

2. Able to and has demonstrated willingness to properly monitor and manage his/her diabetes, and

3. Will not likely suffer any diminution in driving ability due to his/her diabetic condition; and

(b) Secondly, the physical examination must be conducted by a medical examiner who attests that the individual is physically qualified under 49 CFR 391.41, or holds a valid exemption.

(2) Each individual must agree to and must comply with the following conditions:

(a) Carry a source of rapidly absorbable glucose at all times while driving;

(b) Self-monitor blood glucose levels prior to driving and every two to four hours while driving using a portable glucose monitoring device equipped with a computerized memory;

(c) Submit blood glucose records to both the endocrinologist and medical examiner at the annual examinations or when otherwise directed by an authorized agent of FMCSA; and

(d) Provide a copy of the endocrinologist's report to the medical examiner at the time of the annual medical examination; and

(3) Each individual must provide a copy of the optometrist's or ophthalmologist's report indicating that there is no diabetic retinopathy and the individual meets the current vision standards at 49 CFR 391.41(b)(10). If there is any evidence of diabetic retinopathy, the individual must provide to the medical examiner at the time of the annual medical examination a copy of the ophthalmologist's report indicating that the individual does not have unstable proliferative diabetic retinopathy; and

(4) Each individual must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or must keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the certification when driving for presentation to a duly authorized Federal, State, or local enforcement official.

Basis for Determination

Under 49 U.S.C. 31315 and 31136 (e), the FMCSA may grant an exemption for up to a two-year period if it finds that the action would likely achieve a level of safety that is equivalent to, or greater than, the level of safety that would be achieved absent such exemption. This requirement sets the criteria for safety in developing new programs. In this context, relative to diabetes, Section

4018 of TEA-21 directed the Secretary to determine if it is feasible to develop a safe and practicable program for allowing individuals with ITDM to operate CMVs in interstate commerce. In making that determination, the primary focus was on whether such a program could achieve a level of safety that is equal to or greater than the level that exists without the program. To do this, multiple sources of information were sought.

The sources of information sought to reach a determination ranged from background research and risk assessment to consultation with experts and an examination of how other similar programs were conducted. Specifically, this involved: (1) Literature reviews to identify earlier risk studies and how ITDM is treated and managed, (2) investigation of the policies and programs of other DOT modal administrations, (3) an examination of how such States treated drivers with ITDM and their experience in allowing such drivers to operate CMVs, and (4) examining the results of recent risk studies. Further, to obtain expert input concerning the treatment of ITDM, the agency assembled a panel of physicians whose main focus was the treatment of diabetes. Overall, the conclusions reached in this determination were, therefore, based on a broad range of relevant information.

The approach was guided by the best principles of risk assessment in conjunction with program development. The feasibility focused primarily on the potential safety of such a program, and the procedures that can ensure safety, while providing a benefit to the public. The results of the determination led to a conclusion that a safe and practicable program was feasible. The conclusions further showed that a viable program protocol for allowing certain individuals with ITDM to operate CMVs would require three components.

The first component is screening applicants to identify qualified drivers. This process examines the applicant's experience and safety in operating a CMV. As stated above, the screening criteria require three years of safe CMV operation with ITDM. The criteria are based on the evidence available from the above referenced waiver program, previous program reviews by researchers in the field, and the safety prediction literature. FMCSA believes that a safe driving history is a required basis for screening, because the primary focus of the determination is to develop a program with the necessary safety level. The screening component requires an acceptable history of hypoglycemia along with the results of examinations

by required medical specialists. An important aspect of screening also involves education in the management of the condition and awareness of hypoglycemia.

The second component provides guidelines for managing ITDM for the qualified applicants. This includes direction in the supplies to be used and the protocol for monitoring and maintaining appropriate blood glucose levels. This is based on the experience of other successful programs and detailed input from the above referenced medical panel.

The last component specifies the process to be used for monitoring qualified ITDM operators of CMVs. This addresses the required medical examinations and the schedule for their submission. It also specifies how glucose measures should be taken and reviewed and the methods for reporting episodes of severe hypoglycemia and accidents. The monitoring component increases the degree of rigor to meet the needed level of safety. In the program, qualified drivers will be required to reapply and be screened every two years to renew their exemptions. This means that the drivers in the program will need to verify their safe driving behavior, health status, and education in a manner that involves ongoing monitoring. In addition, to monitor health status, the drivers will be required to be examined by an endocrinologist and obtain medical certification on an annual basis.

The FMCSA believes this is a comprehensive program. It thoroughly addresses the wide range of concerns about this type of program. The program's structure reflects the range of input from numerous sources. It also reflects how the most feasible and effective aspects of each input were combined to develop a program that provides great benefit with a primary focus on safety.

Discussion of Comments

There were 396 comments to the notice of intent to issue exemptions published in the **Federal Register** on July 31, 2001 (66 FR 39548), with 373 commenters generally in favor of the proposal and 23 in opposition. Among the comments submitted, some were sent multiple times by the same individuals or organizations. Those in support of the proposed program largely directed their comments to the removal of a comprehensive prohibition on the operation of CMVs by insulin-using diabetics, which would be replaced by an individual assessment of their ability to drive the CMVs. Those in support often did not agree with all aspects of