AMERICAN COLLEGE OF
OCCUPATIONAL AND
ENVIRONMENTAL MEDICINE

September 25, 2017

Docket Management Facility
U.S. Department of Transportation
Room W12–140
1200 New Jersey Avenue, SE
Washington, DC 20590–0001

Docket No. FMCSA–2005–23151

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 Information Collection Request titled *Medical Qualification Requirements*. ACOEM previously submitted comments on the notice of proposed rulemaking (Docket No. FMCSA –2005-23151) which would allow drivers with stable, well-controlled insulin-treated diabetes mellitus (ITDM) to be qualified to operate commercial motor vehicles as well as on the Medical Review Board Task Report on Insulin Treated Diabetes Mellitus and Commercial Motor Vehicle Drivers. Those comments are attached for reference.

ACOEM is an international society of more than 4,200 occupational and environmental physicians and other health care professionals. The College provides leadership to promote the health and safety of workers, stimulate research, enhance 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 a worker's capabilities to the job requirements.

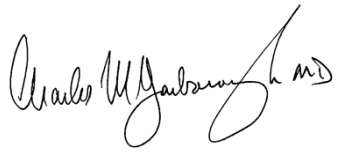
ACOEM believes the information requested in the form should be sufficient for an examiner on the National Registry of Certified Medical Examiner (NRCME) who has appropriate medical training and experience in the diagnosis, treatment and prognosis of individuals with diabetes mellitus to determine if that that driver is at risk of sudden or gradual impairment or incapacitation. We continue to have concerns that it is inappropriate to rely on the opinion of examiners who do not thoroughly understand the potential risks to the driving public from drivers whose diabetes is inadequately controlled or monitored. Many examiners have experienced situations in which information from treating clinicians is inadequate and, only after additional discussion or review of medical records, is the actual risk able to be appropriately assessed. An examiner with insufficient knowledge of the condition will be unable to identify when additional information and discussion is appropriate or be able to interpret any additional medical records.

ACOEM's prior comment on the form included the recommendation that;

ACOEM COMMENT: The examiner reviewing the documentation and making the final determination must have the training and knowledge to evaluate whether the documentation is sufficient and consistent with safe operation of a commercial motor vehicle. They should review at least 3-5 years of medical records so they can independently evaluate the absence of complication, end organ damage and actual compliance and control of the condition.

Thank you for your consideration of our comments. Please do not hesitate to contact either me or Patrick O'Connor, ACOEM's Director of Government Affairs at 703/351-6222, should you have any questions.

Sincerely,



Charles M. Yarborough III, MD, MPH, FACOEM
President

Enclosure: ACOEM Comments dated July 6, 2016 to Docket No. FMCSA –2005-23151

AMERICAN COLLEGE OF
OCCUPATIONAL AND
ENVIRONMENTAL MEDICINE

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.

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.

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 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 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 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