

December 20, 2005

Honorable Annette Sandberg
Administrator
Federal Motor Carrier Safety Administration
400 7th Street, SW
Washington DC 20590

Re: Diabetes Exemption Program
FMCSA-2001-9800

Dear Administrator Sandberg:

We are the physicians who served on the Federal Highway Administration's Expert Medical Panel for the "A Report to Congress on the Feasibility of a Program to Qualify Individuals with Insulin Treated Diabetes Mellitus to Operate Commercial Motor Vehicles in Interstate Commerce as Directed by TEA-21" (2000 Report) which served as the basis for the current exemption program for people with insulin-treated diabetes who wish to drive commercial motor vehicles in interstate commerce.

We are writing to you because we are dismayed to learn that the Federal Motor Carrier Safety Administration (FMCSA) recently added a new criterion to the diabetes exemption program that requires drivers with insulin-treated diabetes to have a glycated hemoglobin (A1C) measurement of between 7% and 10%. This criterion is completely medically unjustified and directly contrary to the advice we provided as the Expert Medical Panel on this issue. We write to clear up the apparent misunderstanding of the A1C test and to discuss how the test can be correctly used to determine whether an individual driver creates a safety risk.

In simplified terms, an A1C provides an average of one's blood glucose level over the past 2 to 3 months. As such, the same result can be reached based on a combination of high or low blood glucose levels, or a steady stream of levels that are all around the same place. Therefore, in determining whether a driver is at risk for incapacitating low blood glucose levels (the major concern in interstate driving) or high blood glucose levels, an A1C result must be considered by the examining endocrinologist in conjunction with the individual's daily blood glucose logs. That is what we recommended and what was originally a part of the diabetes exemption program. This information, taken together with the numerous other screening, operation, and monitoring procedures that we recommended (and that are a part of the diabetes

exemption program), establish a safe system to select drivers with insulin treated diabetes.¹

Moreover, 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 American Diabetes Association has stated the goal for diabetes patients in general is an A1C of <7% and the goal for the individual patient is an A1C as close to normal for people without diabetes (<6%) as possible, without significant hypoglycemia. Indeed, this is the vital message that numerous federal agencies including the Centers for Disease Control and the National Diabetes Education Program continue to work hard to convey to the public.

As correctly pointed out in the 2000 Report, 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 the other screening criteria in the diabetes exemption program. A set A1C range doesn't best identify those people who can be the safest drivers. Rather, this new requirement will screen out those who are doing the very best job in managing their diabetes and force people with diabetes to lessen their chances of avoiding the long-term complications of diabetes in order to find or maintain employment. 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 the wrong message for our patients and the wrong message to increase safety on our roads.

That is not to say that one needs to achieve optimum A1C levels in order to be a safe commercial driver. As we discussed at the time of the original investigation, an A1C above 7, while not ideal for long-term health, does not mean that an individual is not a safe driver. While very high A1C readings do raise a concern, we do not support a specific upper cutoff. Rather, as noted above, A1C results should be reviewed with daily blood glucose readings and an assessment made that takes into account the numerous other screening guidelines that are a part of the diabetes exemption program.

The inclusion of the 7% - 10 % A1C range is unsupported by the science of diabetes management and control. We strongly urge FMCSA to immediately

¹ As we previously discussed in comments on the record in this matter, the original requirement that an individual must have driven a commercial vehicle for three years while using insulin in order to qualify for an exemption was medically unjustified. We are pleased that that requirement has now been removed. However, this new barrier is equally unjustified from a medical perspective.

remove the mandatory A1C range from the criteria in the diabetes exemption program.

We very much appreciated the opportunity to be the agency's medical advisors on establishing the exemption program and hope we have been able to clear up any misunderstandings about the use of the A1C test.

Sincerely,



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