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

JULY 2000

EXECUTIVE SUMMARY

Section 4018 of the Transportation Equity Act for the 21st Century (the Act) directs the Secretary of Transportation to determine if it is feasible to develop a safe and practicable program for allowing individuals with insulin-treated diabetes mellitus (ITDM) to operate commercial motor vehicles (CMVs) in interstate commerce. In making the determination, the Secretary was directed to evaluate research and other relevant information on the effects of ITDM on driving performance. The Act states that, to accomplish this, the Secretary shall consult the states with regard to their programs for CMV operation by ITDM drivers, evaluate the Department of Transportation's (DOT) policies in other modes of transportation, analyze pertinent risk data, consult with interested groups knowledgeable about diabetes and related issues, and assess the possible legal consequences of permitting ITDM individuals to operate CMVs in interstate commerce. The Act also directs the Secretary to report the findings to Congress and, if a program is feasible, describe the elements of a protocol to permit individuals with ITDM to operate CMVs.

The report concludes that a safe and practicable protocol to allow some ITDM individuals to operate CMVs is feasible. The motor carrier regulatory functions of the Federal Highway Administration (FHWA) were transferred to the recently created Federal Motor Carrier Safety Administration (FMCSA). The FMCSA is evaluating alternatives for implementing a process for allowing individuals with ITDM to drive in interstate commerce.

The FMCSA's evaluation presents the background and context of diabetes and CMV operation. The FHWA established the current standard for diabetes in 1970 because several risk studies indicated that diabetic drivers had a higher rate of accident involvement than the general

population. Since 1970, the FHWA engaged in several activities to address the issue of diabetes and CMV operation. On March 28, 1977, the FHWA published an Advance Notice of Proposed Rulemaking (ANPRM) to solicit comments on the diabetes standard (42 FR 16452). The FHWA terminated this rulemaking in November 1977 without amending the standard, after determining that the more substantive comments and the literature cited in the ANPRM supported the prohibition against the operation of CMVs by insulin-using diabetics because of highway safety concerns. On November 25, 1987, the FHWA published a new ANPRM (52 FR 45204) requesting comments on petitions from two individuals and the American Diabetes Association to eliminate the blanket prohibition against insulin-using diabetics and grant waivers on a case-by-case basis. In September 1987, a Conference on Diabetic Disorders and Commercial Drivers was held to review the diabetes standard in light of advances in the care of diabetics. Conference participants (physicians, scientists, federal officials and representatives from the motor carrier industry) recommended that some drivers with diabetes be certified to drive depending upon insulin use and under certain conditions (absence of recurrent hypoglycemia, safe driving record, etc.). Following this, the FHWA published a Notice of Proposed Rulemaking (55 FR 41208) requesting comments on a proposal to revise the diabetes standard to allow insulin-using diabetics to operate CMVs and sponsored a 1990 risk assessment that estimated various levels of accidents among diabetic drivers depending upon the severity of hypoglycemia. The estimated level of accidents was deemed acceptable and a Notice of Intent to Issue Waivers was published in 1992. This led to a 1993 waiver program, based on a three-year safe driving record while using insulin and medical examinations by the required specialists.

The diabetes waiver program, originally part of a research study, was terminated in 1996. The

D.C. Court of Appeals (Advocates for Highway and Auto Safety v. Federal Highway Administration, 28F. 3d 1288, D.C. Circuit 1994) had found that the initial determination that the agency's vision waiver program would not adversely affect the safe operation of CMVs was "devoid of empirical support in the record" and, therefore, contrary to law. Although the decision initially affected only the vision waiver program, it had a direct effect on the diabetes program because of the similar approach used to prequalify drivers. Those drivers holding waivers at the program's termination were allowed to continue to operate CMVs in interstate commerce under grandfather provisions.

Background research was conducted on the risk of driving with diabetes. Although the relationship between diabetes and automobile crashes had been assessed since 1965, the epidemiological evidence from 1965 to 1991 produced conflicting results. The lack of consistent results was in many cases caused by flawed methodology. Further, none of the studies addressed the operation of CMVs. With the termination of the waiver program and its research component, the FHWA lacked clear risk assessment information.

A literature review was conducted on the treatment and management of ITDM. The research results showed positive findings. Six studies have been reported in the literature. 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 and had similar findings. Both showed that patients experienced reductions in blood glucose levels, and significantly fewer microvascular complications, with intensive treatment. However, the studies also showed significant adverse effects from insulin use, notably, a significantly higher rate of hypoglycemia.

Investigation of the policies of other DOT modal administrations regarding ITDM showed that only the Federal Aviation Administration (FAA) has a well-developed program. In 1994, the FAA

determined that selected ITDM individuals can be considered for special issuance of a third-class Airman Medical Certificate under a screening, glucose management, and monitoring protocol. The program evolved through a series of steps in which the agency capitalized on its experience, reviewed relevant research, consulted medical experts, and considered comments from the public and interested organizations.

As a part of its feasibility determination, the FMCSA examined how the states treated drivers with ITDM. Although the states have the option to apply the FMCSRs to the medical qualifications for intrastate CMV operators, they also have the flexibility to deviate from the FMCSRs. Most states have chosen to adopt the federal standards and not allow ITDM individuals to operate CMVs. Some states have granted grandfather rights to drivers who were already driving intrastate, while allowing no new drivers after a specific date. Other states have programs whereby drivers can apply for the opportunity to operate in intrastate commerce. Based on several surveys of the states and contact with individual states, the programs of four states (Utah, Michigan, Kentucky and Delaware) are presented as examples of more extensive approaches. These states have screening, operating and monitoring protocols of varying degrees of intensity and coverage, but do not monitor results.

The report presents four recent risk assessment studies (1995 to 1997) that specifically address diabetes and the operation of CMVs. Two of the studies were performed in Canada, while the other two were conducted by the Office of Motor Carrier Safety (now the FMCSA). The first study analyzed insurance data for 1,307 truck drivers, and found that diabetics operating smaller trucks had significantly higher accident rates (diabetics operating large combination trucks did not have higher rates). Insulin use was not considered. The second Canadian study used the same database, and concluded that diabetic drivers did not have accidents that were significantly more severe than those

without the condition (severity was defined by injuries and fatalities). The third study used data from the FHWA waiver program. These data were reanalyzed to address earlier criticism concerning possible bias when the drivers in the program were compared with national data. The analysis showed that the accident rate of the waiver program drivers was the same as the national rate. The last study looked at 723 ITDM drivers of large trucks and a comparison group of 1,297 drivers with commercial driver's licenses. After adjustment for confounding, the results showed no significant differences between the two groups in accident rate or severity.

The FHWA also assembled a panel of physicians expert in the treatment of diabetes. The panel was asked to address the screening and monitoring issues that would be associated with a process to allow ITDM individuals to operate CMVs. Responding with written reports and through discussion at a meeting in Washington, DC, the panel expressed the opinion that advances in the treatment of diabetes make it possible both to control the disease and to permit the identification of those individuals capable of doing so. The panel identified methods to avoid acute complications, including hypoglycemia, and endorsed a protocol for monitoring glucose before and during the operation of a CMV. The panel concluded that from a medical standpoint a process was feasible for permitting some individuals with ITDM to operate CMVs.

The report concludes that a safe and practicable protocol to allow some ITDM individuals to operate CMVs is feasible. The research on the treatment and management of ITDM, combined with the determinations 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 CMV operators can perform in an acceptably safe manner. Finally, the program operated by

the FAA and the reanalysis of the FHWA's diabetes waiver program demonstrate that it is possible to screen and monitor ITDM individuals so that safe performance is feasible.

The report further concludes that a viable program protocol for allowing individuals with ITDM to operate CMVs would require three components. The first is a screening component to identify qualified applicants. This process would examine the applicant's experience and safety in operating CMVs with ITDM, the history of hypoglycemia, and the results of examinations by the required medical specialists (endocrinologists and ophthalmologists). The second component would provide guidelines for managing ITDM, including supplies to be used and the protocol for monitoring and maintaining appropriate blood glucose levels. The last component would specify the process to be used for monitoring ITDM commercial drivers. It would address the required medical examinations and the schedule for their submission. It also would indicate how glucose measures should be taken and reviewed, and specify how episodes of severe hypoglycemia and accidents should be reported. These components are based largely on the structure of the FAA and FHWA waiver programs. They are presented in detail in the report.

Finally, the report addresses the legal consequences of permitting ITDM individuals to drive CMVs in interstate commerce. It was determined that the legal consequences of a rule (including a regulation, policy or standard adopted pursuant to the Administrative Procedure Act (APA)) fall into two categories: (1) an APA challenge to the validity of the rule, and (2) tort liability for damages sustained in an accident involving an ITDM driver. The assessment concluded that these consequences are no different from those associated with any other rule involving driver standards and qualifications. For employers that hire ITDM drivers, the rule might expose them to new standards of responsibility for monitoring the health of drivers who meet federal guidelines.

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1. Introduction

In Sec. 4018 of the Transportation Equity Act for the 21st Century [Public Law 105-178, 112 Stat. 107, at 413], Congress has directed the Secretary of Transportation to determine if it is possible to develop a safe, practicable and cost-effective screening, operating and monitoring protocol for allowing insulin-treated diabetes mellitus (ITDM) individuals to operate commercial motor vehicles (CMVs) in interstate commerce. In this determination, the protocol will be one which ensures that, for those allowed to operate CMVs, the level of safety will be equal to or greater than that achieved with the current prohibition on these drivers. In making this determination, the Secretary was further directed to compile and evaluate research and other information on the effects of ITDM on driving performance.

In compiling and evaluating relevant information, the Act states that specific areas shall be considered:

- Consult with States that have developed and are implementing a screening process to identify individuals with ITDM who may obtain waivers to drive CMVs in interstate commerce;
- Evaluate the Department's policy and actions to permit certain ITDM individuals who meet selection criteria and who successfully comply with the approved monitoring protocol to operate in other modes of transportation;
- Assess the possible legal consequences of permitting ITDM individuals to drive CMVs in interstate commerce;
- Analyze available data on the safety performance of diabetic drivers and motor vehicles;
- Assess the relevance of intrastate driving and experiences of other modes of transportation to interstate driving and experiences of other modes of transportation to

interstate CMV operations;

- Consult with interested groups knowledgeable about diabetes and related issues.

Finally, the Act directs the Secretary to report to Congress. If no protocol is feasible, the report must present the basis for this decision. Conversely, if a screening and monitoring protocol can be developed, the report must describe the elements of the protocol, and the Secretary must promptly initiate a rulemaking proceeding to implement the protocol described.

2. Background and Context of Diabetes and the Operation of CMVs

a. Overview of the History of Diabetes and the Operations of CMVs

Diabetes was not specifically mentioned in the Federal Motor Carrier Safety Regulations (FMCSRs) until April 22, 1970 (35 FR 6458). However, as early as 1939, the Interstate Commerce Commission (ICC) required a urine glucose test as part of the medical examination for determining whether a person was physically qualified to drive a CMV in interstate or foreign commerce. The standard in 1939 provided that a person was qualified to drive who had "No mental, nervous, organic, or functional disease, likely to interfere with safe driving."

The Federal Highway Administration (FHWA) established the current standard for diabetes in 1970 because the results of several accident studies, including "Accident and Violation Rates of Washington's Medically Restricted Drivers" by A. Crancer and L. McMurray (December 1967), indicated that diabetic drivers have a higher rate of accident involvement than the general driving population.

On March 28, 1977, the FHWA published an Advance Notice of Proposed Rulemaking

(ANPRM) (42 FR 16452) to solicit comments on the diabetes standard. On November 3, 1977, the FHWA terminated this rulemaking without amending the diabetes standard. The agency determined, among other things, that the more substantive medical comments received in response to the ANPRM and the medical literature cited in the ANPRM supported the prohibition of insulin-using diabetics and that highway safety would be better protected by retention of that prohibition (42 FR 57488 (1977)).

In 1986, rulemaking petitions were accepted from two individuals, and from the American Diabetes Association (ADA). These petitioners requested that the FHWA initiate a rulemaking action to eliminate the "blanket prohibition" against insulin-using diabetics and allow such drivers to obtain a waiver on a case-by-case basis. The ADA petition requested that the FHWA develop a waiver program whereby physicians used by the FHWA would make individual determinations of medical qualifications and the FHWA would grant waivers to qualified individuals on a case-by-case basis. On November 25, 1987, the FHWA published an ANPRM (52 FR 45204) requesting comments from interested parties on the ADA petition. In addition to the petitions, ongoing work was being conducted by the FHWA to investigate various aspects of the issue.

b. FHWA Past Investigations of the Issue

The FHWA conducted a number of investigations following the interest shown in the issue of ITDM and the operation of CMVs. The following is a summary of FHWA's activities from the late 1980's until a waiver program was implemented in 1993.

In September 1987, the FHWA convened a conference on diabetic disorders and commercial drivers. The conference was attended by numerous physicians and scientists experienced in the care of

people with diabetes; Federal officials; and representatives from all segments of the motor carrier industry. The focus of the conference was the review of the current medical standards for truck drivers with diabetes mellitus. The attendees were divided into four task forces which reviewed the rule in the context of the many advances that have occurred in the care of diabetes since 1970. Based on this work the following recommendations were made:

? Certified commercial drivers who develop diabetes mellitus after driving for five (5) years and who require insulin therapy may continue to be certified if they meet the particular criteria:

--Absence of recurrent hypoglycemia that results in loss of consciousness or seizure;

--Absence of seizure or coma without antecedent prodromal symptoms of hypoglycemia;

--Absence of recurrent diabetic ketoacidosis or hyperosmolar non-ketotic coma;

--Documentation of regular medical follow-up.

? Persons with diabetes mellitus who use insulin and who have no demonstrated history of safety on the highway as commercial drivers are not eligible for certification;

? All persons with diabetes mellitus who do not require insulin therapy are eligible for certification as commercial drivers unless disqualified by an organ complication of diabetes as defined under current Federal standards.

The conference members also recommended to the Department of Transportation (DOT) that certified commercial drivers requiring insulin for diabetes management be considered eligible for continued certification. While emphasizing the initial eligibility for drivers who develop diabetes requiring insulin therapy and who have proven safety skills as commercial drivers, the conferees encouraged the DOT to accrue prospective data on these drivers after certification. These data would

allow the Department to reevaluate the recommendations after a suitable period of time to study the feasibility of including insulin-treated diabetics who wish to become commercial drivers.

Additionally, it was recommended that:

- All drivers with diabetes should have annual examinations for visual impairment, neurological function, and cardiovascular disease (including hypertension).

- If poor control of the diabetic state based on the suggested guidelines of the American Diabetes Association exists, certification will be deferred until control is improved.

- Drivers taking oral agents should be informed about possible interactions of these drugs with other medications they may be taking and about possible hypoglycemic risks associated with missed meals.

A final report was published in July 1988 (FHWA, 1988).

On October 5, 1990, the FHWA published a Notice of Proposed Rulemaking (NPRM) (55 FR 41028) requesting comments on a proposal to allowed insulin-using diabetics to drive a CMV if they met certain examination criteria and were found qualified by a board-certified endocrinologist. An analysis of the comments submitted showed that public support of the NPRM was predicated upon the belief that (1) medical advances allowed people with diabetes to effectively manage their disease and, therefore, each diabetic's qualifications should be examined individually; (2) the existing rule deprived certain individuals of the right to work in their chosen profession; and (3) the blanket prohibition was discriminatory. Comments opposed to the NPRM centered around the following assertions: (1) the risks from implementing the proposed changes would outweigh any benefits gained (i.e., deaths, injuries, and property losses), and (2) the cost of implementing the changes would be prohibitive.

Also in October 1990, the FHWA contracted with the University of Pittsburgh to perform a risk assessment assuming insulin-using diabetics were allowed to drive CMVs in interstate commerce. The risk assessment was developed by synthesizing available information concerning insulin using drivers and the complications associated with insulin use. The focus of the assessment was to estimate the number of accidents that could be expected based on the number of ITDM individuals who would be allowed to drive and the occurrence of various severity levels of hypoglycemia. The results of this assessment are discussed below in the section presenting earlier risk assessments. This assessment also included a review of the literature concerned with the accident experience of diabetic drivers and state laws regulating insulin-using CMV drivers. In addition, the investigation reviewed the effectiveness of the current treatment of diabetes. The final report was published in May 1992 (FHWA, 1992).

On October 21, 1992, the FHWA published a Notice of Intent to Issue Waivers (57 FR 48011) requesting comments on a proposed waiver program to collect data that could be used in the concurrent rulemaking action to update the diabetes standard. Comments favoring the FHWA's proposal to issue waivers suggested that neither the diabetic drivers who use insulin nor the public would be more at risk if these drivers were allowed to drive CMVs under the conditions set forth in the proposed waiver program. Other comments cited the scientific advances that have been made in the medical treatment of diabetes over the last 50 years as a rationale for the waivers.

The U.S. Equal Employment Opportunity Commission wrote that the diabetes waiver program was an important and positive step in expanding the employment opportunities of qualified individuals with disabilities. Those opposed to the proposed waiver program cited concerns about hypoglycemia,

reliability of self-verifications, tight control of blood sugar levels, work schedules, and additional accidents resulting in injury or death (Advocates for Highway & Auto Safety (AHAS), Insurance Institute for Highway Safety (IIHS), American Trucking Associations (ATA), United Parcel Service (UPS), the American Movers Conference and the Idaho State Police).

On July 29, 1993, the FHWA published a Final Determination (58 FR 40690) to issue waivers from the diabetes requirements at 49 CFR 391.41(b)(3) to certain insulin-using diabetic drivers of CMVs. The waiver was valid for a period of three years unless it was revoked for failure to comply with its conditions, or until resolution of a concurrent rulemaking action, whichever occurred first. To obtain a waiver, an applicant was required to have at least three years of recent experience driving a CMV while using insulin to control his or her diabetes, a safe driving record, and must have been recently examined by a board-certified/eligible endocrinologist and an ophthalmologist. The deadline for submitting applications for waivers was April 30, 1994.

The waiver program developed by the FHWA was originally a part of a research study. This study was designed to investigate if individuals with ITDM who were screened by the program could safely operate CMVs. Those who were successful in the application process and received waivers would become members of a cohort in a prospective study.

The driving behavior of the waiver cohort was to be compared to that of a sample of drivers from the population of CMV operators. However, this planned three year prospective study was not implemented because the agency was unable to recruit a sufficient number of drivers from the relevant populations for a comparison group. Without a comparison group, it was necessary to look elsewhere for information representing a national norm for CMV safety. In an immediate sense this was necessary

so that safety monitoring could be conducted while the waiver program was in operation. Comparative material was found in the General Estimates System (GES), an annual national survey of police accident reports (PARs) sponsored by the National Highway Traffic Safety Administration (NHTSA). The GES produces annual estimates of the number of crashes experienced by large CMVs; when combined with the estimated annual vehicles miles traveled (VMT) for trucks (provided by the FHWA), national accident rates are derived each year for these type of vehicles.

Monitoring was conducted on a periodic basis by comparing the cumulative accident rate of the waived driver cohort to the national accident rate for a similar period of time. This model of analysis was not used to draw conclusions for the prospective study because the study and the program in its original form was terminated by a decision in the United States Court of Appeals for the District of Columbia Circuit (Advocates for Highway and Auto Safety v. FHWA, 28F.306 1288, 1994). This decision is discussed in the section presenting the FHWA Waiver Program for ITDM. The comparative analysis using GES data did, however, provide evidence for a risk assessment. The design of the comparative analysis, while endorsed by some review panels, was criticized by other researchers and safety groups as allowing the possibility of biased results. These criticisms were addressed in an investigation of potential bias in the results. Using sensitivity analysis, this investigation examined the effect on the results under a range of conditions that could cause bias. The outcome of this investigation showed that results were relatively insensitive to bias.

c. FHWA Waiver Program for ITDM

The FHWA announced a final decision to issue waivers on July 29, 1993. Applications were accepted until April 30,1994. In all, 448 applications were received. Of the applicants, 139 individuals were issued diabetes waivers, 183 drivers were rejected for not meeting the acceptance requirements, and 126 drivers never completed their applications. During the course of the program, 26 subjects were lost to the study. Eight drivers had their waivers revoked for failure to meet the obligations of the program, 11 drivers had their waivers canceled for medical reasons, and seven drivers voluntarily withdrew or died.

In order to be accepted by the Diabetes Waiver Program, applicants had to meet certain criteria concerning driving experience and safety record relative to suspensions, revocations, reportable accidents, and convictions. The application process also contained medical requirements for examiners and examinations. Once accepted into the Diabetes Waiver Program, the driver had to meet requirements concerning the management of the diabetic condition, the reporting of accidents and convictions, change of residence, and employment. Those who received waivers also had to report any medical assistance associated with any accident involvement and records of blood glucose values prior to the accident. The waiver recipients had to submit documentation of semi-annual medical examinations and various information describing the extent of their CMV operation. A full description of the Diabetes Waiver Program requirements is given in Appendix A.

Failure to meet the reporting requirements was cause for participants of the Diabetes Waiver Program to lose their waivers. In fact, some waivers were rescinded during the course of the program. An elaborate system of reminders was put in place, and many opportunities were given to participants

to comply with the requirements before their waivers were actually taken away. Of the eight drivers who lost their waivers for failing to meet program obligations, seven had their waivers revoked for failure to meet reporting requirements. Here, four drivers lost their waivers for failure to report monthly driving information, and three had their waivers revoked for failure to submit required medical examinations. One driver waiver was revoked due to a conviction for a disqualifying offense.

Changes in the Waiver Program

The Advocates for Highway and Auto Safety (AHAS), a consortium of insurance companies, law enforcement agencies, and public interest groups, filed suit in the United States Court of Appeals for the District of Columbia Circuit challenging the final rule issued by the FHWA establishing the Vision Waiver Program. While this suit focused on the Vision Waiver Program, it had a later direct effect on the Diabetes Waiver Program because of the similar

approach used to prequalify drivers. In the suit, AHAS argued that the FHWA had not given adequate opportunity for public comment on the waiver program, that the program violated the intent of Congress as set forth in the Motor Carrier Safety Act of 1984, and that, in promulgating the program, the FHWA acted in an arbitrary and capricious manner.

The 1984 Safety Act allowed the Secretary of Transportation (who delegated his authority to the Federal Highway Administrator), to waive any regulation issued on the authority of that act after giving public notice and allowing for the opportunity to comment, if it were determined that "such waiver is not contrary to the public interest and is consistent with the safe operation of motor vehicles."

The AHAS case was argued on November 15, 1993, and the Court's decision was announced

on August 2, 1994. The Court found that the FHWA had given meaningful opportunity for comment through its notices and that the comments received were given due consideration. The Court also found that the FHWA had not acted in an arbitrary and capricious manner in setting up the Vision Waiver Program. However, the Court did find that adoption of the waiver program by the FHWA was contrary to law. The FHWA, it reasoned, had adopted the Vision Waiver Program "in order to procure the hard evidence needed to determine the effect of visual deficiencies on safety." However, to satisfy the Safety Act, waivers must uphold the requirement that there will "not be any diminution of safety resulting from the waiver." The Court therefore determined that the initial determination that the Vision Waiver Program would not adversely affect the safe operation of CMVs was "devoid of empirical support in the record" and, therefore, contrary to law. The Court vacated and remanded the rule which set up the waiver program. (Advocates for Highway and Auto Safety v. FHWA, 28F.3d 1288, DC Circuit 1994).

On October 6, 1994, the FHWA published a notice of determination and request for comments in the Federal Register (59FR 50887, October 6, 1994), extending the validity of the vision waivers for a 30-day period. The notice also proposed to revalidate all existing vision waivers, allowing waiver holders to continue to participate in the study program until its conclusion on or before March 31, 1996. On November 17, 1994, the FHWA published a Notice of Final Determination validating vision waivers until March 31, 1996 (59FR 59386, November 17, 1994).

Resultant Changes in the Program - Performance Conditions, New Waivers

In February 1995, a decision was made regarding new performance conditions for the Vision Waiver Program. In March 1995, the new conditions and expiration date were applied to the Diabetes Waiver Program as well. All diabetes waivers were re-issued to drivers and a letter sent explaining the new criteria of the program and the new expiration date for all waivers.

Drivers were informed that all reporting requirements would now have to be met in full and on time. The previous system of reminders and warnings would no longer be in place. Drivers were also apprised of new conditions that they would have to meet relating to driving performance. A list of offenses that would trigger revocations or evaluation of the driver's fitness to retain his/her waiver was included.

The most important difference that resulted from the changes in the waiver program came in the area of tracking of accidents and citations. Monitoring changes meant that all incidents not only had to be scrutinized for timely reporting, but evaluated for severity and resultant charges against the waived driver. This required extensive tracking through the administrative database. For every driver there had to be an accurate listing of all incidents, their dispostions, the reporting history by the driver, and finally, any evaluation of convictions that was neccessary. The schedule of monitoring was accelerated at that point in order to facilitate timely discovery of traffic incidents. A check of all drivers' motor vehicle histories was completed monthly, instead of every six months as had been scheduled previously. The check of Motor Vehicle Records (MVRs) was accomplished partly through electronic checks via the computerized Commercial Drivers License Information System (CDLIS) and partly through manual checks of MVRs which were obtained directly from the drivers' State of license.

End of the Program - Grandfathering of Drivers

On January 8, 1996, the FHWA published a proposal for comment in the Federal Register regarding the end to the waiver program (61FR 606, January 8, 1996). The FHWA proposed to allow participants in the Federal Waiver Program to continue to operate in interstate commerce after all waivers expire on March 31, 1996, subject to certain operating conditions. The notice requested public comment on the proposal and gave February 7, 1996, as the final date for submission of comments.

On March 26, 1996, the FHWA published a final rule in the Federal Register announcing its decision to allow those participants in the Federal Waiver Program to continue to operate in interstate commerce after March 31, 1996 (61FR 13338, March 26, 1996). The FHWA announced that its decision was consistent with the public interest and safe operation of CMV's. In making the decision, the FHWA considered more than 960 comments which were received regarding the proposal. Also factored into the decision was the five years of safe driving performance by the diabetes-waived drivers. The performance data gathered and a risk analysis performed on the data were the underlying basis for the FHWA decision.

Allowing the drivers to continue to operate in interstate commerce was accomplished by amending the FMCSRs to incorporate grandfather provisions. The new provisions, 49 CFR 391.64, apply only to participants in the Waiver Program, including those with ITDM, who were in good standing at the end of the program. Under these grandfather provisions, drivers are exempt from the vision or diabetes standard provided they are otherwise qualified under 49 CFR 391.41.

The grandfather provisions for diabetic drivers require them to be examined annually by an

endocrinologist prior to having a general exam and receiving a new Medical Examiner's Certificate. The driver must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file and retain a copy on his/her person for presentation to an authorized Federal, State, or local enforcement official on request.

These grandfather provisions were granted to drivers on a conditional basis in order "to ensure the continued safe operation of these drivers." The FHWA also promised to monitor the drivers' performance through periodic checks of their safety records.

All drivers who were eligible to be grandfathered under this new provision were notified by certified letter. Those letters listed in detail what they had to do to become properly certified to continue to operate in interstate commerce now that the waivers were no longer valid. The letter also explained what their new obligations would be in terms of remaining eligible to operate interstate under 49 CFR 391.64. The drivers were given until April 30, 1996, to have a new medical examination and obtain a new Medical Examiners Certificate. At that point the Federal Diabetes Waiver Program effectively closed.

d. Earlier Risk Assessments

In the past, the degree of risk associated with permitting insulin-using diabetics to operate CMVs has not been clearly established. A number of studies of different designs have been performed relative to driving (mostly auto) and diabetes but no clear pattern of results have emerged. Hypoglycemia is identified as the major risk factor relative to driving with diabetes. Simulated driving while in an induced hypoglycemic state has demonstrated the expected decrement in driving

performance. Other work has shown that insulin-using diabetics experience hypoglycemic episodes, especially those with Type I diabetes and those under tight therapeutic control. However, the evidence that accidents actually occur when a diabetic is hypoglycemic is not complete. Yet, there was a sense that insulin-using drivers, especially those who operated CMVs, presented a potential threat to safety. This, combined with the inconclusive evidence, tended to develop a tone of ambiguity toward insulin-using diabetics in relation to driving.

Evidence of this ambiguity was manifested in several ways. For example, an investigation of state regulations to license insulin-using individuals to drive CMVs showed great variation (Gower et al., 1992). Responses of 48 states and the District of Columbia, 9 states denied licenses to diabetics, 14 had no restriction, and the remainder imposed special requirements. The same evidence of ambiguity occurs on an international level. The DiaMond Project on Social Issues (1993) investigating the global regulations on insulin-using CMV operators found, in the 24 countries surveyed, that licensing policies range, as in the states, from a complete ban to no restrictions at all. The uncertainty about insulin-using drivers was also present on in relation to insurance. A case-control study of Type I diabetics showed that, while there was no difference relative to a comparison group in the number who had auto insurance, the diabetics experienced significantly more refusals (Songer et al., 1991). These results suggested that, although most of the cases were able to find insurance, they had to try harder to find it.

In the context of this general ambiguity, it is held by some that it is biologically plausible for diabetes to lead to automobile and truck crashes. This possibility is present because of the acute aspects of the disease such as hyperglycemia and hypoglycemia, and its complications (e.g. neuropathy,

retinopathy and nephropathy). A variety of evidence suggested that hypoglycemia can be a primary factor in causing crashes. A series of earlier case studies supported this notion (Herner et al., 1966; Gratten et al.1968; Leyshon et al. 1972; Sturner & Sullivan, 1983; Rehn & Ross, 1995). More systematic evidence was supplied in a controlled laboratory experiment in which hypoglycemia was induced in diabetic subjects (Cox et al., 1993). Using a randomized single-blind, crossover design, participants performed on a driving simulator under euglycemia and hypoglycemia. Under moderate hypoglycemia several significant results were found. These results indicated that moderate hypoglycemia disrupted such driving behavior as steering, swerving, time over midline, and time off-road.

Other research independently observed the outcomes that are associated with hypoglycemia. In a study in England, it was found that Type 1 diabetics had the most frequent and severe episodes of hypoglycemia (Ferner and Neil, 1988). In a study of the frequency of hypoglycemia and the awareness of this event in Type I diabetics conducted in Scotland, the results showed that those patients with impaired awareness had significantly more episodes of severe hypoglycemia than patients with normal awareness (Gold et al., 1994). It was also found that the patients with impaired awareness experienced a greater proportion of episodes in the evening and those with normal awareness had a greater proportion of their episodes in the early morning.

The earlier epidemiological evidence did little to clarify the relationship between diabetes and automobile crashes. From 1965 to 1991, the epidemiological evidence produced results that were conflicting. In this period, there were four studies demonstrating that diabetic drivers had significantly higher rates or numbers of accidents (Waller, 1965; Crancer and McMurry, 1968; Ysander, 1970;

Hansotia and Broste, 1991). In the period, there were also seven studies in which the accident rates of diabetic drivers did not significantly differ from those of a control group of drivers without the condition (Ysander, 1966; Davis et al., 1973; De Klerk and Armstrong, 1983; Songer et al., 1988; Eadington and Frier, 1989; Stevens et al., 1989; Chantelau et al., 1990). In many of these studies reporting the epidemological evidence, the methodological approaches used had flaws, such as no adjustment for exposures or for potential confounding. This is one possible explanation for the conflicting outcomes.

A number of the studies mentioned above, and some additional work, investigated the role of hyopglycemia in automobile crashes. As in the epidemiological studies, the results of this work were hardly consistent. Four of these reported that hypoglycemia occurred while individuals were driving. The role of this occurrence ranged from 5 percent to 40 percent (5% in Haunz & Brosseau, 1984; 20% in Eadington et al., 1989; 29% in Stevens et al., 1989, and 40% in Clarke et al., 1980).

Included in this collection of work were four surveys which attempted to estimate the rate of occurrence of hypoglycemia in accidents involving diabetics. In one (Frier et al. 1980), 5 percent of the survey sample reported an accident due to hypoglycemia in the period since they began the use of insulin. Another reported that 3.3 percent of the diabetics sampled had been involved in an accident that was related to hypoglycemia in their lifetime (Stevens et al. 1989). In studying Type I diabetics over an eight-year period, an additional survey found that 16 percent of reported accidents were due to hypoglycemia (Eadington et al.1989). And, lastly, a survey in a two-year period reported that the estimated annual rate of hypoglycemia-related accidents among diabetic drivers was about 3 per 100 (Chantelau et al. 1990). This collection of studies does not give a clear, consistent view of the involvement of hypoglycemia in accidents among individuals with ITDM. Not only do the estimates

differ, but the variety of methods used also do not permit comparability among studies.

While the evidence at this point does not give a consistent picture of the role of hypoglycemia in crashes, it would be difficult to dismiss the potential for a significant role. In attempting to define a role, a study mentioned earlier (Gold et al., 1994) provided some insight. This study showed that individuals who had impaired awareness of hypoglycemia had significantly more episodes of severe hypoglycemia. In this area, some work has shown rather clear results. Relative to the awareness of blood glucose levels, a study showed some promising intervention results (Cox et al.,1994). Researchers in this study found that blood glucose awareness training (BGAT) had a long-term effect on the number of automobile crashes experienced. Those receiving the training had significantly better long-term (mean of 4.9 years) effects including fewer lost work days and crashes than control subjects. The BGAT subjects who received booster training were significantly more accurate at estimating their blood glucose levels and were more aware of hypoglycemia.

Since the period covered above, several more have been performed that have been epidemiological in nature. These studies, however, have a rather singular focus in that they investigate the driving behavior of older diabetics. As with all of the previous studies mentioned, they do not concern CMV operation but they do help define the overall context of the problem. In a case-control study of elderly men (70 yrs of age) in Quebec, those with diabetes were not found to have significantly higher risk of road accidents compared to a control group with no medical conditions (Gresset and Meyer, 1994). In another case-control study in the Puget Sound area, a sample of individuals with driving related injuries was compared to those with no injuries (Koepsell et al., 1994). It was found that those with diabetes had a higher risk of injury and an even higher risk for those treated

with insulin or oral hypoglycemic agents. In the investigation of Alzheimer and vascular dementia in a prospective road and laboratory study, the researchers had an interesting ancillary finding (Fitten et al., 1995). The study used three control groups: an older group of diabetics, an older group with no medical conditions, and a younger group with no medical conditions. The older diabetic controls were not significantly different from the older and younger, healthy control groups in relation to driving performance.

A very recent, and well designed, study was also conducted in relation to diabetes and automobile crashes among the elderly (McGwin et al.,1999). Conducted as a case-control study on subjects who were aged 65 or older, those involved in crashes in 1996 who were at fault were compared to two control groups; (1) those involved in crashes who were not at fault and (2) those who had no crashes. The overall findings showed that there was no association between diabetes and at-fault crash involvement. This result held across all of the diabetes characteristics addressed in the study such as insulin use, retinopathy or neuropathy. While all of these results were not significant, there was one interesting finding. Among subjects who had been involved in a crash in the four years preceding 1996, there was a significant relationship between diabetes and crash involvement (an adjusted odds ratio of 2.5). For those not involved in crashes in the preceding four years there was no significant association. Even in a study which appears to have clear results concerning diabetes, there is again some type of mixed outcome. In this case, crash experience seems to act as a modifying influence.

In the mid-1980s, the Federal Aviation Administration (FAA) administration took a comprehensive review of medical certification criteria including those for diabetic pilots. As an adjunct to this review, the FAA conducted a risk analysis for certifying ITDM individuals as pilots with a Class

III private pilot license (FAA, 1986). This analysis was carried out by synthesizing the data available at that time which was related to the issue. Using such data as that provided by the National Health Interview Survey, the National Health and Nutrition Exam Survey, the General Aviation Pilot and Aircraft Survey and the FAA Accident/Incident Data System, various components of exposure and risk were estimated. Some of the major findings of this analysis were:

- 1,620 insulin-taking diabetics would be expected to become Class III pilots if diabetic medical certification criteria were relaxed.

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- The expected rate of fatalities for insulin-taking diabetic pilots was 4.8 per 100,000 pilot hours versus 3.7 for non-diabetic pilots. The estimated safety risks for newly certified insulin-taking diabetic pilots would, therefore, be about 30 percent higher than that of any general aviation pilot.

- Because there is considerable uncertainty surrounding the estimation of the safety risks for diabetic pilots, the actual accident rate experienced by this group could range from about the same rate as other private pilots to twice that rate or more.

The latter finding was based on an extensive sensitivity analysis which showed the wide range of possible outcomes often produced in this type of synthetic investigation. The study seemed to imply that even the estimated, expected 30 percent increase in risk was acceptable when compared to other aviation safety risks. For example, the 30 percent increased risk was somewhat modest when compared with the 82 percent increase in accident rates per active Class III pilot from the 16-24 year old group (.28) to the 50-54 year old group (.51). The FAA found the risk acceptable because, in 1996, it instituted a policy to allow some individuals with ITDM to obtain Class III certification.

As is obvious, none of the risk assessment work presented in this section relates to ITDM and the operation of CMVs. This was also clear to the FHWA in the late 1980's when the agency

contemplated developing a program to allow some individuals with ITDM to operate CMVs in interstate commerce. To address this void, the agency sponsored a risk analysis in late 1990 to investigate ITDM and the operation of CMVs. Performed by the University of Pittsburgh, the risk analysis used a methodological approach similar to that discussed earlier for the FAA (Songer et al. 1993). As with the FAA study, the FHWA risk analysis was a synthesis of the relevant data available at that time. This study used more recent health data from the sources used in FAA analysis to estimate the number of individuals with ITDM expected to be licensed to operate CMVs in interstate commerce. A variety of survey and study data was used to estimate the frequency of hypoglycemia (severe and mild) and the relationship of hypoglycemia and CMV road accidents. The major findings of this analysis were:

- Estimates using existing data suggest that 1,420 drivers with ITDM might be licensed to operate CMVs in interstate commerce.
- If drivers with ITDM were licensed without any restrictions, it was estimated that the risk for hypoglycemia related accidents could be nearly four (4) times the accident risk of non-diabetic drivers.
- Regulations concerning previous episodes of severe hypoglycemia could reduce the accident risk by half.
- There is some degree of uncertainty surrounding the estimates of risk for drivers with ITDM. The available data suggested that the risk ratio of hypoglycemia-related accidents to overall accidents among non-diabetic drivers ranges from 0.25 to 4.0.

The study also pointed out that hypoglycemia unawareness is also a strong risk factor for severe hypoglycemia and concluded that a regulatory program accounting for it could reduce the number and risk of accidents from severe hypoglycemia by a considerable amount. It was also

concluded, however, that a regulatory process regarding hypoglycemia unawareness could be hindered by the uncertainty that these high-risk individuals could be identified in a medical examination.

A subsequent assessment conducted by those at the University of Pittsburgh used the results of the risk analysis to provide an interpretation that could help in the regulatory decision process. This issue was addressed by examining the tradeoffs involved when various options in the regulatory decision framework can be adopted (Lave et al., 1993). This investigation addressed a variety of dimensions of the problem by looking at such facets as whether the excessive number of accidents is significant, the possibility of subclassifying diabetics relative to the history of severe hypoglycemia, the risk tradeoff for allowing these individuals to have employment opportunity, and the level of risk as it is related to other social decisions concerning highway safety, such as allowing 16 year olds to drive or allowing extremely light cars to be driven. The conclusion drawn from this examination was that the additional risk from insulin-using CMV drivers was within the present range of acceptable risks. The conclusion did itemize the notion that the inclusion of persons with a history of severe hypoglycemia significantly increased the cost to society, through an increased number of expected crashes.

e. Research Concerning the Management of ITDM

Diabetes is a metabolic disorder primarily characterized by elevated blood glucose levels with disease-related morbidity and mortality significantly increased by microvascular and cardiovascular complications. Diabetes is typically categorized into two distinct forms. Type I is a form which is characterized by total dependence on exogenous insulin and Type 2 with insulin deficiency and/or insulin resistance. Type 1 diabetes is represented by 10 percent of all cases of diabetes. The more

prevalent Type 2 comprises the remaining 90 percent. While Type 1 diabetes is ITDM by definition, Type 2 may or may not be ITDM depending upon the treatment regimen used.

It has been only in the past three decades that the combined collection of research has directly tied high levels of blood glucose to the development of diabetic complications (Genuth, 1995). Included in this body of work are some studies that have shown the benefits of treatment that lowers blood glucose in reducing the risk of diabetic complications, specifically, retinopathy, nephropathy and neuropathy. Standing out in this work are six studies, five of which were reported in the 1990s. Two of these focus on the treatment of Type I diabetes while the other four investigated medical inventions for Type 2.

The two studies concerned with Type I diabetes clearly showed that reducing blood glucose levels delayed the onset and slowed the progression of microvascular complications. These studies were the Diabetes Control and Complications Trial (DCCT) (Diabetes Control and Complications Trial Research Group, 1993) and the Stockholm Diabetes Intervention Study (Reichard et al. 1993). The DCCT, the larger of the two, was a randomized, controlled clinical trial conducted at 26 centers in the U.S. and 3 centers in Canada. The 1,441 volunteers at these centers were between the ages of 13 and 39 who had Type 1 diabetes for 1 to 15 years. The average length of time these subjects were observed was 6.4 years.

In the DCCT, the subjects were randomly assigned to conventional or intensive diabetes treatment. The goal of intensive treatment was the normalization of blood glucose. While the results for the intensive treatment group were clearly distinguished from the standard group in terms of glycosylated hemoglobin A1C levels and capillary blood glucose values, normalization of glucose values

in the intensively treated group was not achieved. Glycosylated hemoglobin AIC is a measure of the average blood glucose control over the prior 8 to 12 weeks and is given as a percent. The mean glucose values for the intensive group were 40 percent above normal limits. However, risk reductions for various outcomes in the intensive group ranged from 35 to 75 percent with a 60 percent reduction in diabetic retinopathy, nephropathy and neuropathy. Secondary analyses revealed strong relationships between the risk of developing these complications and glycemic exposure over time. These analyses also showed that there was no clear threshold for success since there was a continuous reduction in the complications as the levels of blood glucose approached the normal range.

The results of the DCCT also showed that there was an association between the intensive treatment regimen and adverse events (The Diabetes Control and Complications Trial Research Group, 1995). While the two treatment groups did not differ in mortality, major morbidity following accidents (work place and automobile), or ketoacidosis, they did significantly differ in other adverse events. The intensive treatment group had a threefold increase in the risk of severe hypoglycemia. Hypoglycemia was cited as the principal cause in a significantly higher number of major accidents for the intensive treatment group. Intensive therapy was also associated with a 73 percent higher risk of becoming overweight.

In this research on adverse events in the DCCT, it was recognized that it would be clinically useful to identify a patient risk profile for intensive therapy given the possible occurrence of severe hypoglycemia. It was concluded, however, that there were only a limited number of indicators to accomplish this. Those available were a previous history of repeated severe hypoglycemia, the occurrence of multiple episodes during intensive therapy, or the presence of hypoglycemia

unawareness.

The second trial on Type 1 diabetic patients was conducted in Sweden (Reichard et al. 1993). In this study, 102 subjects were randomly assigned to standard insulin treatment (54 patients) and intensified insulin treatment (48 patients). Periodic evaluations were made for microvascular complications up to 7.5 years. The results of the trial showed that intensive treatment had a significantly higher reduction in glycosylated hemoglobin than the standard therapy. Results also demonstrated that significantly lower percentages of patients in the intensive group developed serious microvascular complications such as retinopathy, nephropathy and neuropathy. No data on adverse events was reported for this study.

Among four of the controlled trials used to investigate therapeutic regimens for Type 2 diabetes, the first was reported in 1970 (University Group Diabetes Program, 1970). This trial showed no benefit of glycemic control in subjects with new-onset of Type 2 diabetes. The study conducted by the University Group Diabetes Program (UGDP) had only 200 subjects in each treatment group and no measure of glycoslated hemoglobin. A major adverse event that emerged from the UGDP study is that the agents (tolbutamide and phenformin) used to reduce hyperglycemia were associated with increased cardiovascular mortality.

Two other small trials used to investigate glycemic control were reported in the mid - 1990s. One study, conducted in Japan with a sample of 110 men, had subjects randomly assigned to conventional and multiple insulin injection groups. The results showed that multiple insulin injections resulted in improved glycemic control (Ohkubo et al. 1995). The appearance and progression of microvascular complications were evaluated every six months for six years. In this study, the

microvascular complications of diabetes were significantly reduced similar to that which occurred in the DCCT.

The second small study was the Veterans Affairs Diabetes Feasibility Trial (Abraira et al. 1997). In this pilot study, 153 men were randomly assigned to intensive or conventional therapy. In a short period of observation (27 months) a difference of two percentage points in glycoslated hemoglobin was found due to intensive intervention. There were, however, no significant differences in cardiovascular events. In an extended analysis, the only significant correlate for new cardiovascular events was the occurrence of previous cardiovascular events. The reported results also indicated that mild and moderate hypoglycemic events were more likely to be present in the intensive than in the conventional group (16.5 vs 1.5 per patient per year, respectively).

In 1998, the results of the fourth study were reported (UK Prospective Diabetes Study Group, 1998). As of the present, the UK Prospective Diabetes Study (UKPDS) is the largest and longest trial on Type 2 diabetic patients. In this study, 3,867 patients with newly diagnosed Type 2 diabetes were randomly assigned to conventional treatment with diet or to intensive therapy with a sulphonylurea (chlorpropamide, glibenclamide, or glipizide) or insulin. These patients were recruited in 23 centers in the UK, had a median age of 54 and were followed for an average of 10 years.

Reported results in the UKPDS showed a 11 percent reduction of glycosylated hemoglobin in the intensive group. No difference in glycosylated hemoglobin was reported among the various therapies in the intensive group. The intensive group showed a significant reduction for any diabetes-related aggregate end point such as sudden death, death from hyperglycemia or hypoglycemia, fatal or non-fatal myocardial infarction, or stroke. Most of the risk reduction in the aggregate endpoint was due

to a significant 25 percent reduction in microvascular endpoints. There were no significant differences in any of the aggregate endpoints between the intensive therapeutic agents.

In this trial, patients in the intensive therapy group had some significantly higher levels of adverse events. Those in the intensive group had significantly more hypoglycemic episodes than those in the conventional group. The rates of major hypoglycemic episodes per year were: 7% with conventional treatment, 1.0% with chlorpropamide, 1.4% with glibenclamide, and 1.8% with insulin. There was also a significant degree of weight gain among those in the intensive group (mean 2.9 kg) compared with those in the conventional group. In the intensive group, patients assigned insulin had a greater weight gain (4.0 kg) than those assigned to the other therapies.

At present, the DCCT and the UKPDS represent the most extensive investigations of the use of insulin therapy for diabetes. While one trial focused on Type 1 diabetes and the other on Type 2, the results were quite similar. Both showed reductions in blood glucose levels with the use of insulin in the intensive treatment groups. Both also showed significant reductions in the microvascular complications of diabetes. In addition to the positive findings, both studies revealed significant levels of adverse effects due to the use of insulin. In particular, insulin- treated subjects in both studies showed a significantly higher rate of hypoglycemia.

Moreover, those treated with insulin in both studies exhibited significant levels of weight gain.

Insulin treatment seems to pose a dilemma for the issue of allowing individuals with ITDM to operate CMVs in interstate commerce. From a positive standpoint, insulin therapy clearly improves the health of individuals who have Type 1 or Type 2 diabetes which should contribute to the safe operation of CMVs. Conversely, the use of insulin can cause the onset of hypoglycemia. This condition, as some

of the literature tends to argue, is seen as a serious risk factor in crash causation. If individuals with ITDM are to be allowed to operate CMVs in interstate commerce, hypoglycemia cannot be ignored. Any process focused on allowing ITDM individuals to operate commercial vehicles must clearly have procedures for controlling that potential for risk and its influence on the level of safety.

f. Other Federal Policy Concerning ITDM and Transportation

Other agencies within the Department of Transportation were contacted in relation to their policies for permitting individuals with ITDM to operate in their modes of transportation. The agencies contacted were the Federal Aviation Administration (FAA), the Federal Railroad Administration (FRA), the Federal Transit Administration (FTA) and the Coast Guard. Of the four, the FAA had a highly developed program for giving waivers to ITDM individuals who apply for a third-class pilots license. The Coast Guard had a policy statement on individuals with ITDM and the FRA and the FTA have no specific guidelines for the issue.

While the FRA and the FTA have no specific policy for ITDM, it does not mean that individuals with this condition are able to operate in those modes of transportation without screening. The determination of whether an individual with ITDM can operate some type of conveyance in the industries regulated by these agencies is made by medical personnel of the companies involved. This determination is made on a case-by-case basis usually involving medical judgement by a physician.

In its oversight of the United States Merchant Marine, the Coast Guard requires all persons employed aboard U. S. merchant vessels of 100 gross tons or more to have a valid U.S. Merchant Mariner's Document (MMD). This document is also known as a Z-card or seaman's papers. All

applicants for a MMD are required to submit a physical examination report completed by a U.S. licensed physician within one year of application. An applicant who does not meet the physical condition required for a MMD is not automatically denied that document. Upon request of the examining physician, a physical waiver may be granted by the Commandant of the Coast Guard in extenuating circumstances which warrant special considerations. However, waivers are not normally granted to applicants with insulin-dependent or poorly controlled diabetes.

The FAA has a very well developed program that permits special issuance of third-class airman medical certificates to certain ITDM individuals. A third-class airman medical certificate is required to exercise the privileges of a private pilot certificate. This program evolved through a series of steps in which the agency capitalized on its experience with other programs, reviewed relevant research, consulted medical experts, and considered comments from the public and interested organizations. Experience with the issue began in the late 1980's when the FAA began to grant special issuance of Airman Medical Certificates to individuals who controlled their diabetes with diet and oral hypoglycemic drugs. However, it had been the long standing policy of the Federal Air Surgeon not to consider an individual for special issuance of a medical certificate if there is a clinical diagnosis of ITDM. The policy was based on the concerns mentioned elsewhere--the long term medical risks associated with diabetes and, the greater concern, the risk of hypoglycemia.

In 1992, the FAA instituted a program to permit selected ITDM air traffic control specialists (ATCS) to continue their safety-related duties. The ATCSs were individually screened, and if accepted, were returned to duty with intensive monitoring under a well-designed medical protocol. The protocol was developed by a panel of endocrinologists and includes screening and monitoring

components. The protocol also requires close supervision and prohibits solo duty.

Prior to the commencement of the program for ATCSs, the ADA, in 1991, petitioned the FAA to amend its policy to allow ITDM individuals to be issued airman medical certificates on a case-by-case basis. This petition was published in the Federal Register (56 FR 10383, March 12, 1991). The ADA also requested the creation of an FAA convened medical task force to develop a protocol that could effect a case-by-case review of individuals with ITDM who applied for an airman's medical certificate. Based on its successful experience with the ATCSs, the FAA presented data describing the program to a panel of endocrinologists for consideration. The panel proposed a new, modified protocol for possible use when ITDM individuals apply for an airman's medical certificate.

In 1994, the FAA published a notice in the Federal Register (59 FR 67246, Dec. 29, 1994) of its intent to consider a policy concerning ITDM individuals who apply for Airman Medical Certificates. In this notice, the FAA invited comment on the medical and monitoring protocol for possible use as the basis of a policy change that would allow certain ITDM individuals to receive special issuance of Airman Medical Certificates. In approaching the policy change, the FAA was considering its application to third-class airman applicants. The Federal Air Surgeon considered the freedom of an airman, exercising the privileges of a private pilot certificate, to accept risks to his/her person and property that are not acceptable in the exercise of commercial or airline transport pilot privileges with their second and first-class certificates.

After careful consideration of the (1) comments to the Docket; (2) comments to the 1991 petition by the American Diabetes Association (56 FR 10383, March 12, 1991); (3) monitoring experience of the FAA medical waiver program for ATCS's with ITDM; (4) medical advances in the

treatment of diabetes; and (5) evaluation of the proposed medical protocol, the Federal Air Surgeon has determined that selected ITDM individuals can be considered for special issuance of an Airman Medical Certificate under the conditions of the evaluation and monitoring protocol with the following restrictions (59FR 67246, December 29, 1994):

> (1) ITDM individuals may be issued only a third-class airman medical certificate.
>
> (2) ITDM individuals may exercise only the privileges of a student.
>
> (3) ITDM individuals are prohibited from operating an aircraft as a required crew member on any flight outside the airspace of the United States of America.
>
> (4) ITDM individuals are required to be in compliance with the proposed protocol while exercising the privileges of a third-class medical certificate.

The protocol used by the FAA has three facets. One is a set of screening components, the second is guidance on glucose management, and the third is the protocol used to monitor the third-class airmen during the period when the medical certificate is active. The screening components of the protocol investigate the history of hypoglycemia, the medical history of diabetes, the applicant's accident experience, and require a complete medical evaluation by appropriate specialists with the provision of specific reports. They also require verification that the applicant is educated in diabetes and its control, and sets the period of time in which applicant must have been receiving insulin prior to application. Next, the guidelines in the protocol specify how glucose management is to be conducted prior to and during flight, and prior to landing. They define the supplies to be used, when blood glucose levels are to be tested and specify the interventions needed. The monitoring components of the

protocol specify how often examinations are to be conducted by specialists, the type of blood glucose monitor to be used, and require an assessment of the individual's ability and willingness to manage the condition. In addition, these components give directions concerning how episodes of hypoglycemia, loss of diabetes control and accident involvement are to be reported. A full description of FAA's protocol is given in the Federal Register notice presenting the agency's policy (61FR 59282, November 21, 1996). A copy of this notice is found in Appendix B.

g. Treatment by Individual States of Commercial Drivers with Insulin-Treated Diabetes Mellitus

While individual States have the option to apply the FMCSRs to the medical qualifications of intrastate operators of CMVs, they also have the flexibility to deviate from the FMCSRs for these drivers. In fact, the individual States vary widely in their treatment of drivers with ITDM.

Most States have chosen to mirror the Federal standards and do not allow insulin-using diabetics to operate CMVs. Others have "grandfathered" drivers who were previously driving intrastate, but will allow no new drivers to operate as of a set date. Within that category, States vary widely in their monitoring of such drivers. Still other States have current programs that provide procedures whereby an ITDM driver can apply for the opportunity to operate commercial vehicles in intrastate commerce. Again, within those States, there is a wide variety of operating protocols. Some States offer a notation on the driver's license; others issue a letter that the driver must carry when driving, and others issue waiver documents.

Several surveys of State practices have been completed in recent years. In 1991, the FHWA

report, "Insulin-Using Commercial Motor Vehicle Drivers" addressed this issue. In 1997, the Association for the Advancement of Automotive Medicine prepared "Update of Medical Review Practices and Procedures in U.S. and Canadian Driver Licensing Programs" for the FHWA, which addressed the issues of diabetes and other medical issues as they affect commercial drivers in individual States and Canada. In 1997, the American Diabetes Association surveyed States to determine their practices with regard to allowing insulin-treated diabetics to operate commercial vehicles in intrastate commerce, and attempted to gather safety data regarding overall driving records or accident rates of commercial drivers who take insulin. The discussion below is illustrative of State programs, gathered from the above-mentioned sources, as well as recent contacts with States. It is not a complete survey of all States, but rather an attempt to identify some States with more extensive programs which contain screening, as well as operating and monitoring protocols, in some cases.

UTAH

The State of Utah has a program whereby a commercial driver who is an insulin-treated diabetic can apply for, and if qualified, receive a medical waiver to operate CMVs in intrastate commerce. The waiver is made possible by a law passed in 1997.

The State utilizes the *State of Utah Functional Ability in Driving: Guidelines and Standards for Health Care Professionals* to determine those individuals who require restrictions, including "intrastate only" requirements. These guidelines were written and developed by a panel of Medical Advisory Board doctors. The guidelines which apply to insulin-using diabetics are found in Appendix III of Utah's guidelines. A profile level chart (See Appendix C) is available for reference

when completing Functional Ability Evaluation froms.

Utah's Appendix III (See Appendix C) recognizes that some insulin-treated diabetics have a minimal risk of hypoglycemia as they (a) easily recognize hypoglycemic sypmtoms; (b) are willing and able to monitor their blood glucose levels on a frequent basis; and (c) are trained in the management of their diabetes.

Utah's Appendix III enumerates the physical qualifications for drivers used for screening applicants. In the case of insulin-using diabetics, the driver's diabetes must not be likely to interfere with his or her ability to operate a CMV and the person:

A. Has within the last five years:

(1) An absence of a hypoglycemic reaction that resulted in loss of consciousness or seizure.

(2) An absence of seizure or coma without antecedent prodromal symptoms of hypoglycemia.

(3) An absence of recurrent diabetic ketoacidosis or hyperosmolar nonketotic coma.

B. Provides to the endocrinologist or internist:

(1) A complete medical history, including all hospitalization, consultation notes, diagnostic examinations, special studies and follow-up reports.

(2) A complete driving record.

(3) Complete information regarding accidents resulting in personal injury or property damage.

(4) Written signed authorization to permit the examiner to obtain information from employers, work associates, health care professionals, or other health care workers, relevant to the person's medical condition.

C. Undergoes a complete medical evaluation by an endocrinologist or internist who will assess the results of the following procedures prior to determining if the person is qualified to operate a commercial vehicle:

(1) At least two results of glycosylated hemoglobin during the last six months, lipid profile, urinalysis and CBC. Blood pressure readings at rest, sitting and standing. Elevated blood pressure, medication for hypertension or other evidence of any cardiovascular abnormality will require a maximal exercise stress EKG.

(2) Ophthalmologic confirmation of absence of visually significant retinal disease.

(3) Examination and tests to detect peripheral neuropathy and/or circulatory deficiencies of the extremities.

(4) A detailed evaluation of insulin dosages and types, diet utilized for control and any significant lifestyle factors, such as smoking, alcohol use and other medications or drugs taken.

The endocrinologist or internist must:

A. Certify that the driver has been educated in diabetes and its control and has demonstrated the understanding of procedures to monitor and manage the disease and what actions should be followed if complications arise.

B. Ascertain the driver has the ability, willingness and equipment to monitor and manage the diabetes. A blood glucose monitor with electronic memory is required.

C. Determine that the driver's diabetes will not adversely affect the ability to safely operate a CMV.

As part of the examination the doctor must fill out the Functional Ability Evaluation medical form (See Appendix C)

Appendix III of Utah's guidelines also lists monitoring and re-evaluation procedures that must be performed by insulin-using diabetics who drive commercial vehicles. These procedures and

conditions may be supplemented by additional procedures and/or operational conditions by the examining health care professional:

A. Drivers shall test their blood glucose concentrations and record them electronically one hour prior to driving and approximately every two hours while driving.

B. Drivers shall make records of blood glucose concentrations available to Federal or State enforcement officials upon request.

C. Drivers shall submit a complete medical re-evaluation annually, or more frequently as indicated by the endocrinologist or internist, including readings of glycosylated hemoglobin. The driver is required to submit any new data on his/her medical condition, driving record or accident involvement. If a new examining physician is used, the driver must follow all procedures set forth for a new applicant.

D. The physician will verify that the insulin-using diabetic can demonstrate the accuracy of self blood glucose measurement within 20% of actual concentration.

E. Drivers shall have annual ophthalmologic confirmation of the absence of visually significant retinal disease.

F. While driving, if circumstances preclude a particular blood glucose test, intake of an appropriate snack or other source of glucose is an acceptable alternative. No two consecutive tests may be replaced, however, by the ingestion of glucose or food.

G. The driver must carry necessary supplies on board the vehicle, including at a minimum, blood sampling lancets, personal blood glucose monitor and strips, a plentiful source of rapidly absorbable glucose. All dated materials must be within their expiration dates.

H. It is suggested that for long distance trips a co-driver or a companion shall be made aware of the signs and symptoms of hypoglycemia and the appropriate treatment thereof.

Drivers who successfully meet the requirement for a waiver in Utah received a “K” restriction (intrastate) on the license. The restriction must be renewed every six months or yearly, depending on

the operator's health care professional's recommendation. The program requires a fee of $25.00 each time the "K" restriction is renewed.

MICHIGAN

The State of Michigan allows insulin-using diabetics to apply for a medical waiver from the physical requirements of an intrastate CDL. The program is administered by the Department of State Police through the Motor Carrier Division, as is the licensing of all commercial drivers. A copy of the application materials is presented in Appendix C. The application procedure requires the applicant to provide the following:

A. Copies of all hospitalization reports, including accident and injuries. Provide copies of treating physician consultation notes for diagnostic examinations, special studies and follow-up.

B. Report and explain any automobile or other incidents or accidents whether resulting in injury or vehicular/equipment damage. Explain cause, especially if related to illness or incapacitation.

C. Provide a minimum of three letters from work associates/employers, physicians, or other health care and diabetes support group personnel, to document absence of subtle or significant incapacitation or mental confusion due to insulin reaction and/or diabetic acidosis. In particular, occurrence or lack of diabetic hypoglycemic-related events during the past two years should be documented. Full names, addresses, work and home phone numbers should be provided by all respondents.

D. A complete medical evaluation by the applicant's personal physician and, if he or she is not a diabetologist, a consultation by a specialist in endocrinology, concerning the applicant's history, current status, and prognosis, both short-term (2-5 years) and long-term (10-20 years). The report must include general physical examination including height, weight, build, and physical defects or signs, and at a minimum the following:

1. Fasting blood/serum studies (glucose, cholesterol, HDL, triglycerides), complete blood count and urinalysis and three readings of glycosylated hemoglobin (A-1c) during the last six months (six months prior, three

months prior and current). Resting electrocardiogram (ECG). Blood pressure reading (sitting) at rest on at least two occasions, a.m. and p.m., approximately one week apart. Elevated blood pressure, medication for hypertension, or other evidence of any cardiovascular abnormality will require a maximal concentration stress EKG study.

2. Ophthalmological confirmation of absence of retinal disease, preferably by a retinal specialist with dilated eye examination.

3. Examination and tests to detect any peripheral neuropathy, or circulatory deficiencies of the extremities, when symptomatic.

4. A detailed report of insulin dosages and types, diet utilized for control and any significant lifestyle factors such as smoking, alcohol use, other medications or drugs taken.

5. Applicants must obtain and utilize a digital whole blood monitoring device which is portable and can be easily used for the testing of blood glucose concentrations before, during, and after driving. Monitors with memories are highly recommended. A log of the last month of whole blood glucose concentrations determined by the applicant at least twice a day and distributed during the month to indicate concentrations at 4-hour intervals during the waking hours shall be provided. This log should be certified as authentic by the specialist. Control of blood glucose concentration is acceptable if fasting blood glucose concentrations are normally between 60 and 140 and postprandial concentrations are normally between 140 and 200. Blood glucose concentrations falling below 50 or above 300 two or more times in a month require re-evaluation by a specialist.

6. In addition to the above, all applicants over age 40 shall present the results of a maximal exercise stress test. Clear copies of all ECG tracings and an interpretation will be provided. Applicants demonstrating abnormal stress tests cannot anticipate certification. However, should the specialist advise and conduct additional clinically indicated studies to rule out underlying arteriosclerotic disease and no evidence of significant disease is found, the actual pictures and reports may be submitted for consideration.

Michigan also has issued monitoring guidelines for insulin-using diabetics who operate CMVs in intrastate commerce:

A. Drivers must have a completed medical re-evaluation by a specialist every six months, with readings of glycosylated hemoglobin (A1C) concentrations.

B. Logs of whole blood glucose concentrations with at least two measurements daily to be kept on a continuing basis and submitted to the specialist upon re-evaluation. The specialist will consider the logs in conjunction with glycosylated

hemoglobin readings to certify that the clinical picture is consistent. Control of blood glucose concentration is acceptable if fasting blood glucose concentrations are normally between 60 and 140 and postprandial concentrations are normally between 140 and 200. Blood glucose concentrations falling below 50 or above 300 two or more times in a month require re-evaluation by a specialist.

C. The specialist will confirm on an annual basis that the person with diabetes can demonstrate accuracy of measurements of blood glucose concentrations within 25 percent of actual concentration.

D. Annual ophthalmological confirmation of absence of retinal disease.

A protocol for driving includes:

:

A. Supplies required while driving: Blood sampling lancet, personal blood glucose monitor and strips, a source of rapidly absorbable glucose, insulin, and syringes or pump, as appropriate.

B. All disposable materials must be within their expiration dates.

C. Blood glucose concentrations must be tested within an hour before driving and approximately every four hours while driving and appropriate measures taken, if necessary. While driving, should circumstances preclude a particular test, intake of an appropriate snack or other source of glucose is an acceptable alternative. However, no two consecutive tests should be replaced by the ingestion of glucose.

DELAWARE

The State of Delaware waives certain intrastate commercial drivers who are insulin-using diabetics as the result of a law which was signed on October 24, 1988. The waiver applies to intrastate drivers operating commercial vehicles over 26,000 pounds. Drivers of vehicles weighing between

10,000 pounds and 26,000 pounds do not need to meet any criteria to be authorized to operate in intrastate commerce. The drivers who meet the waiver criteria may not operate any vehicle which has a primary purpose to transport passengers or a motor vehicle which must be placarded or marked for transportation of hazardous materials. In order to qualify for the waiver, drivers must meet several criteria. First, the driver must have been employed on a full-time basis in the operation of motor vehicles over 26,000 pounds prior to July 19, 1985. Second, the driver must not have incurred three serious moving violations in a commercial vehicle since July 19, 1985. The driver must submit a statement from the employer and a copy of the driving record on file with the Division of Motor Vehicles for the State of Delaware confirming the criteria. A copy of the medical form which must be submitted is in Appendix C. The Department of Motor Vehicles determines whether a driver qualifies for a waiver. If so, the driver receives a letter from the DMV to carry explaining the waiver. Such waivers are issued for a maximum period of two years. The period could be less if recommended by the driver's doctor.

KENTUCKY

The State of Kentucky issues intrastate medical waivers for commercial drivers not meeting certain medical standards of the FMCSRs. A driver seeking an intrastate medical waiver may apply to the Transportation Cabinet, Division of Driver Licensing. The application form should be accompanied by a completed medical examination form, filled out by an appropriate health care professional and indicating the reason the applicant failed to meet the requirements of 49 CFR 391 Subpart E. A supplemental medical report form should be attached to the application, as well.

The Division of Driver Licensing bases its decision on information obtained from the following:

A. Driving record of the applicant;

B. Original medical examination form;

C. Supplemental medical report form;

D. A skills test if suggested by the Medical Review Board, the applicant if his/her medical problem is exoskeletal or visual, or the provisions of this administrative regulation;

E. Any other information supplied to the Division of Driver Licensing about the driving ability of the applicant by the Medical Review Board, a physician, police officer or acquaintance.

For diabetes, the medical guidelines to be considered by the Division of Driver Licensing are that a commercial driver shall not have:

A. An uncontrolled condition of diabetes, and

B. In the year immediately preceding a waiver request, an instance of diabetes shock or coma.

When a commercial driver is granted a medical waiver, he/she must submit to medical re-examinations required by the Division of Driver Licensing. After a re-examination, the waiver will remain in effect if the physician performing the examination certifies that the condition for which the waiver was issued has not worsened and an additional nonqualifying condition has not manifested.

The driving record of a waiver holder may be evaluated by the Division of Driver Licensing at any time, and at least once a year. If a review of the driving record would cause the person to be referred to the Medical Review Board, the waiver or waiver request shall be referred to the Medical Review Board for evaluation.

If the driver completes a driving skills test requested by the Division of Driver Licensing, the Kentucky State Police must submit test results and recommendations for waiver refusal or restrictions on a medical waiver. If a waiver is issued with restrictions, the restrictions will be noted in the driver's operator's commercial driver's license.

Commercial drivers who hold waivers must notify the Division of Driver Licensing immediately of any change in or worsening of their physical or mental condition. If the driver has a progressive disease, the driver may be required to submit to a periodic driving skills test. The failure by the driver to submit a periodic report requested by the Division of Driver Licensing or report for a skills test within 45 days, will result in the medical waiver being canceled. The employer of a commercial driver holding a medical waiver must notify the Division of Driver Licensing of a change in the driver's physical or mental condition or employment or employment conditions. If a driver applies for a medical waiver and is rejected, there are procedures whereby the driver can appeal the decision.

3. Recent Risk Assessments

Except for one analysis that synthesized available data, the earlier assessments of the risk of driving with diabetes did not focus on the operation of CMVs. Since that collection of work was reported in the literature, there have been four studies that investigated the risk of diabetic drivers operating CMVs in particular. Two of these studies were performed in Canada while the other two were conducted by the Office of Motor Carrier Safety (OMCS) in its ongoing investigation of the issue. All of these studies used data which is directly related to the driving behavior of diabetics as they operated CMVs.

The first Canadian study was conducted by researchers at the University of Montreal and the Center for Research on Transportation (Dionne et al. 1995). It was nested case-control study on 1,307 truck drivers, some with medical conditions and some without. The data for this study were taken from insurance databases in Quebec. These data were augmented through a telephone survey which obtained information on vehicle miles driven and driving behavior. The conditions were examined relative to accidents within the class of license held by the driver. The categories of license were Class 1 for the operation of large combination trucks versus all other classes (mostly Class 3 permit holders for straight trucks with a small number in other permit classes). Among the other classes (not Class 1), drivers with diabetes were found to have a significantly higher accident rate. Those diabetic drivers with Class 1 licenses had accident rates that were not significantly higher than other Class 1 drivers. The models used to analyze the data were adjusted for numerous ancillary measures (including mileage driven). The researchers were somewhat at a loss to explain the results. They thought the results could be due to the use of insulin since the diabetic drivers with Class I licenses had fewer individuals treated in this manner than those with other classes of license. The analysis, however, did not examine the interaction of insulin-use and class of license. The results for this study, while being relevant and informative, also are inconclusive and raise the same questions as have been previously raised--Can individuals with ITDM manage their condition and can they safely operate a CMV?

The second Canadian study was carried out by essentially the same group in 1997. This study was, in actuality, a continuation of the first. The researchers were investigating the costs associated with accidents that involve individuals with certain medical conditions such as visual impairment or diabetes. The research group employed the findings of the first study to arrive at estimations of cost. In the

course of addressing this problem, they also investigated the severity of accidents. Severity, in this study, was defined by the number of individuals injured or killed in an accident. The results showed that the drivers with diabetes did not have significantly more severe accidents than those without the condition. The estimations of cost in this study, however, showed that the average cost per accident for diabetics with licenses in the "other" class (that is all other than Class I for combination trucks) were twice that of drivers in good health.

The third set of results were derived from FHWA's Waiver Program for Diabetes. A requirement for that program was the periodic monitoring of CMV operators with waivers to determine the level of safety of their driving. Monitoring was conducted by comparing the cumulative accident rate of the waivered drivers to the national accident rate for large trucks. The measure used was taken from the GES, an annual national survey PARs sponsored by NHTSA. GES produces annual estimates of the number of crashes experienced by large CMVs and, combined with the estimated annual VMT for trucks (provided by FHWA), national accident rates are derived each year for these type of vehicles.

As a part of a complete risk assessment, before the diabetic drivers received grandfather rights when the waiver program closed, the final monitoring report was completed in February 1996. That report showed that the group with waivers (n=118) had an accident rate of 2.309 accidents per million VMT. The comparable measure from GES showed a national accident rate of 2.605 per million VMT. The report was placed in the DOT docket with the rest of the documentation supporting the March 1996 decision to give grandfather rights to these drivers.

The use of a national accident rate for comparative purposes was criticized by some in the

safety community. Those with this view stated that the use of a national rate precluded the researchers from investigating the possibility of comparison bias and, if it were present, eliminated their ability to perform adjustments to provide a fair comparison. Since such measures as age and other demographic data were not available in the national data, bias would remain hidden, if it existed. To address this criticism, sensitivity analyses were performed to assess the possible impact of hidden bias on the comparative results (Rosenbaum, 1995). The analysis showed that the results were relatively insensitive to hidden bias.

The most convincing results in this recent set of risk assessments is provided by a study conducted by the FHWA in 1998 (FHWA, 1999). This study, with a retrospective cohort design, compared a group of large truck drivers with ITDM to a sample of CMV operators from the population of drivers with commercial drivers licenses (CDLs). The individuals with ITDM had been driving at least since 1994 through state programs or by virtue of having received grandfather rights under 49 CFR 391.64. The ITDM sample had 723 drivers while the comparison group contained 1,297 CMV operators with CDLs. Data describing the accident experience of drivers in both groups were taken from motor vehicle records. These data were supplemented with information obtained through a mailed questionnaire which asked about mileage driven, medical problems and treatment, and relevant background factors. The study covered driving behavior in the years from 1994 to 1997.

The analysis of data initially compared the accident rates per million miles in the two groups. The unadjusted data showed that the rate of the ITDM group (1.950) was significantly higher than that of the comparison group (1.444). Further investigation showed there were several factors in the data which could cause the initial outcome to be biased. To answer the questions raised by these factors,

adjustments were made for comparison bias and threats to the statistical models used in the analysis. Adjustments were made for these two threats separately and in combination. In all cases, the results obtained showed that there were no significant differences in the accident rates of the two groups. Analyses were also made for the severity of the accidents in the two groups where severity was defined as the number of injuries or deaths in an accident. In this analysis, the same type of adjustments were used as above and both the unadjusted and the adjusted results showed no significant differences between the two groups.

4. Expert Medical Panel

To fulfill the spirit of the Congressional mandate in Sec. 4018 of TEA-21, the FHWA assembled a panel of physicians who are experts in the treatment of diabetes. This panel was charged with investigating and reporting on the issues concerned with the treatment, medical screening and monitoring of ITDM individuals in the context of operating CMVs. The panel was assembled because the Presidential/Congressional Commission on Risk Assessment and Risk Management strongly suggests that experts be used in a risk assessment when the structure of the underlying problem is highly technical in nature (Presidential/Congressional Commission on Risk Assessment and Risk Management, 1998).

The panel was selected through an ongoing FHWA/Federal Motor Carrier Safety Administration (FMCSA) contact with the medical community relative to the health issues covered in regulations and other health concerns that could impact on CMV operation. The panel that was convened for this regulatory issue included four eminent physicians whose careers have

largely focused on research for the treatment of diabetes:

Michael D. Brennan, M.D., F.R.C.P.I
Associate Chair, Dept of Medicine,
Consultant, Div.of Endocrinology and Metabolism,
Mayo Clinic

George Grunberger, M.D., F.A.C.P.
Henry L. Braszu Professor and Director
Center for Molecular Medicine and Genetics
Professor, Dept. Of Internal Medicine
Director, Center for Clinical Research
Director, Diabetes Program
Wayne State University

Edward S. Horton, M.D.
Vice President and Director of Clinical Research.
Joslin Diabetes Center,
Harvard Medical School

Christopher D. Saudek, M.D.
Professor of Medicine and
Director of the Johns Hopkins Diabetes Center

The panel was asked to address the overall issue in two parts. One part required written input

while the second involved a meeting in Washington, D.C. to discuss the written input and other factors. In the written input, the panel was asked to put together responses concerning the risks associated with diabetes, the treatment of the disease, and the nature of successful, ongoing monitoring and management of the condition. To help focus this input, the panel was given a set of guidelines that structured salient issues in relation to the feasibility of a process for allowing individuals with ITDM to operate CMVs in interstate commerce. The issues in these guidelines were divided into two domains; one was concerned with a screening protocol that could be used to qualify individuals to operate CMVs while the other focused on a protocol to monitor the behavior of qualified individuals relative to their management and control of the disease. The screening issues were of the following nature:

i. The long-term medical risks associated with diabetes, including cardiovascular, neurological, ophthalmological and renal pathologies.

ii. The immediate risk posed by hypoglycemia which cause impaired cognitive function, seizures, unconsciousness, and death.

iii. History of recurrent hypoglycemic reactions resulting in loss of consciousness (number of episodes in a specific time frame, such as “less than one per month”).

iv. Education in the awareness of hypoglycemia; new approaches, the identification of new cues to help awareness.

v. The period of time necessary to demonstrate stable control.

ii The period of time in which insulin has been received prior to qualification to drive.

vii. The efficacy of an individual’s efforts to control the disease.

ii Time frame for having experience in operating a CMV while receiving insulin treatment.

ix. The need for an assessment by a specialist regarding any adverse effect of diabetes on the driver’s ability to safely control a CMV.

x. Medical advances in the treatment of diabetes.

xi. Role of other medical problems in the screening protocol.

xii. Should an insulin-treated diabetic CMV driver be required to operate with another driver?

If some individuals with ITDM are considered qualified to operate CMVs in interstate commerce, a protocol to monitor their management of the disease will be needed. An effective monitoring protocol was the next subject of the investigation. In approaching this question the panel was asked to consider the following issues:

i. Tight control of glucose levels, while useful for protecting an individual's health, has also been shown to make an individual vulnerable to hypoglycemic episodes. Drivers with ITDM often maintain blood glucose levels somewhat higher than usual to prevent or reduce the likelihood of incapacitating hypoglycemia. How should this be handled? Are there other more acceptable strategies?

ii. What is an acceptable blood glucose range?

iii. What should be the frequency of medical evaluations?

iv. How frequently should blood glucose levels be measured?

v. What assessments should be included in a medical evaluation; physical exam, report of glycosylated hemoglobin concentration?

vi. Should medical devices be used by the drivers to monitor and report glucose levels?

vii. Should drivers be required to receive continued education in hypoglycemia awareness and report compliance with the requirement?

The panel's responses to these questions are found in Appendix D.

The Washington, D.C. meeting of the medical panel was held on September 1, 1999 at the Department of Transportation. In addition to the panel, the meeting was attended by officials from the

Office of Motor Carriers and officials from other federal agencies concerned with the issue (See Appendix E for a list of attendees).

After a review of the recent risk assessments to begin the meeting, the discussion proceeded to address the issues given in the guidelines. The meeting lasted one day with most of the issues listed earlier being addressed. The following is a summary of the discussion in relation to each of the screening and monitoring issues.

Screening Issues

(1) What is the role in a screening protocol of long-term medical risks associated with diabetes?

The panel did not think that ITDM individuals should be disqualified solely because they have long-term medical risks. While some conditions caused by the disease may be disqualifying, they should be identified in a thorough physical examination. The panel agreed that diabetics do have special medical concerns that need to be addressed. The question arose whether a non-specialist, in conducting an examination, would detect a critical level of physical deterioration due to diabetes complications. Some of the panel members suggested that a specialist, probably an endocrinologist, should perform physical examinations for diabetic drivers. One panel member stated that all endocrinologists may not be thoroughly familiar with diabetes. He said that some general practitioners and internists could be diabetologists. Others on the panel argued that virtually all endocrinologists are well-trained in diabetes and could be specified as the specialist to conduct a thorough physical examination for diabetics who applied to operate CMVs in interstate commerce. It was then suggested that the Office of Motor Carriers (OMC) could develop a list of physicians who are certified to perform

these examinations. OMC representatives pointed out that the agency did not have the resources to develop such a program. At the end of the discussion, there was a consensus that most endocrinologists would have sufficient training and experience with diabetes to conduct these screening exams.

(2) History of hypoglycemia reactions and its role in the screening process.

The panel members first pointed out that there is a distinction between mild and severe hypoglycemia. Severe hypoglycemia requires the aid of another person to assist or treat. Mild hypoglycemia, it was argued, is less incompatible with driving. The changes are subtle. It may be harder to exclude people based on mild hypoglycemia.

The panel thought that excluding diabetics based on the number of episodes of severe hypoglycemia was difficult because their occurrance depends on circumstances. Some thought the bigger problem was hypoglycemia unawareness, which ought to be an absolute bar to eligibility or qualification. But others said that the definition of unawareness is not always clear, but that a severe insulin reaction is clinically more useful than the concept of unawareness.

The panel also noted that there is a correlation between hypoglycemia unawareness and recurrent severe hypoglycemic episodes, as shown by DCCT data. While each is a risk, it is however the combination of the two that is more frightening. Nonetheless, individuals who are prone to severe hypoglycemia should not drive. While identifying the number of episodes that should bar a diabetic from driving can be difficult, the panel agreed that severe hypoglycemia in the past year or several episodes in the past five years can predict the future.

The discussion turned to the possibility that some patients may be unaware of the consequences of the disease due to a tight control of diabetes. It might be possible to have less rigid control so that a patient could detect some of the early warning symptoms of hypoglycemia. This, it was claimed, is another reason to have an endocrinologist perform the initial screening.

The discussion than moved to the need to have drivers check their blood sugar before driving. But, if drivers did this, how would they know whether to drive or not? This led to the possibility of setting up a monitoring requirement and a protocol for telling drivers the acceptable ranges for operating a CMV. This was addressed later in relation to monitoring issues.

(3) Education in the awareness of hypoglycemia.

The panel agreed that training was necessary for potential drivers of CMVs. Some thought that it need not be as extensive as the Blood Glucose Awareness Training (BGAT) program developed at the University of Virginia but that some education would be necessary. The required program of education should address disease management, including recognition of signs and symptoms of hypoglycemia and appropriate responses to it. Some on the panel said, for this population, it need not be as extensive as BGAT but it is critically important that a formal program have drivers be educated as best as possible, especially in relation to hypoglycemia. This should be a major focus of any qualification program. An endocrinologist and a diabetes nurse educator should be involved in the process.

(4) The period necessary to demonstrate stable control.

The panel did not think that stable control was the critical issue. Most said that the focus should be on hypoglycemia as related to safety. An attempt to measure adequate control through hemoglobin A1C levels may be problematic. Low A1C is associated with hypoglycemia but could indicate good control. On the other hand, the high end of the A1C scale relates to hyperglycemia. If blood sugar is above a certain level there could be drowsiness and blurred vision. However, rapid changes are also unwise. Bringing high glucose levels down too quickly could cause hypoglycemia.

The panel felt that it may be difficult to define stable control. The extremes of A1C would perhaps be defined as unstable control. As a marker, A1C could also be an indicator of how seriously a patient takes the disease. For drivers, who exhibit good disease management, A1C can be combined with other markers to make that determination. It may be difficult to determine what two levels of A1C mean, because they may miss extremes. However, they can be combined with the results of blood glucose monitoring to obtain a better insight into diabetes management. A discussion of specific A1C numbers was deferred to the monitoring segment of meeting.

(5) Minimum period of insulin use before being qualified to drive.

The panel initially discussed the difficulty of getting a specific period of insulin use prior to qualification. The members also discussed the possible impact on a driver's livelihood of setting periods in which they could not be qualified. The panel then agreed that defining a period of insulin use depended on circumstances surrounding the history of diabetes that a driver would bring to the application process.

If a driver had been operating with diabetes on an intrastate basis, the history of his/her diabetes

and its treatment are probably well established, especially if the driver has Type 1 diabetes. Setting a period for insulin use, then, would be necessary mainly for drivers that have type 2 diabetes or are newly diagnosed. If the driver had Type 2 diabetes and were converting to insulin use, the panel thought that a one month learning curve would be sufficient to provide adequate disease management skills. If the driver were a newly diagnosed Type 1 diabetic patient, the panel was comfortable with a two month period. However, if the treating physician concluded that the patient needed an adjustment in the insulin dose or had not adequately learned about diabetes and its management, the period could be extended to a third month or longer, depending on the circumstances.

(6) The ability of an individual to control the disease.

The panel said that basic evidence was needed (in the screening process) to show education and understanding of the disease. While the notion of "well controlled" diabetes is somewhat vague, it was recognized that an evaluation of control was necessary. To do this, the panel concluded that diabetes control would have to be defined with criteria that would disqualify people at the screening stage.

(7) The need for medical assessment by a specialist regarding the adverse effects of diabetes.

The panel discussed who would have the skills and training as a specialist to deal with diabetes. Physicians that specialize in treating diabetes often call themselves diabetologists. These physicians may be internists, nephrologists, neurologists, ophthalmologists, or endocrinologists. There is no board certification for diabetology. Most of the good training programs in endocrinology have an emphasis on

diabetes and its management. The panel also noted that most endocrinologists would have a fairly significant part of their practice devoted to diabetes. However, widely quoted statistics show that 90 percent of the people with diabetes in this country are cared for by family physicians or internists.

This discussion then turned to how diabetic drivers could be assessed by specialists. The panel believed, that the number of diabetic drivers seeking qualification would not be large, probably less than 1500. Based on this, it was suggested that drivers to be screened could be required to go to a diabetes center. Centers should have both an education staff and endocrinologists trained in diabetes. The education staff would train drivers in diabetes self-management skills and evaluate their ability to be serious about the disease. This would also provide an opportunity to monitor drivers and give ongoing education.

(8) The role of other medical problems in the screening protocol.

Some members of the panel did not see how this question related to diabetes. The fact that a driver might be disqualified for another condition would have nothing to do with diabetes. But the panel recognized that there are regulatory as well as medical issues at stake. For example, FMCSA's exemption program does not allow a driver to have more than one condition that would normally be disqualifying. In this case, an examination for diabetes would have to cover other medical problems as well.

A related question is: who should conduct the examination? Some on the panel said that, given that other medical problems may be considered, an examination by two physicians may be necessary: one for diabetes and another for a general examination. That is possible because endocrinologists

often don't want to be knowledgeable of the standards and protocols for other areas of qualification. However, endocrinologists are not precluded from being the certifying physician for the whole process.

The discussion of the screening issues was completed in the morning. After lunch, there was a review of the morning's discussion and the panel then turned to monitoring issues. A summary for each issue follows.

Monitoring Issues

(1) How should tight control be handled?

The goal of the DCCT was to use an aggressive management strategy to get blood glucose as close to normal as possible. The trade off was a three fold increase in hypoglycemic reactions. The panel noted that this trial was not the real world, where newer regimens do not so strongly promote hypoglycemia. This is done with new insulin and better pumps, and better general appreciation of what is called basal bolus therapy regimens. The panel agreed that some people can be brought very close to normal levels of blood glucose without significant risk of hypoglycemia. It was thought that the newer insulins (Lispro insulin, Humolog--very rapidly acting insulin, and others that are going to be available soon) are being developed to give a more stable baseline.

It was also stated that there is an arguable cushion in control. If one points to the goals of the ADA, it can be seen that the normal hemoglobin A1C is not the goal. Therefore, the assumption is that a level exists, above which the patient is in trouble. Thus, there is a little cushion between that and the normal reference range. So numbers can be discussed which are not really tight, as in a normal glucose level.

One member asked if an expert group should suggest specific new products in regulations. The consensus answer was no; it is necessary to judge how a person was doing on a case-by-case basis. A requirement for some products would make it difficult for physicians to change regimens or work with different programs. There was no clear evidence on the effectiveness of forthcoming diabetes products, so one cannot be dogmatic.

There is some flexibility in the definition of tight control. Some endocrinologists say that tight control is intensive control; meaning multiple shots of insulin. Many patients don't need that, however. Tight control perhaps means an A1C under eight or under seven. One panel member said that this is not related to the issue of driver safety. The use of code words like "tight control" should be avoided since they may mean different things to different doctors. Instead, one should look for factors that relate to safety. ITDM drivers should be allowed to decide what is in their best interest. If they chose an A1C of eight rather than seven to keep their job, they should not be judged on that, but rather on if they are safe drivers.

(2) What is an acceptable blood glucose range?

The discussion began with the statement that if one is looking at issues specific to risk and CMV operation, there is a need to avoid the extreme high and low ends of the blood glucose range. Panel members thought that the numbers below 60 and above 300 or 350 were problematic. Someone also mentioned the numbers 100 to 400 as a range but said they were arbitrary. Research, according to one member, showed that blood sugar below 65mg/dl leads to impairment of cognitive function. A normal range in the fasting state is 70 to 110. One panel member said he suggested 100 for the upper

level because it came from the FAA policy. However, setting an upper level was difficult for him. He said if blood sugar goes up to the 300 to 400 range, it depends on how long it is there. It is not uncommon for ITDM individuals to go up to 300 to 400 after a meal. If this were a chronic level, it should cause some concern. It was said that 400 may be a bit generous, that the upper limit should perhaps be 350.

The discussion then moved to the issue of safety on the roads and recommended levels. Levels of 80 to 120 (pre meals) or 160 to 180 (post meals) or A1C less than seven are ideal. In reality, a driver who is less than 100 before driving should intervene and check it until it is over 100. If the level is above 350, some action should be taken to avoid acute complications. Some members of the panel thought that A1C was only relevant at extreme values, say 10 or 11.

(3) What should be the frequency of medical evaluations?

The panel generally agreed that ITDM drivers should have detailed annual examinations, and quarterly reviews of the maintenance of glucose levels to determine if there is good control.

(4) How frequently should glucose be monitored?

The panel endorsed a protocol offered by Dr. Horton for monitoring glucose before and during the operation of a CMV. This protocol is:

- Check glucose before starting to drive and take corrective action if necessary. If glucose is <100 mg/dl take glucose or food and recheck in 30 minutes. Do not drive if glucose is <100 mg/dl. Repeat the process until glucose is >100 mg/dl.
- While driving check glucose every 2 to 4 hours and take appropriate action to maintain it in the range of 100 to 400 mg/dl.

- Have food available at all times while driving. If glucose is <100 mg/dl, stop driving and eat. Recheck in 30 minutes and repeat procedure until glucose is >100 mg/dl.

- If glucose is >400 mg/dl, stop driving until it returns to the 100-400 mg/dl range. If more than 2 hours after last insulin injection and eating, take additional insulin. Recheck blood glucose in 30 minutes. Don't resume driving until glucose is <400 mg/dl.

There was a question about the accuracy of the devices used to monitor glucose. It was stated that the meters that require a drop of blood are accurate to within three to five percent of the actual value. The minimally invasive or non-invasive systems are still experimental and none appears to be reliable enough for practical use. All of the meters that can be used have memories that show the date and time of the test. Some of them have additional features such as automatic recording and the ability to mark events, such as "driving". The panel noted that monitoring would not be a burden on drivers since they are doing it already.

(5) What assessment should be included in a medical evaluation?

The panel thought that the annual medical examination for those with diabetes should include a dilated eye exam by a trained individual, such as an ophthalmologist, and an evaluation of renal function, including albuminuria. It should also include screening for signs and symptoms of significant coronary disease. There may also be the review of sleep apnea and day time drowsiness. This should, it was said, be the prototype for the annual examination. In addition, there should be a list of findings of particular interest which would be considered disqualifying, like decreased visual acuity. It would also include severe retinopathy (if it is a disqualifying condition) and severe peripheral neuropathy which would impair driving. There are conditions of lesser degree that could possibly be corrected. It was

then asked what could be done about the status of retinopathy and a hemorrhage after it was treated with lasers. Here it is an issue of lost peripheral vision and some night vision. In a situation such as this, the question of disqualification goes to an examination by an opthamologist.

(6) Should medical devices be used by drivers to monitor and report glucose levels?

The panel had already agreed that devices should be used to monitor and report glucose levels. There was a question of whether all diabetics use monitors with memories. One panel member said that most people certainly use devices which make it possible to download monitoring data. It is not a matter of cost because these are only minimally more expensive.

Quarterly reports are a good method of determining if the guidelines for monitoring are being followed. The management of data in this situation is important. The devices with memory calculate means at different times of the day, it can be determined when people are likely to be high or low. This will give ample data for monitoring. More sophisticated devices actually provide a printout of patterns, including graphs and analyses. The standard deviation is used to indicate the lability of blood glucose levels, which can be very useful.

(7) Should drivers be required to receive continued education in hypoglycemia awareness and report compliance with the requirement?

The panel agreed that drivers should be educated in hypoglycemia awareness and the management of diabetes. It was also agreed that this should be verified with the annual medical examination. There was some discussion about the standards of education that could be used and the

National Standard for Diabetes Health Management was mentioned as a possibility. However, some panel members thought such standards may be too extensive for the qualifications of drivers. While the drivers should have education in self-management principles and hypoglycemia awareness, some thought it possible that the examining physician could determine how extensive the education should be on a case-by-case basis.

5. Discussion and Conclusions

It seems reasonable to conclude that the evidence concerning ITDM and the operation of CMVs in interstate commerce is clearer now than it was at the beginning of the 1990s. The research reported since then does not have the broad equivocation shown earlier. The risk assessment results have a consistency not seen before. Research reported on the treatment and management of ITDM shows the positive effects of insulin therapy. While the evidence is strong, it does not point in entirely the same direction. There are some exceptions and problems that should be assessed and either resolved or weighed against the overall findings. To do this, a discussion of the evidence is needed.

The evidence provided by risk assessments appears to be relatively strong. The Federal Motor Carrier Safety Administration's (FMCSA; see note at the end of the section) most recent risk assessment showed that a reasonably large sample of individuals with ITDM are presently operating CMVs at a safety level not significantly different than a sample of non-diabetic drivers. Moreover, the experience of the FHWA's Diabetes Waiver Program, as articulated in the associated risk assessment, shows that drivers with ITDM can operate CMVs at a level of safety that is consistent with the national norm for safety. In particular, that assessment shows that it is possible to screen individuals with ITDM

and have them safely operate CMVs. The exception to the foregoing evidence is found in the Canadian studies. There, while diabetic drivers of combination trucks had no significant excessive risk, diabetic drivers of other types of trucks showed a significantly higher accident rate than non-diabetic drivers. The weight of that evidence is, however, somewhat attenuated because the role of insulin use among those diabetics is largely unknown, as is the manner in which those drivers were screened to be allowed to operate CMVs. Therefore, based on the risk evidence and the considerations surrounding it, a fair conclusion would be that it is possible to allow certain selected individuals with ITDM to operate CMVs.

The other aspect of allowing individuals with ITDM to operate CMVs concerns the medical considerations for identifying those who should be qualified and the procedures for maintaining qualifications. The medical research results for the treatment of Type 1 and Type 2 diabetes show that the condition can be largely controlled through an intensive insulin therapy. This indicates that the health of drivers with ITDM can be improved by reducing the susceptibility to the complications of the disease. Having healthy individuals operating CMVs clearly could contribute to safety, but the therapy that promotes that health also has a risk through the increased possibility of severe hypoglycemia. The medical research, however, has shown that not all ITDM individuals are at significant risk for the incapacitation caused by hypoglycemia. Thus, to develop a program that meets the safety standard required, protocols are needed to screen and identify individuals at risk for severe hypoglycemia. The research reviewed indicates that screening can be conducted by examining an ITDM individual's medical history for evidence of hypoglycemia episodes. A technical review of the issue that discussed the clinical evidence and current knowledge related to hypoglycemia, pointed out that the most

powerful predictor of severe hypoglycemia is a history of prior severe hypoglycemia (Cryer et al. 1994). Data from the DCCT also indicates that higher risk for hypoglycemia can be predicted from a history of severe hypoglycemia and a longer duration of diabetes. Other evidence in the research literature shows that ITDM individuals with histories of hypoglycemia unawareness are at a significantly increased risk for severe hypoglycemia as compared to those who are able to recognize the onset of hypoglycemia and intervene to prevent a progression to the severe state. As has been recommended by many experts, a feasible program for qualifying ITDM individuals to operate CMV's should include protocols for screening on the history of severe hypoglycemia and hypoglycemia unawareness. Excluding individuals with these characteristics would significantly reduce risk associated with a program.

The research conducted on the treatment and management of diabetes has shown it is possible to monitor ITDM individuals who have been successfully screened to operate CMVs. Based on this research, the consequences of ranges of blood glucose levels are better understood. This combined with improved methods for self-monitoring, the availability of fast-acting insulin, and a better understanding of the dietary needs of diabetics - results in better control of diabetes. This is also supported through the observed benefits of education for the self-management of the condition. The combined effects of these factors will enable ITDM individuals to greatly mitigate the risk of hypoglycemia. Moreover, the increased understanding of the self-management of diabetes enables physicians to advise those ITDM individuals who qualify so that the disease can be successfully controlled during operation of CMVs. This research-based knowledge will also make it possible to effectively monitor individuals who are operating in interstate commerce.

The evidence reviewed in this evaluation indicates that it is possible to develop a program to qualify some ITDM individuals to safely operate CMVs in interstate commerce. Three facets appear to be necessary for a viable program. These are components for screening drivers, guidance for the management of the disease, and monitoring proper management. Information is available to develop the screening components of a program which can exclude those at high risk of severe hypoglycemia. Program components for guidance in the monitoring and control of diabetes can be clearly articulated, along with components that can effectively monitor the management of the disease. The next step is to identify the potential components of a program. This is done in the next section.

Note: The authority to require medical certification of CMV driver qualification was originally granted to the Interstate Commerce Commission (ICC) in the Motor Carrier Act of 1935. The authority was transferred to the DOT in 1966 and is currently codified at 49 U.S.C. 31502(b). On October 9, 1999, the Secretary of Transportation transferred the motor carrier safety functions performed by the Federal Highway Administration (FHWA) to the Office of Motor Carrier Safety, a new office created in the DOT. This transfer was performed pursuant to section 338 of the DOT and Related Agencies Appropriations Act, Pub.L. 106-69, as amended by Pub.L. 106-73. The Motor Carrier Safety Improvement Act of 1999, Pub.L. 106-159, transferred the function to the Federal Motor Carrier Safety Administration (FMCSA). As a result of the tranfer of these functions, the FMCSA now administers the driver physical qualification standards and examinations in 49 CFR Part 391.

6. Components of a Feasible Program to Allow Individuals with ITDM to Operate CMVs

Through a review of the research literature, relevant DOT and state programs, and with substantial contributions from the medical panel, it was possible to identify a set of program components to allow individuals with ITDM to operate CMVs in interstate commerce. In particular, there was a thorough review of the FAA's processes for granting medical certificates and FHWA's procedures for issuing waivers in the earlier Waiver Program. Both of these protocols were reviewed by the medical panel. Based on the experience of the FAA and the Waiver Program, it was obvious that those two sets of protocols were valid. This was to be expected because both processes were based on the available research literature and reviewed by medical experts. As a result, the program components suggested here, which draw on the same type of background investigation, will reflect a structure that is to some degree similar to the FAA's and FHWA's processes.

A feasible program must address a number of concerns in qualifying drivers to operate CMVs and keep them driving at a level that does not compromise public safety. It is necessary, therefore, that the components of the program define how drivers are to be qualified, give guidance to qualified drivers on the management of diabetes while operating CMVs, and provide methods to ensure safety and proper management of the condition. There must be screening protocols to identify, in the application process, the drivers that should be qualified. There should also be protocols for glucose management prior to and during the operation of a CMV by the drivers who are qualified by the screening process. Lastly, a program must specify how the qualified drivers will be monitored for safe driving behavior and the proper management of glucose. The components for a feasible program that address the three

areas just discussed are presented in detail below:

Screening Components

Applicants must:

(1) Be currently licensed to operate a CMV or have been validly licensed in the past, but could not renew because of their diabetic condition.

(2) Have operated a CMV, with a diabetic condition controlled by the use of insulin, for the three-year period immediately preceding application.

(3) Have a driving record for that three-year period that:

- Contains no suspensions or revocations of the applicant's driver's license for the *operation* of *any* motor vehicle (including their personal vehicle);

- Contains no involvement in an accident for which the applicant received a citation for a moving traffic violation while operating a CMV;

- Contains no convictions for a disqualifying offense or more than one serious traffic violation, as defined in 49 CFR 383.5 while operating a CMV.

(3) Have no other disqualifying conditions including diabetes-related complications.

(4) Have had no recurrent (two or more) hypoglycemic reactions resulting in a loss of consciousness or seizure within the past five years. A period of one year of demonstrated stability is required following the first episode of hypoglycemia.

(5) Have had no recurrent hypoglycemic reactions requiring the assistance of another person within the past five years. A period of one year of demonstrated stability is required following the first episode of hypoglycemia.

(6) Have had no recurrent hypoglycemic reactions resulting in impaired cognitive function which occurred without warning symptoms within the past five years. A period of one year of demonstrated stability is required following the first episode of hypoglycemia.

(7) Have provided a board-certified or board-eligible endocrinologist, who is knowledgeable about diabetes, with a complete medical history including:

- ? The date insulin use began
- ? Diabetes diagnosis and disease history
- ? All hospitalization records
- ? Consultation notes for diagnostic examinations
- ? Special studies pertaining to diabetes
- ? Follow-up reports
- ? Reports of any hypoglycemic insulin reactions within the last five years

(8) Have been examined by a board-certified or board-eligible endocrinologist who has conducted a complete medical examination. The complete medical examination must consist of a comprehensive evaluation of the applicant's medical history and current status with a report including the following information:

- ? Two measures of glycosylated hemoglobin, the first 90 days prior to the last and current measure.
- ? Insulin dosages and types, diet utilized for control and any significant factors such as smoking, alcohol use, and other medications or drugs taken.
- ? Examinations to detect any peripheral neuropathy or circulatory insufficiency of the extremities.

(9) Submit a signed statement prepared by the examining endocrinologist indicating the following medical determinations:

- ? The endocrinologist is familiar with the applicant's medical history for the past five years either through actual treatment over that time or through consultation with a physician who has treated the applicant during that time.
- ? The applicant has been using insulin to control his/her diabetes from the date of the application back to the date the three years of driving experience began.
- ? The applicant has been educated in diabetes and its management, thoroughly

informed of and understands the procedures which must be followed to monitor and manage his/her diabetes and what procedures should be followed if complications arise.

? The applicant has the ability and has demonstrated willingness to properly monitor and manage his/her diabetes.

(10) Submit a separate signed statement from an examining ophthalmologist that the applicant has been examined and does not have *unstable proliferative diabetic retinopathy* (i.e., unstable advancing disease of blood vessels in the retina) and meets the vision standard at 49CFR 391.41(b)(10).

Guidelines for ITDM Individuals Who Have Been Qualified to Operate CMVs

(1) Individuals with ITDM shall maintain appropriate medical supplies for glucose management while preparing for the operation of a CMV and during its operation. The supplies should include the following:

? An acceptable glucose monitor with memory.

? Supplies needed to obtain adequate blood samples and to measure blood glucose.

? Insulin to be used as necessary.

? An amount of rapidly absorbable glucose to be used as necessary.

(2) Prior to and while driving, the individual with ITDM shall adhere to the following protocol for monitoring and maintaining appropriate blood glucose levels:

? Check glucose before starting to drive and take corrective action if necessary. If glucose is <100 mg/dl, take glucose or food and recheck in 30 minutes. Do not drive if glucose is <100 mg/dl. Repeat the process until glucose is >100 mg/dl.

? While driving check glucose every two to four hours and take appropriate action to maintain it in the range of 100 to 400 mg/dl.

? Have food available at all times when driving. If glucose is <100 mg/dl, stop driving and eat. Recheck in 30 min and repeat procedure until glucose is >100

mg/dl.

? If glucose is >400 mg/dl stop driving until glucose returns to the 100-400 mg/dl range. If more than two hours after last insulin injection and eating, take additional insulin. Recheck blood glucose in 30 minutes. Don't resume driving until glucose is <400 mg/dl.

Monitoring for ITDM Individuals Who Have Been Qualified to Operate CMVs

(1) Submit to a comprehensive medical evaluation by a specialist on annual basis. The evaluation will include a general physical examination and a report of glycosylated hemoglobin concentration. The evaluation will also involve an assessment of the individual's willingness and ability to monitor and manage the diabetic condition.

(2) Provide records of all daily glucose measurements taken with an acceptable device (with memory). These measurements will be reviewed by a specialist on a quarterly basis.

(3) Provide on an annual basis confirmation by an ophthalmologist that there is no roliferative diabetic retinopathy and no clinically significant disease that prevents the individual from meeting the current vision standards at 49 CFR 391.41(b)(10).

(4) Annual documentation by a specialist of ongoing education in management of diabetes and hypoglycemia awareness.

(5) Report, upon determination of a specialist or other physician, any episode of severe hypoglycemia, significant complications or inability to manage diabetes.

(6) Report any involvement in an accident or any other adverse event and whether or not they are related to an episode of hypoglycemia.

7. Legal Consequences of Allowing ITDM Drivers in Interstate Commerce

Sec. 4018(b)(4) of TEA-21 requires the Secretary to "assess the possible legal consequences of permitting insulin treated diabetes mellitus individuals to drive commercial motor vehicles in interstate commerce." 112 Stat. 413, at 414. These possible consequences fall into two categories: litigation

involving the rulemaking to allow ITDM drivers to operate CMVs, and litigation caused by accidents involving ITDM drivers.

Litigation Involving Rulemaking

A rule[1] adopted by the Federal Motor Carrier Safety Administration (FMCSA) permitting ITDM drivers to operate CMVs in interstate commerce could be challenged in court under the Administrative Procedure Act (APA) (5 U.S.C. Chapter 5, Subchapter II [Administrative Procedure], and Chapter 7 [Judicial Review]). The agency's actions, findings and conclusions can be set aside under 5 U.S.C. 706(2) if they are found to be

> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
>
> (B) contrary to constitutional right, power, privilege, or immunity;
>
> (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;
>
> (D) without observance of procedure required by law;
>
> (E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or
>
> (F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court. In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error. 5 U.S.C. 706.

Assuming the FMCSA adopts an ITDM rule, a legal challenge under the APA could unfold in the following manner. Plaintiffs might argue that the rule is arbitrary, capricious, or an abuse of

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[1] The word, *rule*, includes a regulation, policy or standard adopted pursuant to the Administrative Procedure Act.

discretion because it fails to meet the standard for a "screening, operating and monitoring protocol . . . that would ensure a level of safety equal to or greater than that achieved with the current prohibition . . ." [Sec. 4018(a)].

A reviewing court would consider the evidence, data and arguments cited by the FMCSA to support any rule related to ITDM drivers, giving the agency the deference required by Chevron, U.S.A., Inc., v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984) and its progeny. If the administrative record did not allow the agency reasonably to reach the conclusions embodied in the final rule, the court would presumably vacate the rule and remand it for further consideration. If the court upheld the rule, the FMCSA would implement it for ITDM drivers in interstate commerce.

Assuming a judicial challenge to a rule allowing ITDM drivers to operate CMVs was rejected, the FMCSA could nevertheless be sued under the APA if it failed to follow its own regulations, for example by rejecting applicants who met the requirements of the rule or approving drivers who did not. The plaintiff's argument would be that the agency acted in an arbirary and capricious manner by failing to observe its own rules. If the court agreed–after reviewing the facts and rule– the agency's decision would be reversed and the case possibly remanded to the FMCSA for appropriate action.

In short, the legal bases for an APA challenge to an ITDM regulation are no different from the grounds for challenging any other rule. The FMCSA can avoid adverse judgments -- though not necessarily lawsuits -- by developing a reasonable regulation well grounded in the relevant facts and scientific evidence, and consistent with the underlying statutes.

Litigation Involving Accidents

If insulin-treated diabetics are allowed to operate CMVs, some of them may eventually have an accident causing injury to others. The injured parties might sue the FMCSA on the theory that it was culpable for allowing ITDM drivers to operate large vehicles at all. The Federal Tort Claims Act (FTCA) (28 U.S.C. Chapter 171) allows the Federal government to be sued by persons who suffer financial or personal injury or death caused by the negligent or wrongful acts or omissions of Federal employees acting within the scope of their office or employment. The FTCA, however, specifically prohibits

> (a) [a]ny claim based upon an act or omission of an employee of the [Federal] Government, exercising due care, in the execution of a statute or regulation, whether or not such statute or regulation be valid, or based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the [Federal] Government, whether or not the discretion involved be abused.
>
> 28 U.S.C. 2680(a).

Rulemaking is a classic example of a "discretionary function." Therefore, the FTCA shields the FMCSA and its employees from liability for damages resulting from an accident involving an ITDM driver operating under the agency regulation.

The injured parties might also sue the driver and his/her employer under State law to prove that the driver's negligence, or that of his employer, caused or increased the severity of the accident. If the driver's diabetes appeared to be a causative or contributory factor in the accident, the plaintiff might

well probe for evidence that the motor carrier knew, or should have known, that the driver's diabetes was no longer adequately controlled because of changed medical conditions, driver carelessness in the management of the disease, or other reasons. At a minimum, a plaintiff could argue that the motor carrier had a duty to monitor closely and constantly the driver's observance of any conditions imposed by the FMCSA regulation. If the plaintiff could show that the carrier had not monitored the ITDM driver closely enough to detect a decline in his/her physical condition and that this declining condition had caused or contributed to the accident, the motor carrier/employer could be held liable.

Conclusion

The legal consequences of a rule permitting ITDM individuals to drive a CMV include (1) An APA challenge to the validity of the rule and (2) tort liability for damages sustained in an accident involving an ITDM driver. For the FMCSA and DOT, these consequences are no different from those associated with any other rule involving driver standards and qualifications. For motor carriers/employers that hire ITDM drivers, the rule might expose them to new standards of responsibility for monitoring the health of drivers who meet Federal guidelines.

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