/ODs. 23

No diabetic retinopathy above Stage 1 is acceptable. The progression risks, which may occur very suddenly, are too high. Disease staging should be on DAF.

No laser treatments for retinopathy. This should be included on the DAF

No intraocular injections for retinopathy. Should be on the DAF

Vision exemptions should not be acceptable in contrast with the proposed rule language.

No hypoglycemia unawareness. This should be included on the HCP part of DAF

No severe hypoglycemia episodes (i.e., no hypoglycemia with seizure, loss of

consciousness, needing help of another to recover or impaired cognitive function without warning). The proposed rule is unclear regarding number. of episodes nor times between them. 24 It must be, and prior published FMCSA criteria would form the basis of a rule change (simple rules could be included on the DAF, similar to those for hypertension on the current CDME):

- The driver is required to report any severe hypoglycemia episodes to their HCP who is treating them for the diabetes mellitus. These and other elements should be included on the DAF
- If there is a severe hypoglycemia episode within any 1-yr period, then there is at least a 1-yr period of removal from driving.
- If there is a third severe hypoglycemic episode in a 5-year period, then the worker is removed from driving for a 5-year period during which they must demonstrate control without severe hypoglycemia before resuming driving.
- Continue to follow prudent guidance against transporting passengers or hazardous materials while using insulin. 25
- Those using high-risk medications such as insulin for hypoglycemia should be examined at least every 6 months.

To address sufficient training in diabetes, complications of diabetes, interactions among diabetic medications, etc., the proposal should state that there should be an MD/DO who at minimum oversees a mid-level provider and counter-signs the form approving the individual with insulin use as safe to drive.

We trust these solutions are helpful.

Sincerely,
The first five FMCSA MRB Members:
Kurt Hegmann, MD, MPH (MRB Chair 2006-2010). Professor and RMCOEH Center Director, U Utah
Gunnar Andersson, MD. Emeritus Professor, Orthopaedics Chair Emeritus and Past Vice President, Rush U.
Michael Greenberg, MD, MPH. Professor of Emergency Medicine and Chief Division of Medical Toxicology, Drexel University
Matthew Rizzo, MD Professor and Chair of Neurology, U. Nebraska
Barbara Phillips, MD, MSPH. Professor and Sleep Center Director, U. Kentucky.

FMCSA-2005-23151-1152-Transportation_Trades_Department,_AFL-CIO

July 6, 2015

Ms. Linda Phillips
Medical Programs Division
Federal Motor Carrier Safety Administration
Department of Transportation
1200 New Jersey Ave., SE
Washington, DC 20590

RE: **Qualifications of Drivers; Diabetes Standard**
Notice of Proposed Rulemaking
Federal Motor Carrier Safety Administration
FMCSA-2005-23151
RIN 2126-AA95

Dear Ms. Phillips:

On behalf of the Transportation Trades Department, AFL-CIO (TTD), I write in support of the Notice of Proposed Rulemaking (NPRM) on Qualifications for Commercial Motor Vehicle (CMV) Drivers; Diabetes Standard. By way of background, TTD consists of 32 affiliate unions representing workers in all modes of transportation, including those who are medically certified to operate a CMV. We therefore have a vested interest in this rulemaking.[1] In addition to the comments that follow, we endorse those separately filed by TTD affiliates, the Amalgamated Transit Union (ATU) and the Sheet Metal, Air, Rail Transportation Union – Transportation Division (SMART-TD).

TTD affiliates represent a diverse group of workers who maintain commercial drivers licenses (CDLs) for employment and are required by the Federal Motor Carrier Safety Administration (FMCSA) to be medically certified in order to operate a CMV. Some of these drivers live with insulin-treated diabetes mellitus (ITDM) and are currently subject to an unnecessary time-consuming and financially burdensome exemption process (49 CFR Part 381) in order to receive certification to drive a CMV. TTD has a history of supporting commonsense changes to alleviate this burden while ensuring that drivers with well-controlled ITDM are safe operators.[2] This rulemaking simplifies the certification process for these workers while maintaining safety, and we commend FMCSA for moving forward with this proposal.

[1] Attached is a complete list of TTD's 32 affiliate unions.

[2] In addition to other advocacy, TTD filed comments to FMCSA's ANPRM under this proceeding. 80 FR 25260, June 15, 2006.

Current regulations prohibit drivers with ITDM from operating a CMV unless they receive an exemption to prove they are healthy and fit to operate. But as FMCSA explains, evidence shows that drivers living with well-controlled ITDM are safe to operate CMVs, and DOT has a responsibility to ensure that drivers with ITDM are not subject to unnecessary additional burdens as a result of their condition. As such, this NPRM eliminates the exemption requirement and establishes physical qualification standards (proposed 49 CFR 391.46) for medically certifying operators with well-controlled ITDM.

Under the proposed standards, individuals with ITDM must be evaluated by a "treating clinician" who manages insulin treatments for individuals with diabetes mellitus. This clinician must determine that the driver has not had a recent severe diabetes episode and properly manages her/his condition. Such information must be provided to the medical examiner (ME) who is certifying the driver, and the ME must determine the driver is physically qualified to operate a CMV. These drivers must also monitor and maintain blood glucose records and provide them to the treating clinician who is evaluating the driver.

We support the requirement that a driver's condition is evaluated by a physician who is knowledgeable of diabetes and familiar with managing and prescribing insulin treatment plans, as these physicians are best positioned to accurately assess the driver's health. Given that MEs are ultimately responsible for certifying drivers, we request FMCSA to encourage discussion between MEs and treating clinicians to resolve any potential miscommunication or confusion that may occur so that fit drivers may begin working as quickly as possible.

This proposed policy will provide welcomed relief to drivers required by FMCSA to be medically certified as well as those subject to state certification standards. As the agency knows, states across the country maintain their own certification requirements applicable to drivers operating within the state's borders. These drivers may also benefit from FMCSA's policy change if their state updates existing medical standards to reflect this NPRM.

No one is more committed to maintaining a high level of safety in the CMV industry than those operating these vehicles, and FMCSA's proposal embraces safety while supporting responsible drivers who manage their ITDM. We support this NPRM and appreciate the opportunity to comment. We hope FMCSA will take our comments into consideration.

Sincerely,

Edward Wytkind
President

Transportation Trades Department, AFL-CIO
A bold voice for transportation workers

TTD MEMBER UNIONS

Air Line Pilots Association **(ALPA)**
Amalgamated Transit Union **(ATU)**
American Federation of Government Employees **(AFGE)**
American Federation of State, County and Municipal Employees **(AFSCME)**
American Federation of Teachers **(AFT)**
Association of Flight Attendants-CWA **(AFA-CWA)**
American Train Dispatchers Association **(ATDA)**
Brotherhood of Railroad Signalmen **(BRS)**
Communications Workers of America **(CWA)**
International Association of Fire Fighters **(IAFF)**
International Association of Machinists and Aerospace Workers **(IAM)**
International Brotherhood of Boilermakers, Iron Ship Builders,
Blacksmiths, Forgers and Helpers **(IBB)**
International Brotherhood of Electrical Workers **(IBEW)**
International Longshoremen's Association **(ILA)**
International Organization of Masters, Mates & Pilots, ILA **(MM&P)**
International Union of Operating Engineers **(IUOE)**
Laborers' International Union of North America **(LIUNA)**
Marine Engineers' Beneficial Association **(MEBA)**
National Air Traffic Controllers Association **(NATCA)**
National Association of Letter Carriers **(NALC)**
National Conference of Firemen and Oilers, SEIU **(NCFO, SEIU)**
National Federation of Public and Private Employees **(NFOPAPE)**
Office and Professional Employees International Union **(OPEIU)**
Professional Aviation Safety Specialists **(PASS)**
Sailors' Union of the Pacific **(SUP)**
Sheet Metal, Air, Rail and Transportation Workers **(SMART)**
SMART-Transportation Division
Transportation Communications Union/ IAM **(TCU)**
Transport Workers Union of America **(TWU)**
UNITE HERE!
United Mine Workers of America **(UMWA)**
United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union **(USW)**

These 32 labor organizations are members of and represented by the TTD

Owner-Operator Independent Drivers Association

National Headquarters: 1 NW OOIDA Drive, Grain Valley, MO 64029
Tel: (816) 229-5791 Fax: (816) 427-4468

Washington Office: 1100 New Jersey Ave, SE, Washington, DC 20003
Tel: (202) 347-2007 Fax: (202) 347-2008

July 6, 2015

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

RE: **Qualification of Drivers; Diabetes Standard, FMCSA-2005-23151**

Dear Acting Administrator Darling:

The Owner-Operator Independent Drivers Association (OOIDA) appreciates the Federal Motor Carrier Safety Administration's (FMCSA) efforts to permit drivers with "stable, well-controlled insulin-treated diabetes mellitus (ITDM) to be qualified to operate commercial motor vehicles (CMVs) in interstate commerce" without needing to obtain an exemption from the FMCSA.

OOIDA is the largest international trade association representing the interests of independent owner-operators of commercial motor vehicles (CMVs), small business motor carriers, and professional drivers. The approximately 150,000 members of OOIDA are professional drivers and small-business men and women located in all 50 states and Canada who collectively own and operate more than 200,000 individual heavy-duty trucks. The average OOIDA member has more than 25 years in the trucking industry and has more than two million miles of accident-free truck driving experience.

Since the implementation of the exemption program by the FMCSA in 2003, drivers with a stable history of treating their insulin dependent diabetes have proven to be safe drivers. However, the exemption process itself is cumbersome and time consuming, placing safe drivers with ITDM at heightened risk of losing their jobs, missing employment opportunities, or being forced out of the trucking industry . The diabetes qualification process proposed by FMCSA in this notice of proposed rulemaking is a much more effective route for the agency and the driver, while continuing to ensure safe operation of CMVs.

Ensuring that the treating clinician, who is most familiar with the patient, is able to evaluate the driver should be the key component in any proposal, and OOIDA is pleased to see this focus in the NPRM. An annual (or even more periodic) visit to a certified medical examiner (CME) will not provide appropriate means for assessing the driver's diabetes-related health and treatment. The ongoing treatment relationship with the treating clinician (not necessarily an endocrinologist) who has experience in diabetes care and the individual's medical condition and history will provide a much better means for determining if the condition is stable and well-controlled.

OOIDA also supports the agency's decision to continue to allow drivers with ITDM to transport hazardous materials. As the FMCSA stated in the NPRM, there is no medical evidence to

support prohibiting drivers with ITDM from certain operations. Drivers who transport hazardous materials are frequently some of the most experienced and safest operators on our nation's highways, and their highway safety performance should be the focus, not an arbitrary condition-based decision.

In addition to our own comments, OOIDA endorses the comments submitted by the American Diabetes Association (ADA) to this NPRM. OOIDA would like to specifically highlight our agreement with the ADA's comments regarding "§ 391.46(b)(1) Evaluation by the Treating Clinician" and "§ 391.46(b)(2) Medical Examiner's Evaluation." Ensuring clarity in the evaluation criteria and in the role of the CME are important steps that the FMCSA should take as the agency finalizes this rulemaking.

The agency's approach in this NPRM is reflective of a risk-based approach to medical conditions, commercial vehicle operations, and safety on our nation's highways. OOIDA is supportive of this approach and is hopeful that the perspective taken by the agency in this rulemaking will guide further conditions-based medical policymaking.

Thank you for your consideration of OOIDA's comments.

Sincerely,

Todd Spencer
Executive Vice President

July 6, 2015

Docket Management Facility
U.S. Department of Transportation
1200 New Jersey Avenue, SE
West Building, Ground Floor
Room W12-140
Washington, D.C. 20590-0001

RE: Docket No. FMCSA-2005-23151 – Notice of Proposed Rulemaking: Qualifications of Drivers; Diabetes Standard

Dear Sir/Madam:

The American Bus Association (ABA) appreciates the opportunity to comment on the Federal Motor Carrier Safety Administration's (FMCSA's or Agency's) notice of proposed rulemaking (NPRM) proposing to permit drivers with controlled insulin-treated diabetes mellitus (ITDM) to be qualified to operate commercial motor vehicles (CMVs) in interstate commerce.

ABA is the leading trade association for private and over-the-road passenger operators who transport the public and serve the motorcoach industry. ABA has been in operation for over 80 years and has over 800 bus operating company members, large and small, intercity and charter and tour operators, rural and urban. Our members provide all manner of passenger transportation services, including intercity scheduled service, charter and tour operations, airport and employee shuttle services. In addition, ABA membership includes hotels, convention and visitors bureaus, attractions, restaurants, motorcoach manufacturers and companies that provide services to the motor coach industry. Motorcoach companies carry out more than 600 million passenger trips per year, moving individual passengers a total of 65 billion miles annually.

ABA's members pride themselves on their commitment to safety. There active participation in such groups s like the Bus Industry Safety Council, the Bus Maintenance and Repair Council, the Commercial Vehicle Safety Alliance, the Transportation Research Board's Bus and Truck Safety Committee and other groups committed to safe and compliance operations, is a clear reflection of this commitment. It is within this context ABA submits these comments on behalf of its membership.

In brief, the ABA supports maintaining the current exemption approach to enabling drivers with

insulin-treated diabetes mellitus (ITDM) be qualified to operate passenger carrying CMVs in interstate commerce.

Motorcoach passenger carrier operations are not unlike aviation passenger carrier operations in terms of the precious cargo that they transport and the safety responsibilities imposed on the vehicle operator, i.e. pilots. In fact, in terms of attentiveness, drivers of motor vehicles operate in an even more challenging environment than airline pilots as they do not have the ability to resort to automatic piloting operations for any segment of their respective trip – they must stay focused on their driving responsibilities at all times during the driving operation. Additionally, airline transport pilots are not flying alone – there is co-pilot, a second, qualified person in the cockpit able to step in to the safety sensitive position in the event of an emergency. Yet for pilots, under the aviation regulatory framework, diabetes mellitus requiring hypoglycemic medications is deemed a disqualifying medical condition for obtaining a medical certificate, a requirement for airline transport pilot licensing. Now, the Federal Aviation Administration (FAA) does provide an opportunity for issuing a contingent medical certificate, not unlike the current FMCSA exemption program, when a medical condition is controlled. But nonetheless, airmen using insulin to control their condition must receive FAA approval to obtain a contingent medical certificate.

As the NPRM notes, there is a long history on how regulators have approached the issue of physical qualification standards for CMV drivers with ITDM. The current exemption approach was based on a lengthy effort that included the compiling and evaluation of information and research, along with a review by a panel of medical experts in the treatment of diabetes, for the sole purpose of determining the feasibility of developing a "practicable and cost-effective" protocol. This protocol has worked; ABA is at a loss on why the Agency now wishes to disturb or change something that works.

Further, FMCSA's own Medical Review Board (MRB) recognizes drivers of passenger vehicles are not conducting the same operation as cargo carrying CMV drivers, and require a higher medical standard. The Agency states it is impermissible under the law to set a higher standard of physical qualification for ITDM drivers; however, the law does provide for exceptions, as exemplified by the current exemption process. Drivers of passenger carriers face unique demands, in terms of meeting customer needs; and of course, their cargo is far more precious, human lives. Based on this fundamental difference, the MRB specifically recommended maintaining a restriction on medical qualification of drivers with ITDM for passenger operations. ABA supports this position. By maintaining the current exemption process for drivers with ITDM who are interested in operating passenger CMVs, the Agency provides these drivers an opportunity to seek a living as a driver, while maintaining an appropriate level of Federal oversight to ensure the safety of drivers engaged passenger carrier operations.

As well, in its notice, FMCSA relies on a position paper provided by the American Diabetes Association (ADA), for the proposition that "Most people with diabetes safely operate motor vehicles without creating any meaningful risk to themselves or others." However, from a passenger carrying motor carrier standpoint, "most people" is not an acceptable risk. Both the MRB and ADA concluded that there are inherent safety risks for drivers with diabetes mellitus, and identified hypoglycemia as the chief safety concern. Further, both MRB and ADA believe

drivers with ITDM whose condition is stable and well-controlled, do not pose an unreasonable risk. While ABA does not question these findings or belief, it does not believe passenger carriers should be placed at the risk of assessing the medical condition of a driver or whether the driver is vigilant in maintaining their condition. ABA does not support the shifting of risk from the Agency to the passenger motor carrier; or alternatively, ABA does not believe FMCSA's proposal sufficiently protects passenger motor carriers from an unacceptable risk.

ABA believes the Agency's current process for issuing an exemption from the federal motor carrier safety regulations (FMCSRs) to certain drivers with ITDM, on a case by case basis, provides a thoughtful, balanced approach to ensuring the safety of the traveling public while still providing the opportunity for these drivers to pursue a driving career. ABA is concerned by the Agency's position, as stated in the NPRM, that "inconvenience and expense to drivers" and "administrative burdens to the agency," are motivating the Agency to pursue this course and outweigh the safety risk to passenger carrier operations and the traveling public. As well, ABA is surprised by the Agency not following its own MRB recommendations, but rather proposing requirements consistent with ADA recommendations. The ADA is a well-respected association serving the needs of the broad community effected by diabetes, and it should be commended for its efforts. However, in terms of motor vehicle safety, we believe the FMCSA plays a key role in determining the physical qualification of drivers with ITDM, and should not relinquish this role by eliminating the exemption process.

As well, ABA is concerned about the NPRM proposal to endocrinologists from the process. These medical professionals who specialize in the identification and treatment of this disease, are the best qualified individuals to be engaged in the process, in ABA's view. So, though while we appreciate the interest in simplifying the process or putting less restrictions on the medical professionals available to drivers with ITDM, it is difficult to understand the reasoning to support this decision.

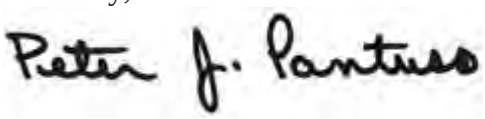
Finally, ABA members who currently employ ITDM drivers with an exemption have shared that their drivers endorse the current exemption process, believing the medical condition requires the vigilance and scrutiny provided through this process. Further, they note the positive impact the exemption process has had on their working relationship with their employer. By having a formal process by which companies are aware of their ITDM drivers condition, companies are better able to put the driver's health and wellness at the forefront of their planning in terms of scheduling and itinerary development. The increased flexibility and collaborative input afforded by the current exemption process would likely disappear or at be minimized if the exemption process were eliminated.

Considering the legacy of driver safety initiatives and efforts by FMCSA/DOT to improve passenger motor carrier safety over the course of time, including establishing drug and alcohol testing standards, distributing fatigue/sleep apnea guidance, implementing minimum age requirements, and developing entry-level driver training curriculum, among others, ABA is struggling to understand why the Agency would pursue an initiative likely to decrease, rather than increase driver safety at this time.

To reiterate, ABA supports maintaining the current exemption approach to enabling ITDM

drivers to be qualified to operate passenger carrying CMVs in interstate commerce. The tragedy of a passenger motor carrier accident cannot be overstated; it not only affects the immediate passengers and company involved, but the entire passenger motor carrier industry and the traveling public. We implore you to heed the MRB's recommendation, and not proceed with this proposal with regard to the passenger motor carrier industry.

Sincerely,



Peter J. Pantuso
President & CEO

OFFICE OF THE SECRETARY OF STATE

JESSE WHITE • Secretary of State

Date: June 30, 2015

[FMCSA-2005-23151-1246-IL Sec of State]

Docket Services (M-30)
U. S. Department of Transportation
West Building Ground Floor, Room W12-140
1200 New Jersey Avenue SE
Washington, DC 20590-0001

RE: Docket Number FMCSA-2005-23151

Dear Sir or Madam:

The Illinois Office of the Secretary of State, in response to the Notice of Proposed Rulemaking (NPRM) published in the May 4, 2015 *Federal Register* regarding "Qualifications of Drivers; Diabetes Standard," would like to offer our comments for your consideration. Within the NPRM to permit drivers with stable, well-controlled insulin-treated diabetes mellitus (ITDM) to be qualified to operate commercial motor vehicles (CMVs) in interstate commerce without holding an exemption, FMCSA requested states specifically comment on five issues. Listed below are the issues and our comments on each one.

In this notice, the proposed rule "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."

FMCSA requests public comment on the proposal to not prohibit drivers with ITDM from being medically qualified to operate CMVs carrying passengers and hazardous materials.
The Illinois Office of the Secretary of State agrees with continuing to permit drivers with well-controlled ITDM to qualify for passenger carrying and hazardous materials transportation, provided drivers with ITDM submit a MEC completed by a certified ME at least annually. We do not believe continuing this practice will be detrimental to traffic safety.

FMCSA seeks comments on the decision to not require annual or more frequent medical recertification for all drivers with diabetes mellitus (as opposed to only those drivers with IDTM).
The Illinois Office of the Secretary of State agrees with FMCSA's proposal to *not* adopt the Medical Review Board's recommendation to require annual or more frequent medical recertification for all drivers with diabetes mellitus. We believe the current regulations are sufficient to safely license drivers with diabetes mellitus; barring any evidence to the contrary, we do not believe any change to the current procedure is warranted.

FMCSA seeks comments on the decision to utilize the TC working in conjunction with the ME (rather than the MRB recommended licensed physician) for the periodic physical examinations of drivers.
The Illinois Office of the Secretary of State is in agreement with FMCSA in its decision to utilize the TC, working in conjunction with the ME, to complete the periodic physical examinations of drivers. It is our belief the TC, having personal knowledge of the driver's past and recent medical history, and working with an ME certified by the National Registry, would be able to make a more accurate determination of a driver's ability to safely operate a motor vehicle.

FMCSA seeks comments regarding whether removing these grandfathering provisions would adversely affect any driver that is operating currently under 391.64.
The Illinois Office of the Secretary of State does not believe removing the grandfathering provisions would adversely affect drivers currently operating under §391.64. There are currently ten (10) drivers in the State of Illinois who are grandfathered under §391.64 and it is our belief that holding them to the proposed standard in this NPRM will not adversely impact their safety, as well as the safety of other motorists, as drivers of CMVs.

FMCSA requests comments 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 Illinois Office of the Secretary of State agrees that drivers with ITDM should not be required to obtain an annual examination by an optometrist or ophthalmologist or a separate examination for diabetic retinopathy provided the driver can meet the standards in §391.41(b)(10) as part of the annual exam by a ME listed in the National Registry of Certified Medical Examiners. We believe this process will provide a reasonable certainty that any drivers who cannot meet the standard in §391.41(b)(10) will be discovered by the ME during the annual exam. Utilization of this process will not present any threat to general traffic safety.

In summary, the State of Illinois agrees with FMCSA's proposal to enable individuals with ITDM to obtain a MEC from a ME at least annually in order to operate in interstate commerce if the TC who is responsible for prescribing insulin for the driver's diabetes provides documentation to the ME that the condition is stable and well controlled. We appreciate the opportunity to comment on this very important issue. If you should have any questions or wish to discuss any of our comments, please do not hesitate to contact my office at (217) 524-5488.

Sincerely,

Michael J. Mayer

Michael J. Mayer, Director
Driver Services Department

MJM:dc

[FMCSA-2005-23151-1247-AAPA]

July 1, 2015

Docket Services (M-30)
U.S. Department of Transportation
West Building Ground Floor
Room W12-140
1200 New Jersey Avenue, S.E.
Washington, D.C. 20590-0001

RE: Docket No. FMCSA-2005-23151

On behalf of the more than 100,000 nationally certified physician assistants (PAs) represented by the American Academy of Physician Assistants (AAPA), I wish to thank the Federal Motor Carrier Safety Administration, U.S. Department of Transportation (FMCSA/DOT) for the opportunity to submit comments on the proposed rule to permit drivers with stable, well-controlled insulin-treated diabetes mellitus (ITDM) to be qualified to operate commercial motor vehicles in interstate commerce. Although the AAPA does not have a position on the proposal to replace the current two year FMCSA exemption for drivers with controlled ITDM with an annual certification, AAPA supports the proposed rule's affirmation of the role of all commercial driver medical examiners (CDMEs) in the medical evaluation and recommends clarification of the definition of "Treating Clinician."

AAPA is pleased that the proposed rule:

- Acknowledges that healthcare professionals other than physicians may be responsible for prescribing insulin for a driver's ITDM and managing the driver's condition through the use of the new term, treating clinician (TC); and
- Encourages communication between the TC and the FMCSA CDME regarding the management of the driver's diabetes.

AAPA wholeheartedly supports the FMCSA decision to not recommend past proposals offered by the FMSCA Medical Review Board to restrict exemptions for a commercial driver with ITDM to CDMEs who are physicians.

AAPA believes that PAs, by virtue of their medical education, ongoing certification of competency, quality of practice, and team-based practice model, are qualified to examine and certify by their signature any commercial driver. The CDME does not need to be an endocrinologist, a sleep specialist, orthopedist, or neurologist to perform an appropriate commercial driver (CD) examination – rather, the CDME needs to understand what medical

information is needed and how it relates to commercial driver safety and health risks. An integral part of the CD medical examination process, particularly for drivers with multiple medical problems, is for the CDME to obtain medical records, consultations, and recommendations from attending medical providers and specialists according to the circumstances of the case. PAs routinely request and assimilate such records and consultations into medical decision-making for patients they treat. Since PAs are capable of routinely performing this medical function in treating patients, PAs are also capable of performing this function for CD medical certifications.

AAPA is pleased with the proposed rule's use of the term, "treating clinician," acknowledging that the healthcare professional who is responsible for managing the driver's ITDM may be a clinician other than a physician. However, the definition of treating clinician is not specific. (The rule defines treating clinician as "a physician or healthcare professional who manages and prescribes insulin for the treatment of individuals with diabetes mellitus.") ***However, AAPA recommends that the definition of treating clinician (Section 391.46 (b)(1)) be more clearly stated through the following definition, "For purposes of this paragraph, 'treating clinician' means a physician, physician assistant, or nurse practitioner who manages and prescribes insulin for the treatment of individuals with diabetes mellitus."***

Physicians, PAs, and nurse practitioners (NPs) represent the three healthcare professionals in the U.S. who provide primary medical care. All three healthcare professionals diagnose illness, develop and manage treatment plans for their patients, manage patient panels, and serve as patients' principal healthcare professional.

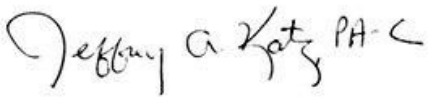
In rural and other medically-underserved communities, a PA may be the only healthcare professional in the community. Chronic care management, including management of diabetes, is a key component of a typical PA's practice. AAPA's 2013 Annual Survey revealed that 64% of PAs provide chronic disease management – and most of these PAs see patients with multiple chronic conditions. Furthermore, PAs provide an important access point in medically underserved areas of the nation.

Just as AAPA utilizes best practices established by the American Diabetes Association (ADA) in its continuing medical education offered to PAs, AAPA believes that the FMCSA should make available to CDMEs ADA guidelines for the management of diabetes mellitus. AAPA applauds the FMCSA rule's embrace of all CDMEs in determining whether the driver may receive the medical certificate, in consultation with the driver's treating clinician. AAPA recommends that the rule's definition of treating clinician be clarified to state that a physician, PA, or NP who manages and prescribes insulin for the treatment of individuals with diabetes mellitus may serve as the treating clinician.

AAPA appreciates the FMCSA's continued outreach to the AAPA throughout the development of the National Registry of Certified Medical Examiners (NRCME) and for its attention to AAPA's comments. AAPA looks forward to a continued partnership with the FMCSA throughout the implementation of the NRCME that best serves the needs of interstate commercial carriers,

drivers, and the public's safety. Should you have any questions regarding the PA profession or the Academy's comments, please do not hesitate to contact Sandy Harding, AAPA senior director of federal advocacy, at 571-319-4338 or sharding@aapa.org.

Sincerely,



Jeffrey A Katz, PA-C, DFAAPA
President and Chair of the Board

FMCSA-2005-23151-DRAFT-1254 Sharon Newman-Kemp

As a diabetes educator, I feel that patients should not be kept from driving commercially just because they take insulin. In fact, many truck drivers have high blood pressure and kidney problems and therefore are safer on insulin than pills. Most pills in this case might trigger low blood sugar and has greater unpredictability than insulin.

I believe that truck drivers should be allowed to drive commercially but there should be standards and guidelines that they should have to follow to make sure that they are safe to drive.

They should have to follow-up every 6 months at minimum with an endocrinologist and diabetes educator to make sure that they are not having multiple episodes of hyperglycemia or hypoglycemia. This will protect the public from those who are not safe to drive. This can be easily done by following up with an endocrinologist, downloading their glucose meter and viewing their readings, monitoring their hemaglobin A1c, and or requiring them to wear a glucose sensor for a week/month if needed and downloading their readings. One can view their glucose values every 5 minutes for the period of wear.

This safety standard should be for any person driving any vehicle; no discrimination needed. If the person is not safe, they should not be allowed to drive. With my many years of experience as a diabetes educator, I believe that a person can be safe to drive a commercial vehicle as long as the diabetes is controlled and therefore their should be guidelines for this just as it is for high blood pressure, etc. It does not make them automatically unsafe. Safety for the person taking insulin and the public is of utmost importance.

July 9, 2015

U. S. DOT Docket No. FMCSA-2005-23151
Docket Management Facility
Room W12-140
U.S. Department of Transportation
1200 New Jersey Avenue, S.E.
Washington, D.C. 20590

Qualifications of Drivers; Diabetes Standard
Notice of Proposed Rulemaking
80 FR 25260, May 4, 2015

Advocates for Highway and Auto Safety (Advocates) files these comments in response to the publication by the Federal Motor Carrier Safety Administration (FMCSA, agency) of a Notice of Proposed Rulemaking (NPRM) to "permit drivers with stable, well-controlled insulin-treated diabetes mellitus (ITDM) to be qualified to operate commercial motor vehicles (CMVs) in interstate commerce.[1] Advocates tentatively supports the proposed rulemaking but only under the condition that the proposed rulemaking conform to the recommendations of the FMCSA's Medical Review Board (MRB); namely that individuals with ITDM be permitted to drive only if they are:

1. free of severe hypoglycemic reactions;
2. have no altered mental status or unawareness of hypoglycemia;
3. manage their diabetes mellitus properly to keep blood sugar levels in the appropriate ranges; and
4. are restricted from passenger and hazardous materials transportation.

The agency should also adjust regulations to require that all drivers diagnosed with diabetes mellitus be required to obtain at least annual recertification by an ME who is a licensed physician, in accordance with the MRB recommendations.[2]

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[1] Qualifications of Drivers; Diabetes Standard; Notice of Proposed Rulemaking, 80 FR 25260 (May 4, 2015).

[2] As of the date of the submission of these comments, the Expert Panel Opinion resulting from the MRB review of the FMCSA Evidence Report: 2010 Update has not been published to the FMCSA website (http://www.fmcsa.dot.gov/regulations/medical/reports-how-medical-conditions-impact-driving), nor has it been added to the public docket FMCSA-2005-23151. As a result Advocates and the public are forced to comment based on the FMCSA's statements regarding the MRB Expert Panel Opinion. Should the MRB Expert Panel Opinion differ from the summary provided by the agency in the present notice, it is likely that opinions express in these and other comments may be different from those initially presented.

While the proposed rule attempts to meet a number of these recommendations, it does ignore several of them and falls short in several other respects. For these reasons, Advocates would endorse the rule if it is modified to adopt the MRB recommendations.

Advocates has long opposed the medical waiver and exemption programs established by the FMCSA because they enshrine exceptions to the established medical standards in the federal motor carrier safety regulations (FMCSR). Advocates has taken the position that if the available medical knowledge supports a change in the prevailing medical the standards the agency should revise the federal standard, but should not operate experimental exemption programs that may endanger public safety. Advocates acknowledges that medical information and the state of knowledge regarding ITDM has advanced in the past decade, and the work of the MRB regarding the specific restrictions needed for drivers with ITDM is to be lauded. Advocates, therefore, does not oppose elimination of the ITDM exemption program and supports revision of the medical standard for diabetes to permit drivers with ITDM to operate motor vehicles in interstate commerce. The restrictions imposed on ITDM drivers, however, must reflect and incorporate the findings of the MRB.

Free of Severe Hypoglycemic Reactions

If a driver sustains hypoglycemic reactions resulting in loss of consciousness or seizure, or requiring the assistance of another person, or resulting in impaired cognitive function, while behind the wheel of a CMV carrying as much as 80,000 lb. this represents a significant risk to the driver and those sharing the road with the driver. Despite the agency's protestations in the NPRM, the most recent evidence report indicates that in the U.S., there is "approximately a 24 percent increase in crash risk among drivers with diabetes compared with drivers without diabetes."[3] Additionally, the report noted that "there was a significant increase [175%] in crash risk for individuals treated with insulin compared with drivers treated with oral medication and/or diet alone." Considering these findings, it is important that the agency heed the MRB's recommendations.

In terms of ensuring that drivers with ITDM are "free of severe hypoglycemic reactions" Advocates concurs with the FMCSA's proposed language to require that the driver, within the previous 12 months, have had no severe hypoglycemic reaction resulting in loss of consciousness or seizure, or requiring the assistance of another person, or resulting in impaired cognitive function. However, without knowing just how wide the population of individuals who could fall under the definition of a "treating clinician" and without knowing the specifics of the MRB recommendations, Advocates is concerned that the reporting requirement may be too lax and open to potential abuse. The agency should require the "treating clinician" be a licensed physician and establish penalties for drivers and treating clinicians who submit falsified reports concerning the medical history of drivers with ITDM, specifically concerning the management of diabetes and the occurrence of severe hypoglycemic reactions.

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[3] Evidence Report: 2010 Update: Diabetes and Commercial motor Vehicle Driver Safety; FMCSA, May 27, 2011, p. 64.

Have no altered mental status or unawareness of hypoglycemia

Unawareness of hypoglycemia was identified as an item of concern by the MRB in the most recent evidence report. The report states that:

> Hypoglycemic unawareness is the reduced ability or failure to recognize hypoglycemia at the physiological plasma glucose concentration at which warning symptoms normally occur. Patients with hypoglycemia unawareness either do not realize that the plasma glucose is decreasing, or they ultimately feel the symptoms, but at much lower plasma glucose levels than normal. Such individuals are more prone to incapacitation consequent to hypoglycemia because preventative action that will increase blood glucose levels is not taken in a timely manner.[4]

Moreover, the MRB report states "[h]ypoglycemia unawareness is of particular concern in a discussion of driver safety."[5] This is of particular concerns because studies noted in the report found that the decision to not drive during a hypoglycemic episode is not often made correctly. The American Diabetes Association similarly recommended that "the driver's ability to recognize imminent hypoglycemia and take appropriate corrective action" be a part of the information reported by the physician to the licensing authority.[6]

The FMCSA must establish hypoglycemic awareness testing and requirements to prevent the issuance of CDLs to those drivers with ITDM with the highest risk and history of failing to identify hypoglycemic episodes which could lead to dangerous reactions.

Manage their diabetes mellitus properly to keep blood sugar levels in the appropriate ranges

Advocates supports the FMCSA's proposal to require the treating clinician to determine that within the previous 12 months that drivers with ITDM properly managed their diabetes, and the requirement for the submission of the blood glucose records. However, similar to concerns about the occurrence of severe hypoglycemic reactions, Advocates is concerned with the possible ambiguity in the proposed language. Concerns with the definition of the "treating clinician" and penalties for falsified records are stated above and are not repeated here. Advocates is also concerned with the lack of a definition of "appropriate ranges" or management which could be left open to considerable interpretation and result in doctor shopping where drivers with ITDM seek out those "treating clinicians" with the loosest definition of "appropriate ranges" or successful management. Finally, the agency should require drivers with ITDM to submit blood glucose records for a specified time period prior to the medical evaluation and issuance of the CDL to support and document the conclusions of the treating clinician. Leaving the definition of the appropriate level of reporting to the treating

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[4] Evidence Report: 2010 Update: Diabetes and Commercial motor Vehicle Driver Safety; FMCSA, May 27, 2011, p. 32.
[5] Evidence Report: 2010 Update: Diabetes and Commercial motor Vehicle Driver Safety; FMCSA, May 27, 2011, p. 32.
[6] 80 FR 25265.

clinician could again encourage treating clinician or doctor shopping. The FMCSA must make efforts to ensure that expanding the opportunity for employment to drivers with ITDM does not place the drivers or the public at risk and does not promote abuse of the system.

R*estricted from passenger and hazardous materials transportation.*

Advocates is most concerned with the FMCSA's decision to not follow the MRB's recommendation to restrict drivers with ITDM from passenger and hazardous materials transportation. Particularly in the absence of access to the MRB expert opinion report, that the MRB made this recommendation in light of the increase risk of injury to multiple persons (in the transportation of passengers) or the increased severity of crashes (in the transportation of hazardous materials). As noted above, the increased crash risk of individuals with diabetes in the U.S. has been confirmed through study, as has the increased risk for drivers treated with insulin. While the agency opines that "the risk posed by a driver with stable, well-controlled ITDM is very low in general,"[7] the intent of the requirements is to ensure that the drivers who are issued CDL's through the program are, in fact, those with stable, well-controlled ITDM. If the agency is unwilling to adopt the MRB's recommendation, it should consider restricting access to passenger and hazardous materials transportation to those drivers with ITDM who have driven freight under the conditions of the proposed regulations and have a safe driving record for a specified amount of time.[8]

Annual Recertification for All Drivers with Diabetes

Advocates recommends that the agency reconsider not requiring all drivers with diabetes to have annual recertification by a medical examiner who is a licensed physician. Without access to the MRB Expert Panel Opinion document, Advocates is left to postulate that the MRB sees this as an opportunity to ensure that drivers with diabetes are not hiding a pending diagnosis of ITDM to evade the requirements. Moreover, this may provide an additional opportunity for drivers with the disease to increase contact with the medical community to support them in stemming the progression of the disease. As the MRB pointed out in the evidence report, risk factors for diabetes include obesity, physical inactivity, and high blood pressure; all of which are prevalent among drivers of commercial motor vehicles. The agency should establish more frequent medical recertification for all drivers with diabetes and consider working with the MRB to identify other diseases for which health and safety concerns could warrant more frequent contact.

Conclusion

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[7] 80 FR 25265.

[8] It is recommended that the agency should consider the circumstances surrounding the 1999 motorcoach crash, investigated by the NTSB, in which 22 passengers were killed and another 22 were injured and the resulting recommendations of the NTSB before electing to ignore the MRB decision. NTSB Highway Accident Report HAR-01/01, available at http://www.ntsb.gov/Investigations/AccidentReports/Pages/HAR0101.aspx

Advocates supports the effort to improve opportunities for individuals with ITDM to pursue careers as CMV drivers, but this effort should be undertaken cautiously and in keeping with the expert advice of the MRB which was established for precisely this reason. In the present case, the proposed rule implements some of the MRB recommendations but not others, and some of the implementing regulatory language is ambiguous enough to permit possible abuse of the system. The agency should release to the public the full MRB expert panel opinion report, adjust the proposed language to implement all MRB recommendations, and rework the proposed language to prevent the opportunity for abuse of the system.

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July 6, 2015

Federal Motor Carrier Safety Administration
Docket Services (M-30)
U.S. Department of Transportation
West Building Ground Floor
Room W12-140
1200 New Jersey Avenue SE.
Washington, DC 20590-0001.

Docket No. FMCSA-2005-23151

Re: Qualifications of Drivers; Diabetes Standard

To Whom It May Concern:

On behalf of the American College of Occupational and Environmental Medicine (ACOEM), we welcome the opportunity to comment on the Federal Motor Carrier Safety Administration's (FMCSA's) proposed changes to the medical qualification standards which would permit drivers with stable, well-controlled insulin-treated diabetes mellitus (ITDM) to be qualified to operate commercial motor vehicles (CMVs) in interstate commerce without needing to obtain an exemption from FMCSA as is presently required. If enacted, this proposed change 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 health care professional responsible for prescribing insulin for the driver's diabetes, provides documentation to the ME that the condition is stable and well controlled.

The American College of Occupational and Environmental Medicine (ACOEM) is an international society of approximately 4,000 occupational and environmental physicians and other health care professionals. The College provides leadership to promote the health and safety of workers, stimulate research, enhancing education, and advance the specialty of OEM, the medical specialty devoted to the prevention and management of occupational and environmental injuries and illnesses. As such, ACOEM is the only medical specialty society uniquely involved in the matching of the worker's capabilities to the job requirements.

While we support simplifying the process by which drivers with ITDM can be qualified to operate CMVs in interstate commerce, we have serious concerns that the proposed rule will sacrifice safety.

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OEM physicians perform hundreds of thousands of physical examinations for interstate truck driver medical certification. Unlike many other health care professionals, OEM physicians understand the importance of evaluating not only the individual's current medical condition, but also the job tasks an individual is required to perform and how that worker's condition may impact safe performance of those tasks.

While we agree that the educated and motivated CMV operator with ITDM should be able to safely perform his/her duties without risk of sudden or gradual impairment or incapacitation, we are concerned that the proposed rule does not adequately ensure that the driver's ITDM is adequately controlled. It is imperative that a complete and individualized assessment of the driver's diabetes be conducted by both the TC and the ME and should include the following:

- history of blood glucose control;
- knowledge of diabetes and its management;
- current stability of blood glucose;
- risk for significant hypoglycemia or hyperglycemia; and
- presence of diabetic complications.

One major concern with the proposed rule is the reliance on the TC to ensure that the driver with ITDM can safely operate a CMV. In the proposed rule, FMCSA states: "The evaluation by the TC would ensure that the driver is complying with an appropriate standard of care for individuals with ITDM and would allow the TC to monitor for any of the progressive conditions associated with diabetes (e.g., nerve damage to the extremities, diabetic retinopathy, cataracts and hypoglycemia unawareness). The ME must obtain information from the TC to demonstrate the driver's condition is stable and well controlled."

While the TC who signs the statement may be an endocrinologist or another physician, the TC may also be a non-physician licensed health care professional who may only treat the diabetic patient under the supervision of a physician. ACOEM members have found many primary care providers and specialists, who are being asked to provide input or clearance for drivers to operate a commercial motor vehicle safely, are often unaware of the safety sensitive tasks and hazards of commercial operations, often basing their statement solely on the subjective reports of the driver. Furthermore, our members frequently relate instances where personal physicians write "return to work" notes for their patients, which fail to take into account the job responsibilities or true safety risks which may be inherent in the job. Personal physicians are often unaware of the lifestyle of truckers – the long days (those in compliance with the hours of service regulations and those who violate this regulation), irregular meal and rest breaks, and the different shift schedules. We also encounter cases where a primary health care professional unwillingly provides a "return to work note" to avoid alienating a patient. These physicians are keenly aware if they do not clear the individual for work, there may be an economic impact resulting in the loss of medical insurance, and ultimately, medical care.

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Treating clinicians, whether physicians or other health care professionals, do not always understand the role and responsibilities of the CMV operator. Depending on the specialty of the treating provider, they may or may not understand the literature on the relationship between crash risk and treatment for a condition. This is true whether considering potentially impairing medications or loss of consciousness of unknown origin. This can especially be an issue in diabetes as the preference for most treating clinicians is for tight management of the diabetes to decrease the risk of long-term complications. While that may be ideal in most diabetic patients, for those in safety sensitive operations, tight control carries an increased risk of hypoglycemia and literature has clearly shown the relationship between hypoglycemia and crash. While some individuals are able to recognize when their blood sugar is below optimal, it has also been shown that individuals are poor at evaluating their level of impairment (whether dues to medication, fatigue or hypoglycemia) and may be aware of the need to take appropriate steps until it is too late.

Allowing the examiner who has the training and understanding to obtain and review additional medical information such as an EKG or stress test, renal function, glucose logs and hemoglobin A1c would increase the margin of safety in the determination while lessening the examiners liability in relying on an TC who may not fully understand the safety concern. Relying solely on the HgBA1c to evaluate risk can give all a false sense of safety. Drivers whose HgBa1c is in what might be felt to be in an acceptable range, may actually be having wide swings in glucose, with some measures being in the dangerous hypoglycemic range. This is especially true when the goal is for tight control and a HgBa1c at the lower range of acceptable.

While it was hoped that the NRCME would standardize certification decisions ensure that all examiners would be working from the "same playbook," our members have found that in many cases, the quality of the examinations may have decreased. The removal of the Medical Examiner Handbook with at least some starting criteria for examiners to consider has left those examiners without adequate training in the diagnosis, treatment and prognosis of many medical conditions even less able to adequately assess any potential safety risk. Examiners who are trying to utilize current best practices, based on current literature, are being challenged by drivers who are now seeking second opinions from examiners who are basing their decision on minimal medical standards or that the driver "looks good enough." Some ME are making certification determinations on drivers with medical conditions they are unable to independently diagnose or treat the conditions they are assessing. If the final determination of whether a driver with ITDM should be certified is shifted to the ME,that ME should be an MD or DO as recommended by the Medical Review Board

The ME should be experienced with the treatment and evaluation of diabetes (DM) and diabetes treated with insulin. If the ME has little experience in this area, it will be the blind leading the blind. This should result in designated MEs to review and medically qualify DM drivers using insulin.

ACOEM has worked with many organizations in creating the Law Enforcement Officer Medical guidelines, including the American Diabetes Association. The

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recommendations in that guideline would be reasonable starting criteria for TCs and MEs to determine if the driver is at an acceptably low risk for sudden or gradual impairment or incapacitation. The recommendations in that guideline should be the minimal criteria for evaluation, treatment and monitoring for the TC and ME to use in reaching a certification determination. Utilization of the form in the LEO Guideline, Appendix B, would require the TC to conduct an adequate evaluated and would allow the ME who understands the treatment, diagnosis, and prognosis of DM to have sufficient information to reach an appropriate but individualized risk assessment of the driver with ITDM. Acquiring the information on this form should not add a significant cost to drivers, as all required information should be obtained in the normal management of a diabetic patient on insulin.

A summary of the ACOEM Law Enforcement Officer Medical Guidelines, include the following:

- The ME should be sent a standardized package of original data to review and not rely solely on the statement or form completion by the TC, including:
  - Summary report from TC to ME, including: Type I or II, diabetes date of onset; date of insulin start; current diabetes medications (both insulin and non-insulin) with name, dosage and frequency; history of medication/dosage changes (both insulin and non-insulin) in past 12 months with rationale for change; compliance with treatment, history of ketoacidosis, hyperosmolar hyperglycemia, and hospitalizations for diabetes over past 3 years.
  - If on insulin pump summary report: type of pump; how long current pump used; documentation of episodes of pump cessation, empty insulin reservoir, battery run down, leaks, cannula dislodgement/occlusion, catheter-site infection; and backup plan (insulin injections) in case of pump failure.
  - Description of all episodes of hypoglycemia over the past 12 months – when, symptoms, recognition and treatment, glucose values, activity at time of episode, need for assistance.
  - What is TC's definition (in mg% blood glucose) of mild and severe hypoglycemia. Surprising the varied responses from TCs and how uninformed the TC is about hypoglycemia.
  - Current A1c.
  - Glucose log. Log must be structured and not "as determined by the TC." The TC may only ask the examinee to check in the morning or before bedtime or before all meals—therefore the logs will be variable and the ME may only receive sporadic testing that will be inconclusive. Request a minimum 2-week log, continuous each day, 4 times per day, before meals and at bedtime. For drivers who are being recertified this may not be practical to test at this frequency, but a structured glucose log report is needed, at least prior to initiating driving at all times during the 2-week period. The glucose log must be downloaded and printed directly from the glucometer—no typed or handwritten logs. The glucose values must have a time stamp for each value; values less than 60mg% must be repeated at least every 30 minutes until 90mg% is

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reached---during this time the driver must document that they were not driving. Values under 60mg% (finger stick glucose reads are 10-15% lower than venipuncture) must have additional documentation (cause, symptoms, corrective action, activity at the time such as driving truck).

- Assessment of chronic DM complications with test results used to evaluate these complications—neuropathy, nephropathy, cardiac.
- Vision report from optometrist or ophthalmologist documenting the presence/absence of retinopathy and macular edema; if present the severity.
- Copy of the TC office medical records covering the previous 12 months. Much information is seen here that will not be reported by the TC otherwise and will provide validation to the absence of hypoglycemia.
- Finally, a new insulin user must demonstrate stability, control and lack of hypoglycemia over a period of time before medically cleared for driving. For LEOs on insulin the ACOEM Guidance requires 3 months, if Type I require 6 months.

ACOEM previously recommended that if medical examiners are responsible for making the final determination, the TC should be part of that determination. The TC should be required to sign a statement that the driver is capable of managing his health condition. If the driver is deemed non-compliant, has inadequate control of the disease, or develops complications as a result of diabetes or discontinues appropriate follow up, the treating physician must be required to notify the FMCSA, a state licensing agency or some other designated organization. FMCSA should require a minimum glucose monitoring cycle as in the exemption program but that could be more frequent at the discretion of the TC and the medical examiner.

While FMCSA explained that removing the requirement for an ophthalmologic evaluation was unnecessary and they indicated that they believed the driver would be motivated to seek appropriate care, examiners have found that drivers often do not take optimal care of their health. MEs have found many drivers whose DM is poorly controlled but they refuse insulin to avoid the exemption requirement. Drivers should continue to be required to have appropriate ophthalmologic evaluation.

ACOEM has previously recommended that in addition to assessing the vision and ability to monitor and manage diabetes, the driver's cardiac and renal status should also be assessed. Diabetes Mellitus is now considered a coronary heart disease (CHD) risk equivalent, that is, the individual has the same cardiovascular risk as someone with established coronary artery disease. Other risk factors for cardiovascular disease such as elevated cholesterol and hypertension should also be assessed prior to issuance of any medical certificate to a driver with diabetes requiring insulin for control. The Cardiovascular Advisory Panel Guidelines for the Medical Examination of Commercial Motor Vehicle Operators recommends that drivers who are over 40 years of age with a Framingham CHD risk for nonfatal myocardial infarction or death of 20% over 10 years or diabetes be subject to the same medical qualifying criteria as those drivers with known CHD. That would include an exercise

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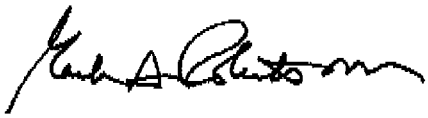
stress test. As these individuals are already considered at higher risk of heart disease and to minimize both false positive and false negative tests, a stress echocardiogram or a nuclear stress test should be the preferred method. In addition, left ventricular function, found to have the highest correlation with cardiac morbidity and mortality, could be assessed by these methods. If there is evidence of ischemia or the left ventricular ejection fraction is less than 40%, also in keeping with the Cardiovascular Panel's guidelines, the driver would be deemed ineligible for certification.

Any diabetic should also be required to submit documentation of recent renal function and if worse than Stage 3 kidney function, should not be qualified and if state 2 should be more closely monitored.

ACOEM had previously recommended that if medical examiners are designated by the FMCSA as the certifying provider, the TC should be part of that determination. The TC must be required to sign a special certificate issued to drivers with ITDM to indicate that the driver is capable of managing his health condition. If the driver is deemed non-compliant, has inadequate control of the disease, or develops complications as a result of diabetes, the treating physician must be required to notify the FMCSA, a state licensing agency or some other designated organization.

Thank you for your consideration of these comments. Please contact Patrick O'Connor, ACOEM's Director of Government Affairs, if you have additional questions or need additional information. He can be reached at 202-223-6222 or by email at patoconnor@kentoconnor.com.

Sincerely,



Mark A. Roberts, MD, PhD, MPH, FACOEM
President

Enclosure: ACOEM Guidance for the Medical Evaluation of Law Enforcement Officers: Diabetes Mellitus

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ACOEM's Guidance for the Medical Evaluation of Law Enforcement Officers (LEOs)

Diabetes Mellitus

Revised April 2015

ACOEM/LEO Panel for the Development of Guidance for the Medical Evaluation of Law Enforcement Officers

AMERICAN COLLEGE OF OCCUPATIONAL AND ENVIRONMENTAL MEDICINE

ACOEM's Guidance for the Medical Evaluation of Law Enforcement Officers

Diabetes Mellitus (Revised April 2015)

This guidance document was created by the ACOEM/LEO Panel for the Development of Guidance for the Medical Evaluation of Law Enforcement Officers.

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**The above Panel members declare no conflicts of interest relevant to this guidance.*

About the ACOEM LEO Medical Guidance:
This chapter on Diabetes Mellitus is a section of the *Guidance for the Medical Evaluation of Law Enforcement Officers* (LEOs), an electronic subscription-based tool that addresses LEO essential job functions, fitness-for-duty criteria, medical conditions, and surveillance issues. Existing chapters include information on initial evaluation, neurology/seizures, sleep disorders, substance use, amputations/ prosthetics, cardiovascular issues, vision, hearing, diabetes, infectious diseases, medications, and pregnancy, with additional medical condition chapters in development. Subscription information is available at http://www.acoem.org/LEOGuidelines.aspx, or by calling ACOEM at 847/818-1800.

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FMCSA-2005-23151-1276-American_College_of_Occupational_and_Environmental_Medicine

4.3 – DIABETES MELLITUS

4.3.1 – INTRODUCTION

The educated and motivated law enforcement officer (LEO) with well-managed diabetes mellitus can be capable of safe and effective job performance.[1(ADA 14)] However, diabetes mellitus may place LEOs at risk for sudden incapacitation, thus jeopardizing their ability to perform critical job functions. (These job functions include those discussed in Appendix A, and in Chapter 3, Essential Job Tasks.)

Therefore, an individualized assessment of the LEO's diabetes should be performed using the following evaluative criteria to determine whether the individual's condition permits safe and effective job performance. Such evaluation must include the following key elements, which are discussed in detail below:

- history of blood glucose control;
- knowledge of diabetes and its management;
- current stability of blood glucose;
- risk for significant hypoglycemia or hyperglycemia; and
- presence of diabetic complications.

4.3.2 – OVERVIEW OF MEDICAL EVALUATION

The treating endocrinologist or other physician knowledgeable regarding diabetes management should provide a narrative report certifying whether the LEO has or has not met the criteria set out in the following discussion below. In addition, the physician should include supporting data (see Appendix B, Physician Evaluation Form).

4.3.2.1 The LEO is under the care of an endocrinologist or other physician knowledgeable regarding diabetes management. Outpatient and in-patient medical record(s) for the last 3 years or since date of diagnosis (whichever is shorter) should be reviewed by the treating physician and provided to the police physician.

4.3.2.2 If the LEO has type 1 diabetes, the individual has been on a stable basal/bolus regimen[a] or an insulin pump using analogue insulins for the 6 months prior to evaluation.[2(ADA S14-S80)]

4.3.2.3 If the LEO has type 2 diabetes on insulin, the individual has been on a stable medication regimen[b] for the 3 months prior to evaluation.[3(Mensing)] If on oral agents alone, the LEO has been on a stable medication regimen for the month prior to evaluation.[c]

4.3.2.4 If the LEO uses an insulin pump, documentation is needed as follows:

- proper understanding and education in the use of the insulin pump;
- start date for the use of the pump;
- history of insulin site infections[d];
- history of pump cessation and pump malfunction;
- backup plan for pump malfunction including use of injectable insulin; and
- frequency of infusion set changes.

4.3.2.5 The LEO 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 or her diabetes and what procedures should be followed if complications arise.[3]

4.3.3 – QUANTITATIVE GLUCOSE MONITORING

Glucose monitoring in the evaluation of the LEO includes assessment of hypoglycemia and overall control using downloaded glucose meter logs and hemoglobin A1C. Only downloaded data directly from the glucose meter is acceptable; handwritten or typed logs are not acceptable. Data recorded by the meter should be tamper-resistant.[e]

4.3.3.1 The LEO has documentation of ongoing self-monitoring of blood glucose.

4.3.3.2s Glucose monitoring must be done with a glucose meter that stores every reading, records date and time of reading and from which data can be downloaded and printed.

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4.3.3.3 Glucose meter logs must be available covering the time period (1, 3, or 6 months) as previously described in the Overview of Medical Evaluation Section. The frequency of glucose monitoring must follow a schedule acceptable to the police physician in consultation with the treating physician.

Testing schedules are individual. What follows is a common pattern, but individual patterns may differ.

DAILY THERAPEUTIC REGIMEN	GLUCOSE TESTING SCHEDULE
Diet alone	Every 1 to 2 weeks[f]
Metformin, thiazolidinediones, or alpha glucosidase, or DPP-4 inhibitors, SGLT-2 inhibitors, GLP-1 agonists – alone or in combination	Every 1 to 2 weeks
Sulfonylureas, meglitinides, or nateglinide – alone or in combination with the above group	• Twice a day ▪ upon awakening (prior to eating) ▪ prior to evening meal. • With any suspected hypoglycemic episodes
Insulin – 1 dose alone or in combination with other medications	• Twice a day ▪ upon awakening (prior to eating) ▪ prior to evening meal. • May also test before lunch or bedtime • With any suspected hypoglycemic episodes or after an increase in overnight insulin, glucose should be checked once a week at 2am to 3am.[g]
Insulin – two or more doses daily or Insulin pump	• Multiple times a day ▪ Prior to eating ▪ Prior to bedtime ▪ Prior to exercise ▪ With any suspected hypoglycemic episodes ▪ After treating low blood glucose repetitively at a minimum of every 30 minutes until normoglycemic ▪ Prior to critical tasks such as driving[4,5(ADA,ADA97] With any suspected hypoglycemic episodes or after an increase in overnight insulin dose, glucose should be checked once a week at 2am to 3am.

4.3.3.4 The LEO has had hemoglobin A1C measured at least 4 times a year (intervals of 2 to 3 months) over the last 12 months prior to evaluation if diagnosis has been present for more than a year.[4(ADA)] If hemoglobin A1C is 8% or greater, this may signal a problem with the LEO's diabetes management that warrants further assessment by the LEO's treating physician.[6(ADAS1480)] The A1C value should not be the sole determinant of ability of the LEO to carry out his or her duties.[7(Smaldone)]

4.3.3.5 A blood glucose less than 60 mg/dl needs to be rechecked and treated immediately, and then repeated, at a minimum, every 30 minutes until a glucose value of 90 mg/dl or greater can be demonstrated.

4.3.4 – IMPAIRING EVENTS

4.3.4.1 The LEO should be restricted for severe hypoglycemia (defined as an event requiring assistance of others):

- One or more episode(s) within the past 1 year or
- More than 2 episodes in the past 3 years (or since diagnosis of diabetes whichever is shorter).

4.3.4.2 Repeated episodes of blood glucose < 60 mg/dl should be reviewed by the police physician to assess the frequency of events, presence of hypoglycemia unawareness, and potential for increased risk of incapacitating events.

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4.3.5 – CHRONIC COMPLICATION SCREENING

4.3.5.1 Chronic complications of diabetes may be associated with increased risk for severe hypoglycemic episodes or sudden incapacitation and warrant further assessment.

4.3.5.2 The components of screening for chronic complications are:

4.3.5.2.1 A complete eye exam by a qualified ophthalmologist or optometrist, including a dilated retinal exam. Examination should occur every other year for those without retinopathy, and annually for those with retinopathy or more frequently, as recommended by the qualified eye professional.[8,9(ADA/Viswanath)]

4.3.5.2.1.1 More than moderate non-proliferative diabetic retinopathy or diabetic macular edema should require further ophthalmologic evaluation[h] (for additional guidance see the Vision chapter).

4.3.5.2.2 Neurological

- Vibratory testing with a 128 Hz tuning fork
- Sensation testing with 10 gram Semmes-Weinstein monofilament
- Orthostatic blood pressure and pulse testing.[i,10,11(Michigan/Bradley)]

Severe autonomic and/or peripheral diabetic neuropathy can impair the LEOs safe and effective performance of essential job functions and may require restrictions.

4.3.5.2.3 Cardiac

LEOs, both those with and without diabetes, should be annually assessed for risk of cardiovascular disease using the ASCVD [arteriosclerotic cardiovascular disease] Risk Estimator (http://tools.cardiosource.org/ASCVD-Risk-Estimator/) based on the 2013 American College of Cardiology/American Heart Association Guideline on the Assessment of Cardiovascular Risk.[12(JACC 2014)] Those assessed at intermediate (10 to <20% of ASCVD risk over the next 10 years) or high risk (≥20% ASCVD risk over the next 10 years) should be further evaluated using cardiac exercise testing to at least 12 METs. Determination of cardiac testing intervals for intermediate or high risk LEOs should be individually based and can range from every 1 to 5 years.

This document addresses the risk of sudden incapacitation during performance of law enforcement essential job functions. The ACOEM LEO Task Group has reviewed current cardiovascular literature, including American College of Cardiology/American Heart Association guidelines,[12,13,14,15(JACC 2014/Beaser/JACC 2010/Deferranti)] and current American Diabetes Association (ADA) guidelines concerning the assessment of cardiovascular risk of asymptomatic adults.[16(ADA)] For LEOs with an ASCVD risk score of less than 10% over the next 10 years, further cardiac evaluation is not indicated. For LEOs with an ASCVD risk score of 10% or greater over the next 10 years, the risk of sudden incapacitation warrants further individualized cardiac evaluation. This should include, at a minimum, exercise cardiac testing to at least 12 METs.

4.3.5.2.4 Renal Function

- Serum Creatinine and eGFR (estimated Glomerular Filtration Rate)[j]

4.3.5.2.4.1 GFR levels less than 45 ml/min may suggest changes that can impair the LEOs safe and effective performance of essential job functions and may require restrictions. This level of renal impairment is associated with greater risk of anemia, malaise, and greater risk for hypoglycemia in those treated with some sulfonylureas or insulin.[17,18(ADA, Molitch)]

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4.3.6 – ONGOING EVALUATION AND REQUIREMENTS

4.3.6.1 Medical records and glucose meter logs should be reviewed periodically by the police physician. Because of the nature of diabetes it is important that regular medical follow up be provided to the LEO. The frequency and content of the evaluation should be determined on an individual basis by the police physician in consultation with the treating physician.[k]

4.3.6.2 Must advise police physician of any change in type of medication (e.g., addition of a sulfonylurea or insulin).

4.3.6.3 Must advise police physician of any episodes of symptomatic hypoglycemia or severe hypergiycemia (ketoacidosis, hyperosmolar hyperglycemic nonketotic state).[19 (Kitabchi)]

4.3.6.4 Must provide documentation of ongoing evaluation of cardiac, ophthalmological, neurological and/or renal status (see Section on Chronic Complication Screening).

---

[a]A basal/bolus insulin regimen consists of the use of a basal insulin (glargine [Lantus], detemir [Levemir], or NPH) in a once or twice daily regimen to provide between-meal insulin, combined with the use of a short acting insulin (Regular, Lispro, Aspart, or Glulisine) at meal-times. Insulin pumps are small (beeper sized) battery powered devices that deliver small amounts of short-acting insulin in a constant infusion to meet basal insulin requirements. The wearer selects an additional mealtime bolus to be infused at the time of meals. For more information on pumps, visit the manufacturers' web sites – www.minimed.com, www.go-vgo.com, www.myomnipod.com, www.snappump.com, www.tandemdiabetes.com/Products/t-slim-Insulin-Pump/, www.animas.com/animas-insulin-pumps/onetouch-ping.

[b]A stable insulin regimen is defined as maintaining the same types of insulin (long acting, intermediate acting, short or rapid acting). Changes in insulin dose are part of the appropriate self-management of diabetes and do not disqualify an applicant or incumbent under this section.

[c]Changes in dose within the evaluation period will be allowed, but addition of a new class of medications or insulin should result in a new period of observation:

- 1 month for addition of a sulfonylurea;
- 1 month for the addition of an additional agent to insulin or a sulfonylurea; or
- 3 months for the addition of insulin.

[d]LEO has not had more than one pump-site infection that caused him/her to miss work or usual daily activities in preceding 6 months.

[e]Tamper resistance is required so that the user cannot remove or insert either hyper or hypoglycemic readings.

[f]Glucose monitoring in this setting is intended to help the LEO be informed if glycemic control through dietary and medical management is not optimal.

[g]Or for persons with sleep cycles out of standard night hours, at the time the middle of their sleep cycle.

[h]The International Classification of Diabetic Retinopathy and Diabetic Macular Edema published by the American Academy of Ophthalmology.

[i]Orthostatic hypotension is a physical finding defined by the American Autonomic Society and the American Academy of Neurology as a systolic blood pressure decrease of at least 20mm Hg or a diastolic blood pressure decrease of at least 10mm Hg within 3 minutes of standing.

[j]See MDRD GFR Calculator available on line at http://nkdep.nih.gov/lab-evaluation/gfr/estimating.shtml.

[k]The consensus of the ACOEM Task Group is that the review by the police physician of glucose monitoring records and reports from the treating physician should occur at a minimum of every 12 months, but may need to be more frequent in specific cases.

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4.3.7 – APPENDIX A: COMMENTARY

Diabetes Definitions and Treatments:
Type 1 diabetes was previously called insulin-dependent diabetes mellitus (IDDM) or juvenile-onset diabetes. Type 1 diabetes develops when the body's immune system destroys pancreatic beta cells, the only cells in the body that make the hormone insulin that regulates blood glucose. This form of diabetes usually strikes children and young adults, although disease onset can occur at any age. Type 1 diabetes may account for 5 to 10% of all diagnosed cases of diabetes. In order to survive, people with type 1 diabetes must have insulin delivered by injections or a pump.

Type 2 diabetes was previously called non-insulin-dependent diabetes mellitus (NIDDM) or adult-onset diabetes. Type 2 diabetes may account for 90 to 95% of all diagnosed cases of diabetes. It usually begins as insulin resistance, a disorder in which the cells do not use insulin properly. As the need for insulin rises, the pancreas gradually loses its ability to produce sufficient insulin. Type 2 diabetes is associated with older age, obesity, family history of diabetes, prior history of gestational diabetes, impaired glucose tolerance, physical inactivity, and race/ethnicity. Type 2 diabetes is increasingly being diagnosed in children and adolescents. Many people with type 2 diabetes can control their blood glucose by following a careful diet and exercise program, losing excess weight, and taking oral medication. According to 2010-2012 statistics from the U.S. Centers for Disease Control and Prevention (CDC), among adults with diagnosed diabetes, about 14.7% take both insulin and oral medications, 14% take insulin only, 56.9% take oral medications only, and 14.4% do not take either insulin or oral medications.[20(CDC)]

Risk of hypoglycemia remains the major concern in regard to those with diabetes being or becoming law enforcement officers (LEOs). This risk occurs primarily in those taking insulin, particularly those with type 1 diabetes, although it may also occur in those with type 2 diabetes who take insulin and/or certain oral anti-diabetic medications. Patients treated with metformin, alpha-glucosidase inhibitors, thiazolidinediones, GLP-1 agonists, DPP-4 inhibitors or SGLT2 inhibitors alone or in combination with each other are at little or no risk of significant hypoglycemia.

Diabetes Medications Risk for Hypoglycemia

Medication	Monotherapy	Combinations	Increased Monotherapy Hypoglycemic Risk
Biguanides (Metformin)	Negligible	High with sulfonylureas, insulin	Not as monotherapy
Sulfonylureas (Glipizide, Glimepiride, Glyburide)	Moderate to high*	Increased with insulin or with the addition of any second agent	Erratic eating habits, intense or prolonged exercise, ethanol use, renal or hepatic disease, adrenal or pituitary insufficiency, advanced age (>85 years).
DPP-4 inhibitors (Sitagliptin, Saxagliptin, Linagliptin)	Negligible**	High with sulfonylureas, insulin	Not as monotherapy
Thiazolidinediones (Pioglitazone, Rosiglitazone)	Negligible	High with sulfonylureas, insulin	Not as monotherapy
GLP-1 agonists (Liraglutide, Exanatide)	Low***	High with sulfonylureas, insulin	Generally not as monotherapy
Meglitinides (Repaglinide/ Prandin)	Moderate to high****	Should not be used in combination with sulfonylureas or insulin	

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D-Phenylalanine Derivatives (Nateglinide/ Starlix)	Mild to moderate	Should not be used in combination with sulfonylureas or insulin	
Amylin analogs (Pramlintide)	Negligible	High with insulin	
Alpha-glucosidase inhibitors (Acarbose)	Negligible	High with sulfonylureas, insulin	
Sodium-glucose co-transporter 2 (SGLT2) Inhibitors (Canagliflozin)	Negligible	High with sulfonylureas, insulin	
Insulin	High	Increased with addition of any second agent	Erratic eating habits, intense or prolonged exercise, ethanol use, renal or hepatic disease, advanced age (> 85 years). Tight glucose control, low insulin reserves, adrenal or pituitary insufficiency. Lower risk with long-acting basal insulin formulations insulin glargine and insulin detemir. Increased with more years on insulin

*Sulfonylureas: Incidence of reported hypoglycemia symptoms was up to 19.7% with glimepiride, 3.2% with placebo over 22 weeks
** DPP-4 Inhibitors: Incidence of reported hypoglycemia was up to 5.6% with saxagliptin, 4.1% with placebo over 24 weeks
***GLP-1 analogs: Incidence of reported hypoglycemia was up to 5.2% with exenatide, 1.3% with placebo over 24 weeks
****Meglitinides: Incidence of reported hypoglycemia was up to 31% with repaglinide, 7% with placebo over 12 to 24 weeks

Reference: www.rxlist.com/(insert diabetes drug)-drug/side-effects-interactions.htm. Accessed June 11, 2014.

Law enforcement entails a unique set of conditions that need to be considered in regard to those with diabetes and the risks of impairment from either hypo or hyperglycemia. These may include (depending upon the duties of the particular LEO position):

- unpredictable meal schedules;
- brief periods of maximal physical exertion;
- prolonged driving with responsibility for others in the vehicle;
- high-speed pursuit driving;
- surveillance requiring sustained attention for prolonged periods of time;
- rapid decision making regarding the use of force, including deadly force;
- rapid analysis of complex visual stimuli to differentiate weapons from other objects; and
- control of one's emotions under stress.

The criteria and individualized assessment process included in this Guidance are intended to serve as a means to minimize the risk to individual LEOs and the public while allowing well motivated, well-educated persons with well-controlled diabetes to serve as LEOs. Nonetheless, certain persons with diabetes, despite their motivation and adherence to optimum care, are unable to attain adequate control of their diabetes, and therefore have a greater tendency for significant hypoglycemia. Such individuals would not be acceptable candidates to be LEOs.

This individualized assessment is possible in large part because a great deal of change has occurred in the treatment of diabetes over the last number of years. Previously, patients used insulins that were somewhat unpredictable in the

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time course of their action and generally took two or fewer injections per day. Today, there are insulins that are far more predictable and are either very long acting and essentially treat only basal hepatic glucose production (and therefore do not depend on a patient eating on a regular schedule) or are very rapid and therefore can be administered directly before or even shortly after eating, significantly decreasing the chance of insulin being taken and then the meal being interrupted due to professional duties.

Insulin regimens, now referred to as "basal bolus," are composed of a very long acting basal (or background) insulin, and rapid-acting (bolus) insulins. The basal insulin controls glucose levels overnight in the absence of carbohydrate intake. The rapid-acting (bolus) insulins that are dosed just prior to, during, or after meals based on blood glucose levels at that time, the amount of carbohydrate that the person expects to consume, and any anticipated change in physical activity patterns over the next several hours. These regimens have resulted in improved overall blood glucose control with significantly less risk of hypoglycemia for many patients.

Additional major advances in the size, speed, and sophistication of blood glucose meters provide for easy, accurate, and rapid assessment of blood glucose levels. All current blood glucose meters can be downloaded to computer programs, facilitating confirmation and review of blood glucose results. Such monitoring techniques, as well as the generally increased self-awareness that accompanies consistent self-monitoring, enables the motivated person with diabetes to assess blood glucose levels and ingest a safety net of carbohydrates before entering a hazardous environment. Similarly, major advances in insulin delivery systems have greatly increased the ability of the motivated individual with diabetes to achieve a level of diabetes self-management consistent with the duties of a LEO.

In order to obtain maximum effect from these medical advances, and to minimize the risk of hypoglycemia, patients with diabetes must check their blood glucose level frequently (as recommended based on factors such as type of therapy and glycemic history), review these results on a regular basis, and see their diabetes care provider regularly for discussion in regard to any necessary changes in treatment. Patient evaluation needs to look for any of the known risk factors for serious hypoglycemia or evidence of any of the known microvascular (eye disease, kidney disease, or nerve disease) or macrovascular (cardiovascular disease, peripheral arterial disease) complications of diabetes.

Periodic ophthalmologic evaluation of the LEO with diabetes is necessary due to the increased risk of advanced retinopathy with retinal blood vessel leakage or hemorrhage or retinal detachment. It is clinically appropriate for individuals with severe non-proliferative or proliferative diabetic retinopathy to avoid participating in vigorous physical intensity, jarring, straining, or Valsalva-like activities.[13(pp163-5)]

The above described individualized assessment demands a very close and good working relationship between the patient and the diabetes health care provider.

Conclusion:

Current published data suggest that persons with diabetes who can safely and effectively function as LEOs can be reliably identified through careful individualized assessment. Thus blanket bans of all people with diabetes, in addition to being illegal, are not consistent with current medical knowledge. Because diabetes affects individuals very differently, whether or not an individual can safely perform a particular job must be determined using the combined expertise of the treating physician and the police physician. This guidance provides the information necessary for the police physician to work with a diabetes expert on this important task.

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4.3.8 – APPENDIX B: PHYSICIAN EVALUATION FORM FOR LEO WITH DIABETES

I. INTRODUCTION

The educated and motivated law enforcement officer (LEO) or applicant with well-managed diabetes mellitus can be capable of safe and effective job performance. An individualized assessment of the LEO's or applicant's diabetes should be performed including an assessment of the following:

- history of blood glucose control;
- current stability of blood glucose;
- risk for significant hypoglycemia or hyperglycemia;
- presence of diabetic complications; and
- knowledge of diabetes and its management.

Risk of hypoglycemia remains the major concern in regard to those with diabetes being or becoming LEOs. This risk occurs primarily in those taking insulin, particularly those with type 1 diabetes, although it may also occur in those with type 2 diabetes who take insulin and/or sulfonylureas and other secretagogues.

Law enforcement entails a unique set of conditions that need to be considered in regard to those with diabetes and the risks of either hypo or hyperglycemia. These may include (depending upon the duties of the particular LEO position):

- unpredictable meal schedules;
- brief periods of maximal physical exertion;
- prolonged driving with responsibility for others in the vehicle;
- high-speed pursuit driving;
- surveillance requiring sustained attention for prolonged periods of time;
- rapid decision making regarding the use of force, including deadly force;
- rapid analysis of complex visual stimuli to differentiate weapons from other objects; and
- control of one's emotions under stress.

II. ASSESSMENT*

Times cited for durations of stable treatment regimen or stability of management are in reference to the date of current evaluation for a law enforcement position. **Date sought is when patient first began current insulin regimen (pump or injection) using current types of insulin (long acting, intermediate acting, short or rapid acting).*

1. LEO has been under the care of an endocrinologist or other physician knowledgeable about diabetes management. Outpatient and in-patient medical record(s) of the last three years or since date of diagnosis (whichever is shorter) should be reviewed by the treating physician and provided to the police physician.

   My credentials as a physician knowledgeable about diabetes management are as follows (or attach CV):

   _____

   _____

   This person has: ☐ type 1 diabetes ☐ type 2 diabetes
   Date of diagnosis: ____ / ____ / _____

   Attached records for prior 3 years or since onset of diabetes whichever is shorter for:
   ☐ out-patient treatment ☐ in-patient treatment

2. If type 1 diabetes, patient has been on a basal/bolus regimen or an insulin pump using analogue insulins for the six (6) months prior to evaluation.

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Current insulin regimen: _____

_____

_____

Insulin pump brand and model: _____

Pump settings:

Start Time					
Basal Rate					

Start Time					
Basal Rate					

Usual bolus doses:
Breakfast _____
Lunch _____
Supper _____
Other _____
Correction factor _____

Multiple dose insulin (specify regimen):
Basal: _____
Bolus: _____

Starting date on current regimen: _____/_____/_____

3. If type 2 diabetes on insulin, has been on a stable medication regimen for the three (3) months prior to evaluation. If on oral agents alone, should be on a stable medication regimen for the month prior to evaluation.

   Current medication regimen:

Oral agents	Insulin
_____	_____
_____	_____
_____	_____
_____	_____

   Starting date on current regimen: _____/_____/_____

4. Has documentation of ongoing self-monitoring of blood glucose. This must be done with a glucose meter that stores every reading, records date and time of reading and from which data can be downloaded. Monitoring records must be available covering the time periods (1, 3, or 6 months), as described in Sections 2 and 3, following a schedule acceptable to the police physician.

   The individual has been asked to test glucose _____ times a day, and

   ☐ is adhering to my recommended schedule for testing.

   ☐ is **not** adhering to my recommended schedule for testing.

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Glucose logs:
☐ are attached for review
☐ are not attached for review (please explain):_____

5. 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.

   The individual has completed the following diabetes education (include year of completion):

6. If an insulin pump user, documents:
   - proper understanding and education in the use of the insulin pump
   - start date for the use of the pump
   - history of insulin site infections
   - history of pump cessation and pump malfunction
   - backup plan for pump malfunction including use of injectable insulin
   - frequency of infusion set changes

   The individual has completed the following education in the use of a continuous insulin infusion pump (indicate year of completion): _____

   The individual routinely carries appropriate supplies to compensate for pump malfunction, including syringes and insulin vials or insulin pens.
   ☐ Yes
   ☐ No – please explain: _____

   The individual has had more than one pump site infection that caused him/her to miss work or usual daily activities in the preceding six (6) months.
   ☐ Yes – please explain: _____
   ☐ No

7. Has this individual used a continuous glucose monitor?
   ☐ Yes
   Dates used: _____
   Why used: _____
   Frequency of use: _____
   ☐ No

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8. Has had hemoglobin A1C measured at least four times a year (intervals of 2 to 3 months) over the last 12 months prior to evaluation if diagnosis has been present over a year.

Date	HbA1C
_____	_____
_____	_____
_____	_____
_____	_____

9. Impairing events – Has not had any within the past one (1) year and no more than two (2) episodes in the past three (3) years, or since diagnosis of diabetes (whichever is shorter) episodes of:
   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.

   Has this individual had an episode of hypoglycemia as described above?

   ☐ Yes ☐ No

   If the individual has had such episode(s), please describe episodes and provide dates of episodes:

   _____

   _____

10. Has had a complete eye exam by a qualified ophthalmologist or optometrist, including a dilated retinal exam, 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).

    Copy of ophthalmology or optometry report is attached:

    ☐ Yes ☐ No – please explain: _____

    Copy of automated visual perimetry field test (Humphrey or equivalent) is attached:

    ☐ Yes ☐ No – please explain: _____

11. Has normal vibratory testing with 128 Hz tuning fork, has normal testing with 10 gram Semmes-Weinstein monofilament and normal orthostatic blood pressure and pulse testing.

    Vibration sensation: _____

    Monofilament: _____

    BP supine: _____ Pulse supine: _____

    BP standing: _____ Pulse standing: _____

12. Has normal cardiac physical exam and normal cardiac stress testing to at least 12 METS. Annual cardiac stress testing should begin when any of the following criteria are met:
    - age greater than 35 years
    - Type 1 DM greater than 15 years duration
    - Type 2 DM greater than 10 years duration
    - signs of target organ damage (eyes, kidneys, autonomic, cardiac)
    - any other coronary artery disease risk factors

    Copy of stress test report performed within the last 12 months is attached:

    ☐ Yes ☐ No – please explain: _____

    _____

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13. Has normal renal function based on albumin/creatinine ratio ≤30:1, and calculated eGFR (Glomerular Filtration Rate).

Serum Creatinine: _____

Urine microalbumin/creatinine ratio: _____

eGFR: _____

III. Treating Physician Statement

Please provide additional information, not included above, that may be helpful to the police physician:

_____

_____

_____

_____

_____

_____

_____

_____

_____ _____

Signature of Physician Date

_____ _____

Printed or Typed Name of Physician Telephone Number

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AMERICAN ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

July 15, 2015

Elaine M. Papp, RN MSN COHN-S CM
U.S. Department Of Transportation
Federal Motor Carrier Safety Administration
1200 New Jersey Ave., SE
Washington, DC 20590

RE: Family physicians and application forms regarding the Federal Diabetes Exemption Program

Dear Ms. Papp:

On behalf of the American Academy of Family Physicians (AAFP), which represents 120,900 family physicians and medical students across the country, I strongly urge you to address what we hope is an oversight in the Federal Motor Carrier Safety Administration's online guidance to applicants for the Federal Diabetes Exemption Program. The document does not allow board-certified family physicians to examine applicants and complete the evaluation checklist they need for the program. Instead, it states, "The applicant must be examined by a physician who is a board-certified or board-eligible endocrinologist." We urge you to change the guidance and application to make it clear that applicants may be examined by their family physician rather than an endocrinologist if they wish. We request that you change the guidance.

Family physicians are dedicated and trained to treating the whole person and are more than capable of managing and treating patients with diabetes. The AAFP believes that family physicians are able to complete the forms needed by commercial motor vehicle drivers with diabetes who are applying for this program. Aside from patients and their families, there is no group more involved in managing patients with chronic disease like diabetes than family physicians. According to the Robert Graham Center's analysis of the Medical Expenditure Panel Survey (2008-2010), approximately 34 percent of ambulatory care visits to physicians of patients with a diabetes diagnosis were to family physicians or general practitioners. An additional 10 percent of visits were to other primary care physicians, including general internists and geriatricians, and only 56 percent of visits were to a subspecialist. One out of every four physician office visits in America takes place in a family physician's office and not all applicants will have access to an endocrinologist. Managing patients with diabetes goes to the very heart of family medicine.

Thank you for your time and consideration of this request. For any questions you might have please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or rbennett@aafp.org. We look forward to your response and rapid action on this important matter.

Sincerely,

Reid B. Blackwelder, MD, FAAFP
Board Chair

www.aafp.org

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