

progression of the condition. This change covers the screening process in both the initial application and the annual examination.

Comments In Opposition

The Insurance Institute for Highway Safety (IIHS) opposes FMCSA's proposal to issue exemptions to certain insulin-using drivers of CMVs. In voicing its opposition, IIHS resubmitted the various comments it had submitted to the agency between 1991 through 1996 concerning the implementation and disposition of the diabetes waiver program. In those comments, IIHS raised concerns that: (1) Diabetes Mellitus is a risk factor for motor vehicle crash involvement, (2) severe hypoglycemia and hypoglycemia unawareness are a common consequence of insulin therapy and of tight control of blood glucose levels in particular, (3) no studies support the protocols in a program that would issue exemptions, (4) compliance by drivers and employers to program requirements is unlikely, (5) studies designed to investigate the safety of issuing waivers or exemptions would produce no scientifically valid conclusions, and (6) the research design used to investigate safety in an earlier waiver program was inadequate. The issues raised in these previous comments have been addressed at length in 58 FR 40690 (July 29, 1993) (FHWA Docket No. MC-87-17) and 61 FR 13337 (March 26, 1996) (FHWA Docket No. MC-96-2). FMCSA will not address these points again here, but refer interested parties to the earlier discussions. The IIHS has, however, raised a new issue and this is discussed in the following paragraph.

The IIHS stated that the agency has ignored the concern that the working conditions of interstate truck drivers are not compatible with the medical needs of people with insulin-treated diabetes. IIHS states that long and irregular work hours, night responsibilities, variations in the amount of exercise, and variations in the amount of food consumed are integral aspects of long-haul trucking. These factors, IIHS argues, make it difficult to calibrate insulin doses to maintain blood glucose at healthy levels.

FMCSA is aware that operating a CMV in interstate commerce is an arduous occupation. The agency designed the screening criteria in the exemption program to identify those insulin-using diabetics, who will have a high degree of responsibility in managing the condition while driving in interstate commerce. The agency bases this assertion on the experience obtained in the above referenced

diabetes waiver program. The evidence generated by that program, which had the same screening criteria as that proposed for the exemption program, demonstrated that responsible insulin-using diabetics can safely operate a CMV in interstate commerce. The evidence obtained in that program represents over 9 million miles of CMV operation by individuals who were successfully screened by the criteria. In addition, FMCSA will require that an applicant for the diabetes exemption program be educated in diabetes and its management, and have demonstrated a willingness to properly monitor and manage his or her diabetes. Finally, not all operations in interstate commerce are long-haul.

The Advocates for Highway Safety (AHAS) stated strong opposition to the FMCSA proposal to issue exemptions to selected insulin-using diabetic CMV operators. In stating its opposition, AHAS claims that the proposed exemption program lacks a sufficient scientific foundation. In particular, AHAS argues that FMCSA's assertion that the ITDM exemption is scientifically sound and based on good medical information is conclusionary and not an accurate representation of the factual record. AHAS states that FMCSA is reaching a conclusion that selectively highlights the most salient pieces of evidence in the TEA-21 Report to Congress, to support the implementation of an ITDM exemption program. In making this claim, AHAS points to FMCSA's reference to two studies in the TEA-21 Report to Congress ("The Diabetes Control and Complications Trial" (1995) and the "United Kingdom Prospective Diabetes Study" (1998)), as the most extensive investigation of insulin therapy to date.

In the presentation of these studies, AHAS argues that FMCSA claims the studies show positive results for reduction in blood glucose levels and microvascular complications, and that the agency also reports results that show significantly higher rates of hypoglycemia due to the use of insulin. AHAS states that the agency's notice of intent did not explain how these results support the agency's determination that an exemption program for ITDM will have a safety level that is equal to or better than the prevailing level.

FMCSA is acutely aware of the threat presented by tight control of blood glucose levels and hypoglycemia. It was not the agency's intent to use the results of those studies to support the determination of safety. Rather, the intent was to identify a potential threat that had to be accounted for in the protocols of the proposed exemption

program. To this end, the expert medical panel addressed this issue in the FMCSA's TEA-21 Report to Congress. The panel, while clearly recognizing hypoglycemia as a threat, also thought awareness was a bigger problem. It noted that there was a correlation between hypoglycemia awareness and recurrent, severe hypoglycemic episodes, as shown in the Diabetes Control and Complications Trial data. The panel stated that individuals who are prone to severe hypoglycemia should not drive. The panel agreed that severe hypoglycemia in the past year or several episodes in the past five years can predict the future. The panel also agreed that training in the awareness of hypoglycemia is necessary for drivers of CMVs. Because of this, awareness education is a requirement in the protocols of the exemption program announced today.

AHAS points to a 1999 study (Clarke, W. *et al.* "Hypoglycemia and the Decision to Drive a Motor Vehicle by Persons with Diabetes." JAMA, August 1999, Vol. 282, No. 8, 750-754) to raise questions about an exemption program. According to AHAS, the study found that even when individuals accurately estimated low blood sugars levels, a significant proportion still decided to drive. However, the researchers in this study also said that these findings did not mean ITDM individuals should be prohibited from driving. They said it was reasonable for individuals to measure their blood sugar levels before driving and take steps to raise potentially low levels. The researchers said that drivers with ITDM should always carry rapid-acting glucose when they drive. Moreover, these researchers claim that individuals with ITDM could benefit from awareness training. In fact, in a subsequent study by these same researchers, the results showed that awareness training improved the detection of hypoglycemia and improved judgment for knowing when to raise low blood glucose, or to lower elevated blood glucose, and for knowing when not to drive while hypoglycemia is a threat (Cox, D. J. *et al.* "Blood Glucose Awareness Training; Long-Term Benefits, Diabetic Care, 2001, 24:637-642). Because of the concerns about hypoglycemia, FMCSA has incorporated all of the suggested interventions in the protocols of today's exemption program. The California Department of Motor Vehicles also described the same article as AHAS raising the same concerns. There is an additional response to their comments later in this discussion.