

The goal of the Federal Motor Carrier Safety Administration (FMCSA) is to reduce the number and severity of large truck- and bus-involved crashes through more commercial motor vehicle and operator inspections and compliance reviews, stronger enforcement measures against violators, expedited completion of rulemaking proceedings, scientifically sound research, and effective commercial driver's license testing, recordkeeping, and sanctions. The Office of Research and Technology (R&T) manages research and technology development and deployment programs for the FMCSA.

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*Driver physical qualifications* concentrates on the research of specific medical conditions in relation to commercial motor vehicle driving safety, with emphasis on medical standards guidelines.



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## FEDERAL MOTOR CARRIER SAFETY ADMINISTRATION

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# Qualifying Individuals with Insulin-Treated Diabetes to Operate Commercial Motor Vehicles

## Introduction

The Transportation Equity Act for the 21st Century directs the U.S. Department of Transportation (DOT) to determine whether it is feasible to develop a safe and practical protocol to allow individuals with insulin-treated diabetes mellitus to operate commercial motor vehicles in interstate commerce. This Tech Brief summarizes the resulting report, which was submitted to Congress by the Federal Motor Carrier Safety Administration (FMCSA), formerly the Office of Motor Carriers in the Federal Highway Administration (FHWA), in August 2000. The report is available at <http://www.fmcsa.dot.gov/rulesregs/medreports.htm>.

## Background

Current law prohibits insulin-treated diabetics from driving commercial motor vehicles (i.e., large trucks and motorcoaches) in interstate commerce. The Agency established that standard in 1970 in response to several studies that indicated that diabetic drivers had a higher rate of involvement in accidents than the general driving population. In 1977 the Agency solicited comments on a proposed change to the diabetes standard, but maintained the prohibition after considering comments and literature citing highway safety concerns.

## Diabetes Waiver Program

In 1986 the American Diabetes Association and others petitioned the Agency to grant waivers to qualified insulin-treated diabetics on a case-by-case basis. The Agency solicited comments and conducted extensive research on the proposal, including convening a conference to review the diabetes standard. Conference participants recommended that some drivers with diabetes be certified to drive, depending on their insulin use and certain conditions, including whether they had safe driving records.

In 1990 the Agency requested comments on a proposal to allow insulin-treated diabetics to drive commercial motor vehicles if they met certain criteria and were found to be qualified by an endocrinologist. The Agency also sponsored a risk assessment study and requested comments on a proposed waiver program to collect data to be used in updating the diabetes standard.

A diabetes waiver program began in 1993. The program originally was developed as part of a research study



to investigate if insulin-treated diabetic drivers admitted to the program could safely operate commercial motor vehicles. Under the program, the waivers would last for 3 years—or until resolution of the concurrent rulemaking action—whichever occurred first. The waiver program required each participating driver to have at least 3 years of recent commercial driving experience while using insulin, a safe driving record, and a certification by an endocrinologist and an ophthalmologist.

In 1996 the District of Columbia Court of Appeals, in *Advocates for Highway and Auto Safety v. Federal Highway Administration*, ruled that the Agency's vision waiver program, which used an approach similar to the diabetes program to qualify drivers, was contrary to law. As a result the diabetes waiver program was terminated. Drivers with diabetes waivers at the end of the program were allowed to continue to operate commercial motor vehicles in interstate commerce under "grandfather" provisions.

## Purpose

The report determines whether it is feasible to develop a safe and practical protocol to allow insulin-treated diabetics to operate commercial motor vehicles in interstate commerce.

## Methodology

To evaluate the feasibility of allowing insulin-treated diabetics to operate commercial motor vehicles, the Agency:

- reviewed relevant background material and literature,
- studied related policies of other DOT administrations and States,
- analyzed recent risk assessments, and
- convened a panel of medical experts.

## Background Research and Literature Review

The Agency conducted background research on the risk of driving with diabetes. The evidence collected in earlier studies on the relationship between diabetes and automobile crashes had produced conflicting results, in many cases due to flawed

methodology. Further, none of the studies addressed the operation of commercial motor vehicles. Upon the termination of the waiver program and its research component, the Agency lacked clear risk assessment information.

A literature review on the treatment and management of insulin-treated diabetes focused on six reported studies and revealed positive findings. The two largest and most reported studies—The Diabetes Control and Complications Trial, and the United Kingdom Prospective Diabetes Study Group—represented the most extensive investigations of insulin therapy. Both studies found that patients experienced reductions in blood glucose levels and significantly fewer microvascular complications (i.e., related to small blood vessels) with intensive treatment. However, the two studies also showed significant adverse effects from insulin use, notably a significantly higher rate of hypoglycemia (i.e., an abnormal decrease of sugar in the blood).

## Policies of Other Federal Agencies

Of the other DOT agencies, only the Federal Aviation Administration (FAA) has a well-developed program regarding insulin-treated diabetes. In 1994 the FAA determined that selected insulin-treated diabetics can be considered for special issuance of a third-class Airman Medical Certificate under a screening, glucose management, and monitoring protocol. The program developed through a series of steps in which the FAA capitalized on its experience, reviewed relevant research, consulted medical experts, and considered comments from the public and interested organizations.

## States and Insulin-Treated Diabetic Drivers

The Agency examined how States regulate insulin-treated diabetic drivers. States are permitted to choose whether to apply Federal regulations to the medical qualifications for intrastate commercial drivers. Some States have chosen to adopt the Federal standards and not allow insulin-treated diabetics to operate commercial motor vehicles. Some States have given "grandfather" rights to insulin-treated diabetic drivers who were already driving intrastate, while allowing no new drivers after a certain date. Other States have programs to allow drivers to apply to operate in intrastate commerce. Among the States that allow some insulin-treated diabetics to drive commercial motor vehicles, the monitoring of the drivers varies widely.

## Risk Assessments

The report presents four recent risk assessment studies that address diabetes and the operation of commercial motor vehicles:

- two Canadian studies analyzing insurance data for a group of truck drivers,
- an FHWA study analyzing data from the diabetes waiver program, and
- an FMCSA study analyzing insulin-treated diabetic drivers of large trucks and a comparison group of drivers with commercial licenses.

The first study, in which insulin use was not considered, analyzed insurance data for 1,307 truck drivers and found that diabetic drivers of large combination trucks did not have higher accident rates than their non-diabetic counterparts. However, that study found a significantly higher accident rate for diabetic drivers of smaller trucks than for their non-diabetic counterparts. The second Canadian study used the same database and concluded that diabetic drivers did not have accidents that were significantly more severe (measured in injuries and fatalities) than non-diabetic drivers. The third study re-analyzed data from the FHWA waiver program to address earlier criticism about possible bias when the drivers in the program were compared to national data. The analysis showed that the accident rate of the waiver program drivers was the same as the national rate. The last study examined 723 insulin-treated diabetic drivers of large trucks and a comparison group of 1,297 drivers with commercial driver's licenses. The results, after adjustment for confounding effect (i.e., variation related to the independent and dependent variables), showed no significant differences between the two groups in the rate or severity of accidents.

## Expert Medical Panel

In 1999 the Agency convened a panel of experts in the treatment of diabetes. The panel addressed the screening and monitoring issues associated with a program allowing insulin-treated diabetics to operate commercial motor vehicles. In its written reports and discussion at a meeting in Washington, DC, the panel suggested that advances in the treatment of diabetes make it possible to control the disease and identify individuals who are capable of doing so. The panel identified methods to avoid acute complications, including hypoglycemia, and endorsed



***FMCSA's proposed exemption process would evaluate insulin-treated diabetic truck drivers on a case-by-case basis.***

a protocol for monitoring glucose before and during the operation of a commercial motor vehicle. The panel concluded that from a medical standpoint it is feasible to permit some individuals with insulin-treated diabetes to operate commercial motor vehicles.

## Findings and Recommendations

The report concludes that it is feasible to develop a safe and practicable protocol to allow some insulin-treated diabetics to operate commercial motor vehicles. Research on the treatment and management of insulin-treated diabetes, combined with the determination of the medical panel, indicate that the disease and its adverse effects can be successfully controlled and monitored. Moreover, recent risk assessments provide evidence that diabetic commercial drivers can perform in an acceptably safe manner. Finally, the FAA program and the re-analysis of the FHWA's diabetes waiver program demonstrate that it is possible to screen and monitor insulin-treated diabetics so that safe performance is feasible.

Based largely on the experience of the FAA and FHWA, a viable program for allowing individuals with insulin-treated diabetes to drive commercial motor vehicles must have three components:

1. a screening component to identify qualified applicants that would examine the applicants' experience and safety in operating commercial motor vehicles with insulin-treated diabetes, their history of hypoglycemia, and the results of examinations by endocrinologists and ophthalmologists;

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The report is available on the FMCSA Web site at <http://www.fmcsa.dot.gov/rules/regs/medreports.htm>.

## Key Words

diabetes, commercial motor vehicle, driver, insulin, waiver

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2. guidelines for drivers for the management of insulin-treated diabetes, including maintaining appropriate supplies and monitoring safe blood glucose levels; and
3. a specific process to be used for monitoring insulin-treated diabetic drivers, including the required medical examinations and their submission requirements, how to take and review glucose measurements, and how to report episodes of severe hypoglycemia and accidents.

## Assessment of Legal Issues

The report addresses the legal consequences of permitting insulin-treated diabetics to drive commercial motor vehicles in interstate commerce. Such a rule would be subject to a challenge of its validity, and tort liability for damages sustained in an accident involving an insulin-treated diabetic driver. However, these consequences are similar to those associated with any other rule involving driver standards and qualifications. For employers who hire insulin-treated diabetic individuals, the rule might expose them to new standards of responsibility for monitoring the health of drivers meeting Federal guidelines.

## New Developments

On July 31, 2001, the FMCSA published a Federal Register notice seeking comments on an exemption process to allow certain insulin-treated diabetic drivers to operate commercial motor vehicles in interstate commerce. Federal law (49 U.S.C. 31315 and 31136(e)) permits the Agency to grant an exemption from the diabetes standard if it is likely to achieve an equivalent or greater level of safety than without the exemption.

Under the proposal, the Agency would implement an exemption process using case-by-case evaluations, similar to the vision exemption process. Federal diabetes requirements would *not* be amended. The process would consist of three parts. First, a screening component would identify qualified applicants after examining their experience and safety operating commercial motor vehicles with insulin-treated diabetes, any history of hypoglycemia, and medical exam results. Second, the Agency would provide guidelines to drivers for managing their diabetes, including appropriate supplies and protocol. Finally, the Agency would specify the process for monitoring insulin-treated commercial drivers, including required medical exams and submission requirements, how to take and review glucose measures, and how to report episodes of severe hypoglycemia and accidents.

## Reference

*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 the Transportation Equity Act for the 21st Century.* FMCSA, Washington, DC, July 2000.