Annex II

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE
WASHINGTON, D.C. 20508

GSP – 2002 COUNTRY PRACTICES REVIEW

PUBLIC COMMENT AND HEARING SCHEDULE
Address for Electronic Submissions: FR0052@USTR.GOV

September 26, 2003	Due Date for Requests to Appear at Public Hearings and Submission of Pre-hearing Briefs.
	Due Date for Providing the Name, Address, Telephone, Fax, Email Address and Organization of Witnesses.
October 7, 2003	TPSC GSP Subcommittee Public Hearings to Be Held at 10:00 A.M. at the Office of the U.S. Trade Representative, 1724 F Street, N.W., Washington, D.C.
October 31, 2003	Due Date for Submission of Post-hearing and Rebuttal Briefs.
June 30, 2004	Annual Review Decisions Scheduled to Be Announced on or about this Date.
For Further Information Contact:	GSP Information Center Office of the U.S. Trade Representative 1724 F Street, N.W. Washington, D.C. 20508 Telephone (202) 395-6971; Facsimile (202) 395-9481
For Public Documents Related to this Review:	USTR Public Reading Room, 1724 F Street N.W., Washington, D.C. Appointments May Be Made from 9:30 A.M. to Noon and 1 P.M. to 4 P.M., Monday Through Friday by Calling (202) 395-6186.

Notification of Any Changes Will Be Given in the *Federal Register*.

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DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2001–9800]

Qualification of Drivers; Exemption Applications; Diabetes

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: This notice announces FMCSA's decision to issue exemptions to certain insulin-using diabetic drivers of commercial motor vehicles (CMVs) from the diabetes mellitus prohibitions contained in the Federal Motor Carrier Safety Regulations (FMCSRs). The FMCSA will grant exemptions only to those applicants who meet the specific conditions and comply with all the requirements of the exemption. The FMCSA will issue exemptions for not more than a period of two years. Upon expiration, those holding exemptions may apply to FMCSA for a renewal under procedures in effect at that time. The FMCSA is leaving the docket open so that interested persons can provide comments on any changes to the specific conditions needed to qualify for the exemption program.

DATES: This notice is effective on September 3, 2003. FMCSA will begin accepting applications for exemptions on September 22, 2003.

ADDRESSES: Qualified insulin-treated diabetes mellitus drivers may now request a diabetes exemption from the regulations of 49 CFR 391.41(b)(3) by sending an exemption request to: Diabetes Exemption Program (MC–PSP), Office of Bus and Truck Standards and Operations, Federal Motor Carrier Safety Administration, 400 Seventh Street, SW., Washington, DC 20590–0001.

FOR FURTHER INFORMATION CONTACT: Ms. Sandra Zywokarte, Office of Bus and Truck Standards and Operations, (202) 366–4001, FMCSA, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Docket: For access to the docket to read background documents or comments received, go to *http://dms.dot.gov* at any time, or to Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, *etc.*). You may review the Department of Transportation's (DOT) complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit *http://dms.dot.gov.*

Background

The agency 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. The diabetes requirement provides that: A person is physically qualified to drive a commercial motor vehicle if that person has no established medical history or clinical diagnosis of diabetes mellitus currently requiring insulin for control (49 CFR 391.41(b)(3)).

Since 1970, the agency has considered the diabetes requirement and undertaken studies to determine if its diabetes standard for commercial drivers in interstate commerce should be amended. It is FMCSA's view that its physical qualification standards should be based on sound medical, scientific and technological grounds, and that individual determinations should be made to the maximum extent possible consistent with FMCSA's responsibility to ensure safety on the nation's highways. The FMCSA published a notice of intent to issue exemptions to insulin-using diabetic drivers in the **Federal Register** on July 31, 2001 (66 FR 39548). This notice of intent discussed the regulatory history and research activity addressing the issue of diabetes and CMV operation.

Feasibility Study To Qualify Insulin-Treated Diabetics to Operate CMVs

Section 4018 of the Transportation Equity Act for the 21st Century (TEA–21) (Pub. L. 105–178, 112 Stat. 107) directed the Secretary of Transportation (the Secretary) to determine if it is feasible to develop a safe and practicable program for allowing individuals with insulin-treated diabetes mellitus (ITDM) to operate 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. TEA–21 stated that, to accomplish this, the Secretary shall consult the states with regard to their programs for CMV operation by ITDM drivers, evaluate the 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. TEA–21 also directed 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 FMCSA submitted the report to Congress on August 23, 2000. It is entitled ''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 (TEA–21 Report to Congress). It concludes that a safe and practicable protocol to allow some ITDM individuals to operate CMVs is feasible. For a detailed discussion of the report findings and conclusions, see July 31, 2001 (66 FR 39548). A copy of the report is on FMCSA's Web site at *www.fmcsa.dot.gov/rulesregs/medreports.htm.*

Authority—Exemptions

Under 49 U.S.C. 31315 and 31136(e), FMCSA may grant an exemption for a period up to two years if it finds ''such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption.'' The statute also allows the agency to renew exemptions at the end of the two-year period, or after the current exemption expires.

FMCSA must publish a notice in the **Federal Register** for each exemption requested, explaining that the request has been filed, and providing the public an opportunity to inspect the safety analysis and any other relevant information known to the agency, and comment on the request. Prior to granting a request for an exemption, the agency must publish a notice in the **Federal Register** identifying the person or class of persons who will receive the exemption, the provisions from which the person will be exempt, the effective period, and all terms and conditions of the exemption. The terms and conditions established by FMCSA must ensure that the exemption will likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved by complying with the regulation.

In addition, the agency is required to monitor the implementation of each exemption to ensure compliance with its terms and conditions. If FMCSA denies a request for an exemption, the agency must periodically publish a notice in the **Federal Register** identifying the person(s) whom the agency denied the exemption to and the reasons for the denial.

Generally, the duration of exemptions is limited to two years from the date of approval, but may be renewed. FMCSA is required to immediately revoke an exemption if:

(1) The person fails to comply with the terms and conditions of the exemption;

(2) The exemption has resulted in a lower level of safety than was maintained before the exemption was granted; or

(3) Continuation of the exemption would not be consistent with the goals and objectives of the regulations issued under the authority of 49 U.S.C. 31315 and 31136(e).

Process for Applying for an Exemption

The procedures for applying for an exemption may be found at 49 CFR 381.300 through 381.330. The person applying for an exemption is required to send a written request to the FMCSA Administrator. The written request must include basic information such as the identity of the person who would be covered by the exemption, the name of the motor carrier or other entity that would be responsible for the use or operation of CMVs during the exemption period, and the principal place of business of the motor carrier or other entity. Under section 381.310, the application must include a written statement that:

(1) Describes the event or CMV operation for which the exemption would be used;

(2) Identifies the regulation from which the applicant is requesting relief;

(3) Estimates the total number of drivers and CMVs that would be operating under the terms and conditions of the exemption; and

(4) Explains how the recipient of the exemption would ensure that they achieve a level of safety that is equivalent to, or greater than, the level of safety that would be obtained by complying with the regulation.

FMCSA Procedures for the Review of Exemption Applications

Section 381.315 requires FMCSA to review an application for an exemption and prepare, for the Administrator's signature, a **Federal Register** notice requesting public comment. After a review of the comments received, FMCSA staff will make a recommendation to the Administrator. FMCSA will publish a notice of the Administrator's final decision in the **Federal Register**. FMCSA will issue a final decision within 180 days of the date it receives an individual's completed application. However, if the applicant should omit important details or other information necessary for the agency to conduct a comprehensive evaluation, FMCSA will issue a final decision within 180 days of the date that it receives sufficient information (49 CFR 381.315 and 381.320). FMCSA recognizes that this potential six-month waiting period may seem burdensome. However, the agency must carefully evaluate each and every application for regulatory relief from the diabetes standard, to assess the potential safety performance of each applicant. In addition, the agency must prepare and submit the candidate's application for public notice and comment in the **Federal Register** and then evaluate comments received before making a final decision. FMCSA's overriding concern is to ensure the safety of interstate CMV operations. The agency will notify all applicants in writing once it makes a final decision.

Application Information

In considering exemptions, the FMCSA must ensure that the issuance of diabetes exemptions will not be contrary to the public interest and that the exemption achieves an acceptable level of safety. The FMCSA will only grant exemptions, therefore, to ITDM individuals who meet certain conditions. These conditions are set forth below and the FMCSA based the conditions on the research literature, relevant DOT and State exemption programs, and substantial medical input from a panel of endocrinologists. FMCSA will require applicants for an exemption from the ITDM prohibition to submit their applications in a letter (there will be no application form), include all supporting documentation, and use the following format:

Vital Statistics

Name (First Name, Middle Initial, Last Name).
Address (House Number and Street Name, City, State, and ZIP Code).
Telephone Number (Area Code and Number).
Sex (Male or Female).
Date of Birth (Month, Day, Year).
Age.
Social Security Number.
State Driver's License Number (List all licenses held to operate a commercial motor vehicle during the 3-year period immediately preceding the date of application).
Driver's License Expiration Date.
Driver's License Classification Code (If not a commercial driver's license (CDL) classification code, specify what vehicles may be operated under such code).
Driver's License Date of Issuance (Month, Day, Year).

Experience

Number of years driving straight trucks.
Approximate number of miles *per year* driving straight trucks.
Number of years driving tractor-trailer combinations.
Approximate number of miles *per year* driving tractor-trailer combinations.
Number of years driving buses.
Approximate number of miles *per year* driving buses.

Present Employment

Employer's Name (If Applicable).
Employer's Address.
Employer's Telephone Number.
Type of Vehicle Operated and GVWR (Straight Truck, Tractor-Trailer Combination, Bus).
Commodities Transported (*e.g.*, General Freight, Liquids in Bulk (in cargo tanks), Steel, Dry-Bulk, Large Heavy Machinery, Refrigerated Products).
Estimated number of miles driven *per week.*
Estimated number of daylight driving hours *per week.*
Estimated number of nighttime driving hours *per week.*
States in which you will drive if issued an exemption.

In addition, the applications must include supporting documentation showing that the applicant:

(1) Possesses a valid intrastate CDL or a license (non-CDL) to operate a CMV;

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

(3) Has 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 involvement in an accident for which the applicant contributed to the cause of the accident, and

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;

(4) Has no other disqualifying conditions including diabetes-related complications;

(5) Has 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;

(6) Has 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;

(7) Has had no recurrent hypoglycemic reactions resulting in impaired cognitive function that 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,

(8) Has been examined by a board-certified or board-eligible endocrinologist (who is knowledgeable about diabetes) 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:

(A) The date insulin use began,

(B) Diabetes diagnosis and disease history,

(C) Hospitalization records,

(D) Consultation notes for diagnostic examinations,

(E) Special studies pertaining to the diabetes,

(F) Follow-up reports,

(G) Reports of any hypoglycemic insulin reactions within the last five years,

(H) Two measures of glycosylated hemoglobin, the first 90 days before the last and current measure,

(I) Insulin dosages and types, diet utilized for control and any significant factors such as smoking, alcohol use, and other medications or drugs taken, and

(J) Examinations to detect any peripheral neuropathy or circulatory insufficiency of the extremities;

(9) Submits a signed statement from an 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, and

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

(10) Submits a separate signed statement from an ophthalmologist or optometrist that the applicant has been examined and that the applicant does not have diabetic retinopathy and meets the vision standard at 49 CFR 391.41(b)(10), or has been issued a valid medical exemption. If the applicant has any evidence of diabetic retinopathy, he or she must be examined by an ophthalmologist and submit a separate signed statement from the ophthalmologist that he or she does not have unstable proliferative diabetic retinopathy (*i.e.,* unstable advancing disease of blood vessels in the retina).

Requirements for ITDM Individuals Who Have Been Issued an Exemption To Operate CMVs

There are special conditions attached to the issuance of any exemption for ITDM. The FMCSA will impose the following requirements:

(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 shall include the following:

(A) An acceptable glucose monitor with memory,

(B) Supplies needed to obtain adequate blood samples and to measure blood glucose,

(C) Insulin to be used as necessary, and

(D) An amount of rapidly absorbable glucose to be used as necessary;

(2) Individuals with ITDM shall maintain a daily record of actual driving time to correlate with the daily glucose measurements; and

(3) 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 less than 100 milligrams per deciliter (mg/dl), take glucose or food and recheck in 30 minutes. Do not drive if glucose is less than 100 mg/dl. Repeat the process until glucose is greater than 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 less than 100 mg/dl, stop driving and eat. Recheck in 30 minutes and repeat procedure until glucose is greater than 100 mg/dl; and

If glucose is greater than 400 mg/dl, stop driving until glucose returns to the 100 to 400 mg/dl range. If more than two hours after last insulin injection and eating, take additional insulin. Recheck blood glucose in 30 minutes. Do not resume driving until glucose is less than 400 mg/dl.

Monitoring for ITDM Individuals Who Have Been Issued an Exemption To Operate CMVs

In addition to the requirements for controlling ITDM, FMCSA will monitor exemption recipients during the period that the exemption is valid. FMCSA will conduct monitoring by requiring the exemption recipients to submit the following information to the Diabetes Exemption Program, MC–PSP, Office of Bus and Truck Standards and Operations, Federal Motor Carrier Safety Administration, 400 Seventh Street, SW., Washington, DC 20590–0001:

(1) Provide written confirmation from the endocrinologist on a quarterly basis:

(A) The make and model of the glucose monitoring device with memory;

(B) The individual's blood glucose measurements and glycosylated hemoglobin are generally in an adequate range based on:

a. All daily glucose measurements taken with the glucose monitoring device and correlated with the daily records of driving time; and

b. A current measurement of glycosylated hemoglobin.

(2) Submit on an annual basis, a comprehensive medical evaluation by an endocrinologist. 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;

(3) Provide on an annual basis confirmation by an ophthalmologist or optometrist that there is no diabetic retinopathy and the individual meets the current vision standards at 49 CFR 391.41(b)(10). If there is any evidence of diabetic retinopathy, provide annual documentation by an ophthalmologist that the individual does not have unstable proliferative diabetic retinopathy;

(4) Submit annual documentation by an endocrinologist of ongoing education in management of diabetes and hypoglycemia awareness;

(5) Report all episodes of severe hypoglycemia, significant complications, or inability to manage diabetes; and

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

Medical Examination-Certificate of Physical Examination for ITDM Individuals Who Have Been Issued an Exemption To Operate CMVs

Because diabetes is a chronic disease requiring constant control and monitoring, FMCSA will impose conditions on ITDM individuals, who have been issued an exemption, similar to the provisions that apply to drivers who participated in the agency's diabetes waiver program before March 31, 1996 under 49 CFR 391.64. The required conditions include the following:

(1) Each individual must have a physical examination every year:

(a) The physical examination must first be conducted by an endocrinologist indicating the driver is:

1. Free of insulin reactions. ''Free of insulin reactions'' in this context means that the individual has had:

(A) 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,

(B) 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, and

(C) No recurrent hypoglycemic reactions resulting in impaired cognitive function that 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,

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

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

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

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

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

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

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

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

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

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

Basis for Determination

Under 49 U.S.C. 31315 and 31136 (e), the FMCSA may grant an exemption for up to a two-year period if it finds that the action would likely achieve a level of safety that is equivalent to, or greater than, the level of safety that would be achieved absent such exemption. This requirement sets the criteria for safety in developing new programs. In this context, relative to diabetes, Section 4018 of TEA–21 directed the Secretary to determine if it is feasible to develop a safe and practicable program for allowing individuals with ITDM to operate CMVs in interstate commerce. In making that determination, the primary focus was on whether such a program could achieve a level of safety that is equal to or greater than the level that exists without the program. To do this, multiple sources of information were sought.

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

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

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

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

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

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

Discussion of Comments

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

the proposed program, citing complexities of the application process, the extent of the medical examination, and the length of time until FMCSA grants an exemption. Among the comments in support, while citing problems with other elements of the program, 191 wrote specific comments about the requirement for three years of driving experience with the condition.

Nine organizations and individuals submitted 23 comments in opposition to the proposal. They argued that available evidence does not support implementation of an exemption program that must meet the safety requirements for new programs. They assert that the medical examination process cannot conclusively identify safe drivers with ITDM, that interstate driving is too arduous for such individuals, and the risk assessment results are not sufficient to justify a program that will be as safe or safer than the existing absence of a program.

The comments on the proposed program are further discussed below. Numerous commenters have substantive concerns about the same issues. The FMCSA presents its response after the comments are described.

Comments In Support

The American Diabetes Association (ADA) generally supports the FMCSA proposal to end the blanket ban prohibiting insulin-treated diabetics from operating CMVs. It believes that this proposal is long overdue and it would institute a process for the individual assessment of applicants. The ADA said that it does not believe all individuals with insulin-treated diabetes should qualify for a CDL. It strongly supports replacing the blanket ban with a medically sound protocol that maximizes safety and employment opportunities for individuals with diabetes. Consistent with that support, the ADA states that it supports most aspects of the proposed program. Specifically, the ADA agrees with three aspects of the proposed protocol; the careful medical screening, the stringent guidelines for drivers to use when driving, and the aggressive monitoring for safety. It supports the rigorous approach to assuring the highest levels of safety and believes that most aspects of the proposal are excellent.

The ADA, however, disagrees with the exemption requirement that insulin-treated drivers should have three years of safe driving experience with the condition. It states that nothing in the TEA–21 Report to Congress supports this requirement, and that the proposed requirement disregards currently available medical treatment and supplies for people with diabetes. The ADA claims that the agency's own medical panel recommended a one or two month period for a person to adjust to insulin before applying for a CDL, and urges the adoption of that standard. It goes on to state that the three-year screening criteria should be replaced with a one-month adjustment period for those with non-ITDM that are moving to the use of insulin, and a two month adjustment period for those newly diagnosed with the ITDM condition. Individual circumstances could extend this latter period. Moreover, the ADA believes that there should be no requirement for the CDL applicant to have any experience driving a CMV.

The ADA also believes that DOT should change the regulations in relation to diabetes. It believes that the proposed exemption program has a number of difficulties that a regulatory change would not. The ADA believes the exemption program could be terminated at any time in the same manner the FHWA did when it ended the diabetes waiver program. It also believes that an exemption program may not be able to protect qualified ITDM drivers from employer discrimination, citing a supreme court decision, *Albertson's Inc.* v. *Kirkingberg,* 527 U.S. 555 (1999). The ADA states that an exemption program could result in more discrimination and litigation. As a result, the ADA argues that the general regulatory standard in 49 CFR 391.41(b)(3) should not continue when the DOT has determined that individual assessment is feasible.

The U.S. Equal Employment Opportunity Commission (EEOC) states that the proposed exemption program is intended to increase employment opportunities for individuals with disabilities while monitoring for safety. In this sense, the EEOC claims that the process is consistent with the Americans with Disabilities Act. However, the EEOC is concerned about the requirement for three years of driving experience with the condition. It is concerned that this screening process may exclude a large number of drivers from interstate commerce, which may limit diabetic drivers to a small number of lower paying jobs. It was also concerned that some drivers may live in states that do not allow diabetic drivers to operate CMVs in intrastate commerce. The EEOC urges the FMCSA to monitor the three-year experience requirement if it is used and reassess it if it becomes too exclusionary.

The Congressional Diabetic Caucus (Caucus) generally supports the program, saying that it is pleased that the TEA–21 Report to Congress ''concludes that a safe and practicable protocol to allow some individuals with insulin-treated diabetes mellitus to operate commercial motor vehicles is feasible.'' However, it has concerns about the three-year requirement for driving experience. It claims that the proposed three-year requirement ignores advances in medical treatment. The Caucus points to the input given by a DOT medical advisory panel which recommended a one to two month adjustment period before driving for those individuals newly treated with insulin.

The Caucus also believes that DOT should not implement the proposed policy through another exemption or waiver program. It believes the vast majority of States and the Federal Government have successfully experimented with allowing a limited number of insulin-treated drivers to operate CMVs. With the Federal government's analysis of the issue, another exemption (waiver) program would be inadequate to provide benefits for all involved. Based on this, it urged DOT to permanently change the regulations concerning insulin-treated diabetes and the operation of CMVs.

The Civil Rights Division of the U.S. Department of Justice (DOJ) generally supports the proposed exemption program as a positive step toward permitting an individual assessment of persons with ITDM to operate CMVs in interstate commerce. The DOJ, however, has concerns regarding the three-year driving requirement and urged the FMCSA to continue to obtain and analyze data on the safety records of CMV operators with ITDM from all available sources. This should permit the FMCSA to consider if it is appropriate to modify the three-year requirement. The DOJ believes that among those States that allow drivers with ITDM to operate CMVs, some monitor the drivers for a variety of reasons. As a result, those states should be able to provide the FMCSA with several years of data to examine the risk associated with relaxing the three-year requirement.

The Amalgamated Transit Union (ATU), which represents over 175,000 members maintaining and operating bus, light rail, ferry, over-the-road bus, school bus, and paratransit vehicles in the U.S. and Canada, strongly supports the proposed program because advances in the treatment of diabetes make it possible for some ITDM individuals to operate a CMV. However, the ATU strongly opposes the requirement for three years of safe CMV operation with the condition. This aspect of the proposal, the ATU argues, would place

a huge obstacle in the path of qualified individuals with ITDM. This requirement discriminates against drivers in non-waiver States. In light of the medical advances in the treatment of ITDM, the ATU states there is no justification for the three-year requirement. Instead, the ATU claims that the FMCSA should adopt the recommendation of the medical panel in the TEA–21 Report to Congress, wherein a one or two-month period for adjustment to insulin would be required for seeking or maintaining a CDL.

The International Brotherhood of Teamsters (IBT) applauds the FMCSA's efforts to eliminate the blanket ban on insulin-using diabetic drivers. However, the IBT agrees with the other organizations relative to the three-year driving requirement. In their opposition to the requirement, the IBT cites the absence of waivers in some States that would exclude many drivers. The IBT also claims that it is not easy for drivers to obtain the required experience even in States with waiver programs because there are significantly fewer jobs in intrastate operation. They also point to the unfairness of experienced interstate drivers losing their CDL when newly diagnosed with ITDM.

The IBT is also concerned about the requirement that a CDL applicant have a safe driving record. It states that the requirement bears no relation to the applicant's medical condition and that this goes too far even in trying to ensure safety. It is most concerned about the requirement that a driving record could prevent the applicant from obtaining an exemption based on the applicant's accident involvement for which the driver ''contributed to the cause.'' The IBT believes this standard is too broad and subjective.

The IBT also believes that rulemaking rather than an exemption program would better serve the process of granting CDLs to insulin-using diabetics. It sees little benefit in the exemption process of publishing an application in the **Federal Register** and requesting comments on the applicants' diabetic conditions. The IBT states that it understands that rulemaking can be a lengthy process and encourages the FMCSA to proceed with the exemption program while continuing to work on the more permanent solution through a change in the regulations.

The Owner-Operator Independent Drivers Association, Inc. (OOIDA) generally supports and welcomes the changes proposed by the FMCSA in the exemption program. Based on reports from its membership, OOIDA believes that a number of drivers with ITDM can safely operate CMVs in interstate commerce. OOIDA believes that FMCSA's proposed program has a number of steps that will ensure that no increased safety risks will be present. However, OOIDA is concerned about the three-year driving requirement, and believes that it runs counter to the proposal to require an activity currently prohibited in interstate commerce. It believes that the requirement limits access to the CDL program because there are few intrastate driving opportunities. OOIDA is further concerned about experienced drivers who would be using insulin, but choose not to do so because they will lose their CDLs. While the proposed exemption program may help lessen this problem, the three-year requirement places them in a difficult economic and health position.

The National Private Truck Council (NPTC) agrees with the FMCSA that a blanket prohibition on the operation of CMVs by individuals with ITDM is unwarranted and understands the agency's concerns relative to the safe performance of drivers with this condition. The NPTC, however, believes that the protocol is so burdensome that it will discourage participation in the program. The most onerous provision in the program, according to the NPTC, is the requirement for three years of CMV driving experience with the diabetic condition. They believe that the requirement is unnecessary from a safety standpoint, and presents an excessive burden on applicants to the program.

The American Trucking Associations, Inc. (ATA) supports FMCSA's proposed exemption program. ATA recognizes the advances made in the treatment of ITDM, the advances in the treatment of diabetes related heart disease, and the success of the agency's earlier diabetes waiver program. ATA's support is given if the proposed exemption program contains specific components related to screening, safe driving experience, medical history and examinations, guidelines, and monitoring.

The American Optometric Association (AOA), while supporting the proposal, takes exception with the omission of optometrists from the examination requirements in the application process. The AOA states that this omission is inconsistent with all existing Federal guidelines on the matter in addition to those put forth by the AOA, the National Committee on Quality Assurance, and the recommendations of the agency's medical panel member Edward S. Horton, M.D. Moreover, the AOA argues that the omission of optometrists implies that they are not able to monitor proliferative diabetic retinopathy. The AOA states that this is not true because studies indicate that optometrists can detect non-proliferative and proliferative retinopathy, as well as general ophthalmologists. The AOA clinical guidelines for the optometric care of diabetic patients is identical to the procedure used by ophthalmologists to detect proliferative diabetic retinopathy. Finally, the AOA argues that it would be inconsistent for the agency to include optometrists in the annual medical examination for diabetics in 49 CFR 391.64, and then exclude them in the proposed exemption process.

The Oregon Department of Transportation and the Illinois State Police both endorse the proposed exemption program. Oregon has extensive experience in issuing intrastate waivers to insulin-using diabetic CMV drivers based on stringent medical requirements. Oregon maintains crash data for intrastate commercial operations and had found no accidents related to complications from diabetes. Likewise, the State of Illinois currently allows diabetic drivers under its grandfather provisions and has no data to indicate ITDM drivers are a greater safety risk than other drivers. The Illinois State Police takes no exception to the proposed exemption program if there is strict oversight and careful scrutiny of each applicant.

The State of Delaware also supports the proposed exemption program since it has had a similar program in effect for 15 years. Delaware states that it has no indication that the program has reduced highway safety. However, the State believes that the agency proposal is overly complex. It points specifically to the publication of individual exemptions in the **Federal Register** for comment, the decision period of up to six months, the annual physician report, and the quarterly specialist review. It suggests a reduction in these requirements.

FMCSA's Response

The comments about the requirement for three years of driving experience with the ITDM condition are understandable. It does place a constraint on some ITDM drivers who want to operate a CMV in interstate commerce. However, under 49 U.S.C. 31315 and 31136(e), FMCSA may grant an exemption from the diabetes standard only if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. FMCSA believes that thorough screening of exemption applicants, and periodic monitoring of their safety performance, are the most

practical and effective ways to ensure the diabetes exemption program satisfies the statutory requirement achieving a level of safety equivalent to, or greater than, the level of safety obtained by complying with the safety regulation. FMCSA believes that the three-year requirement is crucial to this screening and monitoring protocol until data supports a different threshold. The three-year requirement provides sufficient time to expose anomalies in driving records that enhance predictability of future driving performance. It also allows the driver to develop a routine for managing his or her diabetic condition and establish a driving record demonstrating those adaptive skills.

FMCSA based the three-year driving experience requirement on the best available scientific evidence. The previous work the agency performed under its diabetes waiver program in the mid-1990s supports the three-year requirement. Drivers in that program, who had three years of experience while using insulin, had accident rates lower than the national rate. The driving performance of those who met the three-year requirement and other program requirements was analyzed relative to 1993 through 1996 large truck national accident rates found in the National Highway Traffic Safety Administration's General Estimates System. The accident rate of the waiver group with over 9 million miles of driving exposure was 1.960 accidents per million miles versus a national accident rate of 2.272 for the same period.

On August 24, 1994, the agency convened a meeting to conduct a review of the vision waiver program. The diabetes waiver program used the same three-year requirement as the vision program. Agency officials and a variety of researchers in highway safety and vision attended the meeting. (See the Final Descriptive Report ''Qualification of Drivers—Vision, Diabetes, Hearing and Epilepsy;'' FHWA; DTFH61–92–Z–00158, May 30, 1997). The group discussed both the formation of the waiver program and the design of the associated study. Relative to the design of the waiver program and the enrollment of drivers, it was decided that the program was well conceived within the context of congressional mandate expressed in the Motor Carrier Safety Act of 1984. The group determined that the conditions developed for screening and enrolling drivers into the waiver program were appropriate. To qualify for a vision waiver, a driver had to have an extremely safe driving record for three full years before applying to the program. The group agreed based on the safety literature that the best predictor of future driving performance is past performance. As a result, the group concluded that the enrolled drivers would be as safe in the waiver program as they were before the program.

Because the FMCSA is required to develop programs that are as safe as or safer than the prevailing norm, the agency believes this is compelling evidence to require the three-year driving experience requirement in its diabetes exemption program. However, the agency will revisit the issue in the future. FMCSA will examine how reducing the three-year experience requirement can be accomplished while satisfying the statutory requirement under 49 U.S.C. 31315 and 31136(e).

FMCSA believes that its medical advisory panel recommendation that persons could be qualified to drive a CMV, after a one-or two-month period of adjustment to insulin use, does not take into account the complex demands of operating a large vehicle in interstate commerce. Diabetes is a chronic disease requiring constant control and monitoring. CMV drivers, however, are frequently required to work long hours and travel significant distances, often requiring overnight stays away from home. Because of economic pressures to arrive at a delivery site on schedule, drivers may often have difficulty maintaining a regular diet, exercise, and the blood sugar monitoring patterns necessary to manage their diabetes properly. Failure to manage diabetes properly significantly increases the likelihood of an adverse event, such as loss of consciousness while driving due to hypoglycemia (low levels of glucose in the blood). Advances in the medical treatment of diabetes do not equal compliance. There is a strong behavioral component in managing diabetes.

With respect to comments urging FMCSA to change the regulations on ITDM and CMV operation, FMCSA does not believe there is evidence to support such a change. In the TEA–21 Report to Congress conducted for this program, the FMCSA could find no precedence for regulatory change for a condition like ITDM. ITDM is a chronic health problem.

Diabetes is a condition that is potentially quite labile, even if an individual demonstrates good control of blood glucose levels at a point in time. The expert medical panel convened for the TEA–21 Report to Congress agreed that diabetics have special medical problems. For this reason, they concurred that diabetics should be examined by endocrinologists who are experienced with the condition. In relation to monitoring the ITDM driver's management of the condition, the panel suggested, among other things, that quarterly reporting of glucose monitoring data would be a good method of determining whether the driver is following the monitoring guidelines. The panel also agreed that these drivers should receive ongoing education in hypoglycemia awareness, and that this education should be monitored on an annual basis. For this reason, FMCSA believes the evidence supports the requirement that a responsible, qualified driver should undergo periodic examinations. The need for periodic examinations is underscored by the possible occurrence of diabetic complications such as retinal disease and peripheral neuropathy.

FMCSA believes that the periodic examinations, and the monitoring of the examinations, both assure the health of the individual and the safety of the public at large. Consequently, FMCSA has determined that the prefered context in which to guarantee such screening and monitoring is in an exemption program.

IBT was concerned about the driver record requirement that prevents the applicant from obtaining an exemption because of involvement in an accident for which the driver ''contributed to the cause.'' IBT believes this type of assessment is too subjective. However, FMCSA's analysis of the driving record of each individual driver is not subjective. The analysis of the accident report seeks to determine whether the reporting police officer has issued a citation indicating that the driver is at fault or has contributed to the cause of the accident. The analysis also examines the accident report to determine whether there is evidence of driving behavior that could indicate a hypoglycemic event, such as crossing the median, swerving, or driving off the road. In cases where a diabetic driver receives medical attention, reports on glucose levels can be obtained.

The AOA took exception to the exclusion of optometrists from the proposed exemption process. The protocols that were in the proposed program have been revised, today's final disposition notice allows applicants to obtain and submit a signed statement from an ophthalmologist or optometrist, indicating that they have been examined, the applicant does not have diabetic retinopathy, and meets the vision standard at 49 CFR 391.41(b)(10). However, if the driver has any evidence of diabetic retinopathy, FMCSA requires an examination by an ophthalmologist to offer additional expert opinion regarding stability and risk of

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

Comments In Opposition

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

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

FMSCA is aware that operating a CMV in interstate commerce is an arduous occupation. The agency designed the screening criteria in the exemption program to identify those insulin-using diabetics, who will have a high degree of responsibility in managing the condition while driving in interstate commerce. The agency bases this assertion on the experience obtained in the above referenced diabetes waiver program. The evidence generated by that program, which had the same screening criteria as that proposed for the exemption program, demonstrated that responsible insulin-using diabetics can safely operate a CMV in interstate commerce. The evidence obtained in that program represents over 9 million miles of CMV operation by individuals who were successfully screened by the criteria. In addition, FMCSA will require that an applicant for the diabetes exemption program be educated in diabetes and its management, and have demonstrated a willingness to properly monitor and manage his or her diabetes. Finally, not all operations in interstate commerce are long-haul.

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

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

FMCSA is acutely aware of the threat presented by tight control of blood glucose levels and hypoglycemia. It was not the agency's intent to use the results of those studies to support the determination of safety. Rather, the intent was to identify a potential threat that had to be accounted for in the protocols of the proposed exemption program. To this end, the expert medical panel addressed this issue in the FMCSA's TEA–21 Report to Congress. The panel, while clearly recognizing hypoglycemia as a threat, also thought awareness was a bigger problem. It noted that there was a correlation between hypoglycemia awareness and recurrent, severe hypoglycemic episodes, as shown in the Diabetes Control and Complications Trial data. The panel stated that individuals who are prone to severe hypoglycemia should not drive. The panel agreed that severe hypoglycemia in the past year or several episodes in the past five years can predict the future. The panel also agreed that training in the awareness of hypoglycemia is necessary for drivers of CMVs. Because of this, awareness education is a requirement in the protocols of the exemption program announced today.

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

AHAS also took exception to FMCSA's interpretation of four recent risk studies presented in the TEA–21 Report to Congress and the July 2001 notice of intent. It first addressed two Canadian studies:

1. Dionne, G. *et al.* ''Medical Conditions, Risk Exposure, and Truck Drivers' Accidents: An Analysis with Count Data Regression Models,'' Accident and Prevention, 27(3): 295–305 (1995); and

2. Dionne G. *et al.* ''Analysis of the Economic Impact of Medical and Optometric Driving Standards on Costs Incurred By Trucking Firms and on the Social Costs of Traffic Accidents'' in Dionne, G. and Laberge-Nadeau, C. (Eds.) Automobile Insurance: Road Safety, New Drivers, Risk Insurance Fraud and Regulation, Kluwer Academic Publishers, Boston (1999).

AHAS states that these studies do not offer any evidence in support of an exemption program.

The first of these studies (1995) examined truck drivers in two licensure classes. One class was for the operation of large combination trucks, while the other included truck drivers holding all other classes of license that were mostly holders of permits for straight trucks. The risk analysis in each class considered diabetic drivers versus all other drivers. The diabetic drivers of large combination trucks had an accident rate that was not significant, while the diabetic drivers of small trucks had a significantly higher accident rate. The analysis did not consider the use of insulin by the diabetic drivers. Relative to this, AHAS alleges that FMCSA's notice of intent does not state to the public that although the researchers were actually at a loss to explain the results, they believed that the results could be due to the use of insulin since the diabetic drivers of large trucks had fewer individuals treated in this manner than those with other classes of license.

For the second study, AHAS states that the results FMCSA relies on were not the focus of the study nor its primary consideration, and that the primary focus of the study was estimation of cost per accident. FMCSA reported a secondary finding, according to AHAS, in that the data showed that drivers with diabetes did not have significantly more severe accidents than those in the comparison groups. Severity was measured as the total number of individuals injured or killed in an accident. AHAS points out that the work in the second study was based on the data used in the first and was a continuation of that study. It also states that the use of insulin was not considered in the second study.

FMCSA believes the AHAS claim that the studies do not contribute to the finding that ITDM drivers have an acceptable level of risk is unfounded. Aside from the finding that diabetic drivers of small truck CMVs had a significantly higher accident rate, none of the other findings refute the position that diabetics could operate CMVs in interstate commerce with a level of safety that is the same or better than the prevailing standard. While insulin was not taken into consideration in the analyses, the studies do nonetheless offer evidence in support of the exemption program by virtue of not contradicting the conceptual design. Contradiction and refutation are acceptable approaches in science to revise a stated theory. None of the work contradicts the determination that diabetic drivers have an acceptable level of risk. In performing risk assessments through observational studies, it is necessary to examine all of the evidence to determine the direction the preponderance of evidence supports.

After the FMCSA issued the notice of intent, there has been an additional contribution to the collection of evidence on this issue. Some of the same Canadian researchers who conducted the previous studies used the same insurance database to conduct a third study (Laberge-Nadeau, C. *et al.* ''Impact of Diabetes on Crash Risks of Truck-Permit Holders and Commercial Drivers.'' Diabetes Care, Vol. 23(5): 612–617, 2000). These data were augmented with health status data from a public health insurer where insulin use was identified, along with the existence of complications due to diabetes. Portions of the database were analyzed with the new information in a new research design where diabetic driver permit holders were group-matched by age to a random sample of healthy permit-holders. Risk was analyzed relative to type of permit holder (large combination trucks and straight trucks), use of insulin, and diabetic complications. Relative to both classes of trucks, insulin-using diabetics showed no significant risk regardless of complication status. The only group of diabetics to show significant risk was the permit holders for straight trucks who did not use insulin and were without complications. To explain the results concerning insulin use and complications, the researchers stated that employers hiring drivers for large combination trucks use higher medical standards presumably for insulin-using diabetics and other drivers. This is what the protocols in the FMCSA diabetes exemption program are designed to do.

Many of the points argued by AHAS in relation to their criticism of the research design in the waiver program and their rejection of the legal basis for the exemption program, have been previously presented and have been addressed at length in 58 FR 40690 (July 29, 1993) (FHWA Docket No. MC–87–17), 61 FR 13337 (March 26, 1996) (FHWA Docket No. MC–96–2), 63 FR 67601 (December 8, 1998) (DMS Docket No. FMCSA–1998–4145) and 64 FR 51568 (September 23, 1999) (DMS Docket No. FMCSA–1999–5578). FMCSA will not address the points again here. Interested parties are referred to the earlier discussions.

In its comments to this notice, AHAS also raises some new issues. In particular, it has some concerns relative to the most recent risk study conducted by the agency (''A Study of the Risk Associated with the Operation of Commercial Motor Vehicles by Drivers with Insulin-Treated Diabetes Mellitus,'' FHWA, 1999). AHAS states that the comparisons made in the study could be suspect because the comparison group was composed of interstate drivers, while the diabetes group contained mostly intrastate drivers. While it is true that the diabetes group did primarily contain intrastate drivers, the comparison group of CDL holders also had intrastate drivers, albeit in smaller proportion. This disparity in representation by the two groups did contribute to the range of CMV operation (intrastate versus interstate) being identified as a confounding factor in the study. As a result, FMCSA used the factor to adjust the initial results. Observational study research literature supports this type of adjustment. Had this factor and others been ignored in the analyses, the unadjusted results would have been biased and detracted from the internal validity of the study.

This aspect of FMCSA's response also addresses another AHAS concern involving the nature of the unadjusted study results. AHAS correctly pointed out that the initial (unadjusted) results show that the diabetes group had a higher crash rate than the comparison group. However, since this study was observational in nature, as are almost all practical risk investigations, it is necessary to assess the factors that could introduce bias into the results and invalidate the findings. FMCSA did this and found several factors, including intrastate versus interstate operation and marital status. The other source of potential bias that FMCSA found was over-dispersion in the distribution of accidents (a larger than expected

variation in the number of accidents). Both of these sources of bias tend to produce false positive (significant) results if not subjected to adjustment. FMCSA analyzed the two sources of potential bias with adjustment procedures, both separately and jointly, and found the results were consistent across all analyses showing no significant difference in risk between the two groups. While the AHAS seemed to characterize this multifaceted approach to analysis as a contrived strategy, it is the approach which is required in an observational study (see U.S. General Accounting Office, ''Cross Design Synthesis; A New Strategy for Medical Effectiveness Research,'' March 1992 GAO/PEMD–92–18). It is the consistent results across the varied adjustment procedures that gives the FMCSA confidence that bias was present in the initial (unadjusted) results and was eliminated in the ensuing analysis.

AHAS also claims that the Federal Aviation Administration (FAA) exemption program for ITDM individuals is an inappropriate model for FMCSA's program for the operation of CMVs. It stated that the FAA program issues exemptions only for third-class airman medical certificates and not for commercial pilots. The AHAS is correct in their assessment of the FAA program; however, the FMCSA had no intention of using the FAA's program as a model for the FMCSA program with respect to type of target population. FMCSA used the FAA program as evidence that it could develop a process of medical examination and screening to issue exemptions to individuals with ITDM. To this end, FMCSA used the FAA process as part of the template for development of the proposed medical examination and screening protocol. That is why the protocol is analogous to that of the FAA.

In its opposition, the California Department of Motor Vehicles (California) states that the proposed FMCSA program will unnecessarily increase the risk to the public and the drivers receiving the exemptions. While California regulatory guidelines allow some experienced ITDM individuals to operate intrastate, it believes that the FMCSA exemption program could greatly expand the number of these drivers who operate interstate and thereby increase risk. California limits the number of exemptions because of the risk of hypoglycemia. It states blood sugar is affected by almost everything including exercise and stress. This in combination with arduous work conditions associated with interstate operation makes it difficult for drivers with ITDM to control their blood sugar.

California does not believe that the proposed FMCSA screening procedures adequately address the issue of hypoglycemia. The requirement for a complete medical examination, by a board-certified or eligible endocrinologist with a statement of familiarity with the applicant's five-year medical history, will not preclude an ITDM driver from experiencing a hypoglycemia episode.

FMCSA believes it has addressed this type of circumstance in the exemption program's screening protocol. Specifically, the criteria state that the applicant must have had no recurrent (two or more) hypoglycemia 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. Moreover, the criteria require that the applicant does not have recurrent hypoglycemia reactions requiring the assistance of another person and does not have reactions resulting in impaired cognitive function that occurred without warning symptoms within the past five years. In addition, as a test of these responses under arduous working conditions, the screening criteria also require three years of CMV operation with ITDM. The same screening criteria were used in the agency's previous diabetes waiver program, and in the three years of that program, there were no reported cases of impairment due to episodes of hypoglycemia. Moreover, screening is stricter now. In place of a single screening episode under the previous program, the driver must reapply for an exemption every two years, or sooner if the exemption was issued for a shorter period. Screening is performed at each reapplication. In addition, screening is performed annually by an endocrinologist, as well as the medical examiner performing the annual examination and certification required under 49 CFR 391.43.

In another issue of concern for California, it points out that the protocol proposed in the FMCSA program requires the exempted drivers to check their blood sugar levels every two to four hours. Because of this and other measures needed to control blood sugar, California believes that employers would not let the drivers take the time necessary to perform all of these activities. FMCSA, based on its previous experience, is not aware of any evidence to suggest that employers would not allow drivers to take the time needed to check their blood sugar levels.

California points to a 1999 study as another basis for its opposition (Clark, W. L. *et al.* ''Hypoglycemia and the Decision to Drive a Motor Vehicle by Persons with Diabetes.'' JAMA, August 1999, Vol. 282, No. 8, 750–754). An objective of the study was to examine an ITDM individual's decision to drive during the individual's daily routine, based on perception of blood sugar levels compared to actual levels. The researchers found that significant numbers of subjects did not correctly estimate how low their blood sugar was, and therefore decided to drive. The findings also showed that even when individuals accurately estimated low blood sugar levels, a significant portion still decided to drive. California, however, does not indicate the researchers stated that ITDM individuals should not be permitted to drive. California did say the data suggested that individuals with ITDM need to be cautious before driving a motor vehicle. The researchers said that the suggestion that individuals measure their blood sugar levels, and raise potentially low levels before driving, did not seem unreasonable. They said that drivers with diabetes should always carry rapid-acting glucose with them when they drive. Moreover, the researchers claim that individuals with ITDM could benefit from awareness training to help detect blood sugar levels. They stated that this type of training has been shown to improve the detection abilities of even those with reduced awareness of hypoglycemia, and that the improvement has been sustained for at least a year.

The protocol being adopted in this final disposition is very consistent with the conclusions of these researchers. In the screening component the applicant must present a signed statement prepared by the examining endocrinologist indicating that 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. In addition, the protocol requires, in the guideline component, that the qualified applicant have a supply of rapidly absorbable glucose to be used as necessary. The protocol also requires, in the monitoring component, that the qualified driver provide annual documentation by a specialist of ongoing education in diabetes management and hypoglycemia awareness. While Clark W. L., *et al.* was valuable in identifying the potential

problems with hypoglycemia awareness, it also suggested methods for intervention. The suggestions of the researchers concerning how they believe the problem should be addressed are clearly contained in the protocols of the exemption program.

Conclusion

After analyzing the comments to the notice of intent, the FMCSA is convinced that the proposed program is responsive to the need and requirements of the various interested individuals and organizations. The comments raised a number of valid issues of concern. The agency believes that it has successfully addressed those concerns in the development of this program. The public's concerns must be addressed because they mainly focus on safety issues. This is the reason there is a three-year driving experience requirement in a part of the exemption program, in addition to medical screening, guidance, and monitoring. The three-year requirement of the program provides certainty to public safety, and also protects ITDM drivers. The ability to operate CMVs safely for three years clearly helps to indicate that applicants can perform the arduous work required in this type of job category. While we believe this requirement to be essential, all of the proposed components are required for a safe and practicable program.

Nonetheless, FMCSA recognizes that the three-year requirement will restrict the number of drivers eligible for an exemption. The agency has no desire to make the program more stringent than necessary and will therefore leave this docket open indefinitely in order to provide a means for the submission of additional views and data on the need for three years of driving experience. FMCSA is particularly interested in obtaining statistical data on the accident rates of ITDM drivers before and after they begin a course of insulin treatment. This analysis depends on knowing, among other things: (1) The number of miles driven and accidents experienced by the driver before beginning insulin treatment, thus providing a baseline accident rate; (2) the length of time an ITDM driver has taken insulin before resuming a driving career; (3) the date the ITDM driver resumed driving and the interval to the first (and any subsequent) accident; and (4) the number of miles driven by an ITDM driver, preferably on a monthly and annual basis. Although FMCSA will not ignore any relevant information that may be submitted, the statutory standard for an exemption requires the agency to focus its attention on the question whether ITDM drivers with less experience driving CMVs can achieve accident rates comparable to those of ITDM drivers who have at least three years of experience driving CMVs prior to applying for an exemption. This is an issue that can be resolved only by more and better data. FMCSA is also interested in learning which segments of the motor carrier industry have work conditions most (or least) conducive to the self-monitoring routines that ITDM drivers must maintain in order to control their blood sugar level.

For the reasons above, the FMCSA has determined that the most desirable structure to support these components is an exemption program. Therefore, in accordance with 49 U.S.C. 31315 and 31136(e), the FMCSA will implement a program that will issue exemptions to qualified ITDM drivers. Each exemption will be valid for up to two years and require renewal at the end of that period. Qualified ITDM drivers may request a diabetes exemption from the 49 CFR 391.41(b)(3) regulation by sending an exemption request on or after September 22, 2003, to the Diabetes Exemption Program at the address in the **ADDRESSES** section above.

Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct, sponsor, or require through regulations. An analysis of this proposal was made by the FMCSA, and it has determined that this Notice of Final Disposition would add an element, *i.e.*, diabetes exemption program, to a currently-approved information collection (OMB Approval No. 2126–0006), titled Medical Qualifications Requirements.

The FMCSA estimates that approximately 700 applications for exemption could be filed annually, and that it would take an average of 90 minutes to complete an application. The addition of the diabetes exemption program to this existing information collection would increase the annual burden by 1,050 hours (700 × 90 minutes / 60 minutes).

Interested parties are invited to send comments regarding any aspect of this information collection requirement, including, but not limited to: (1) Whether the collection of information is necessary for the performance of the functions of the FMCSA, including whether the information has practical utility, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the collected information, and (4) ways to minimize the collection burden without reducing the quality of the information collected.

You may submit comments on this *information collection burden* directly to OMB. The OMB must receive your comments by November 3, 2003. You must mail or hand deliver your comments to: Attention: Desk Officer for the Department of Transportation, Docket Library, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, 725 17th Street, NW., Washington, DC 20503.

Authority: 49 U.S.C. 322, 31136 and 31315; and 49 CFR 1.73.

Issued on: August 27, 2003.

Annette M. Sandberg,

Administrator.

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DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Environmental Impact Statement for the Bi-County Transitway Project

AGENCY: Federal Transit Administration (FTA), U.S. Department of Transportation.

ACTION: Notice of Intent To Prepare an Environmental Impact Statement (EIS).

SUMMARY: The Federal Transit Administration (FTA) and the Maryland Transit Administration (MTA) intend to prepare an Environmental Impact Statement (EIS) in accordance to the National Environmental Policy Act (NEPA) of 1969, as amended, on the proposed Bi-County Transitway Project in Montgomery and Prince George's Counties, Maryland, which are in the metropolitan area of Washington, DC. The corridor extends 14 miles from the western branch of the Metrorail Red Line in Bethesda to the New Carrollton Metrorail Station. The Bi-County Transitway will provide high-capacity transit along the corridor. As a result of rapid growth in travel and development, the Bethesda to New Carrollton study area is facing numerous transportation challenges. The growing service sector job base has increased the vitally important need for efficient transit. The transit investment will compliment and support ongoing revitalization efforts currently underway in the study area.

This project includes the alignment previously known as the Georgetown Branch Transitway/Trail (Bethesda to Silver Spring). A notice of intent to prepare an EIS for the Georgetown Branch Transitway and Trail was