

Docket No. FMCSA-2005-23151

Federal Motor Carrier Safety Administration Notice and Request for Comments: Agency Information Collection Activities; Information Collection Revision Request – Medical Qualification Requirements, OMB Control Number 2126-0006, 82 Fed. Reg. 35041

Comments of the American Diabetes Association

The American Diabetes Association (Association) submits these comments in response to the July 27, 2017 Notice and request for comments on the agency's Information Collection Revision Request concerning the Medical Qualification Requirements for interstate commercial drivers with insulin-treated diabetes.

Background

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. 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.

For many years, the Association has been advocating for the adoption of medically appropriate, fair rules for the medical certification of commercial motor vehicle drivers with insulin-treated diabetes. Great progress was made in 2015 with the publication of the Notice of Proposed Rulemaking (NPRM), which acknowledged drivers with insulin-treated diabetes do not pose an unreasonable risk to public safety. The Association supports the new standard outlined in the NPRM, which provides for individual assessment and allows for updates consistent with changing diabetes medicine.

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¹ American Diabetes Association: Standards of Medical Care in Diabetes 2017, *Diabetes Care* 40: Supp. 1 (2017).
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).

<u>Comments on the Information Collection Revision Request</u>

The information proposed in the ICR for completion of a form by the Treating Clinician addresses most of the concerns we raised in our comments in response to the September 2016 Notice of Availability.

The one exception is the new requirement, reflected throughout the form in questions 3(c), 4(a), and 5(c), that the driver be on a stable insulin regimen for the prior three months. This is a stricter requirement than that of the current Diabetes Exemption Program, and one that does not provide any extra measurable safety to the evaluation and certification process. Currently, the Diabetes Exemption Program requires that drivers seeking medical certification for insulin treated diabetes be on a stable insulin regimen for a period of one month if they have type 2 diabetes and are converting to insulin treatment, and two months if they have newly diagnosed type 1 diabetes. This criteria was recommended by a panel of diabetes experts when the Exemption Program was developed, and there have been no medical changes in the 14 years this program has been in existence that would render this criteria now unsafe. In fact, diabetes management has improved drastically since the start of the program in 2003, so in fact a shorter, rather than longer, period of time could be justified.

One of the goals of the agency's Notice of Proposed Rulemaking is to take the diabetes standard into the 21st century by providing for a smoother medical certification process for drivers with insulin treated diabetes without compromising public safety. By requiring a driver be on a stable insulin regimen for three months before they can even be evaluated, the agency is erecting new barriers to certification, licensure, and steady employment (and with that, access to health care to manage diabetes) where they are not needed. The Association is not aware of any drivers for whom additional time was necessary to ensure proper, thorough evaluation of diabetes for commercial driving. Even if that was the case, the Treating Clinician should be empowered to make that determination, without a blanket rule requiring all drivers to wait a certain minimum period of time.

On the contrary, the Association hears from many drivers who are dissuaded from applying for an exemption (and decide to delay insulin treatment even when it is needed) because of the barriers posed by the waiting period on the front end (1-2 months) and the administrative delays on the back end (the time for the agency to process the exemption application). Taken together, these delays can add up to 8 months that a driver is unable to work. We urge FMCSA to not require a minimum period of time on insulin, leaving this assessment to the Treating Clinician who is best suited to evaluate the stability of a driver's diabetes management. In the alternative, we request FMCSA to adopt the criteria of the Diabetes Exemption Program and require no more than one or two months.

Finally, we note that in question 5(c), the agency requires the driver to have had his or her HbA1C measured intermittently over the last 12 months with the most recent measure within the preceding three months. Individuals who are recently diagnosed will not have 12 months of HbA1C data to provide, and should not be disqualified on that basis alone. Individuals who have recently begun insulin treatment may have HbA1C results from prior to insulin treatment that will not be relevant to the evaluation.

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