DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

49 CFR Part 391

[FHWA Docket No. MC–96–2]

RIN 2125–AD73

Qualification of Drivers; Vision and Diabetes; Limited Exemptions

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule.

SUMMARY: The FHWA announces a final determination and final rule to allow those drivers currently holding valid waivers from both the vision and diabetes standards contained in the Federal Motor Carrier Safety Regulations (FMCSRs) to continue to operate in interstate commerce after March 31, 1996. This action is directed solely at those drivers who have been granted temporary waivers to participate in either the Federal vision waiver study or the Federal diabetes waiver study, who numbered 2210 and 116, respectively, as of March 1, 1996. The FHWA believes that allowing this special group of drivers to continue to drive after March 31, 1996, is consistent with the public interest and safe operation of commercial motor vehicles (CMV). This action is necessary because the waiver program will be terminated on March 31, 1996, and without this action, the drivers will no longer be qualified to operate in interstate commerce after that date. With this final rule, the FHWA allows these drivers to continue operations, subject to certain operating conditions. This action also includes a technical amendment to relocate an existing provision so that all waivers are consistent with the public interest and the safe operation of CMVs. The safety performance data collected under the vision and diabetes waiver programs were used as the basis for this determination. Historically, the FHWA has issued limited waivers and does not intend to enter into any large scale program of exemptions. A separate research effort would form the basis for any future adjustments, if warranted, to the current vision and diabetes standards.

Vision Waiver Program Background

The FHWA announced its vision waiver study in a notice of final disposition on July 16, 1992 (57 FR 31458). The intent of the program was to obtain valuable information on the relationship between visual capacity and the ability to operate a CMV safely. This vision waiver study program was initiated as part of an overall regulatory review of the medical qualification standards applicable to interstate CMV drivers. For a complete description of the waiver program, see the FHWA’s October 6, 1994, notice of determination; request for comments, at 59 FR 50887.

A. Court Decision

On August 2, 1994, the U.S. Court of Appeals for the D.C. Circuit found that the agency’s determination that the waiver program will not adversely affect the safe operation of CMVs lacked empirical support in the record and accordingly, the court found that the FHWA failed to meet the exacting statutory test as construed by the court. Consequently, the court concluded that the FHWA’s adoption of the waiver program was contrary to law, and vacated and remanded the rule to the agency.

B. Proceedings After the Court Decision

On November 17, 1994, the FHWA announced its vision waiver study in a notice of final disposition on July 16, 1992 (57 FR 31458). The intent of the program was to obtain valuable information on the relationship between visual capacity and the ability to operate a CMV safely. This vision waiver study program was initiated as part of an overall regulatory review of the medical qualification standards applicable to interstate CMV drivers. For a complete description of the waiver program, see the FHWA’s October 6, 1994, notice of determination; request for comments, at 59 FR 50887.

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The current Federal vision standard for CMV drivers requires: distant visual acuity of at least 20/40 Snellen in each eye without corrective lenses or visual acuity separately corrected to 20/40 Snellen or better with corrective lenses, distant binocular acuity of at least 20/40 Snellen in both eyes with or without corrective lenses, field of vision of at least 70 degrees in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing standard red, green, and amber. 49 CFR 391.41(b)(10).

The current Federal diabetes standard for CMV drivers requires no established medical history or clinical diagnosis of diabetes mellitus currently requiring insulin for control. 49 CFR 391.41(b)(3).
1996. Their comments addressed their safe driving records and the significant economic and emotional hardships that would likely befall them without the relief proposed in the NPRM. Other commenters in favor of the proposal include the National Private Truck Council (NPTC), the Owner-Operator Independent Drivers Association (OOIDA), the American Association of Motor Vehicle Administrators (AAMVA), the State of Utah Department of Public Safety, the U.S. Equal Employment Opportunity Commission (EEOC), the Disabilities Law Project, and the American Optometric Association (AOA). Eglis K. Bogdanovics, M.D., the International Brotherhood of Teamsters, Teamsters, Chauffeurs, Warehousemen and Helpers (Local Union No. 110), Teamsters “General” (Local Union No. 200), the International Union of Operating Engineers (IUOE) and the Institute for Public Representation of the Georgetown University Law Center.

While the majority of the commenters supported the NPRM as proposed, some supported it with slight modifications. Some of the waived drivers believed that the required medical monitoring, especially the requirement for an annual physical examination pursuant to § 391.43, instead of every 2 years as is required of other drivers, was burdensome, expensive and unnecessary. One supporter believed that the proposed level of medical monitoring was insufficient and made recommendations for additional monitoring. Other supporters of the NPRM contended that the FHWA’s proposal did not go far enough and urged the FHWA to extend its proposed grandfathering rights to other similarly qualified drivers who were not currently participating in the waiver programs and/or to amend its physical qualification standards to allow individual determination of the ability to drive, rather than blanket exclusions.

Phillips Petroleum Company supported the proposal for drivers currently holding vision waivers, but opposed it for those drivers holding diabetes waivers, stating that the insulin-using diabetic drivers pose a higher medical risk with potentially disastrous consequences. The American Trucking Associations (ATA) supported a “case-by-case review that considered the merits of individual waived drivers,” but opposed the broad issuance of waivers stating that the “analysis doesn’t justify grandfathering all waived drivers.”

Four commenters, the Advocates for Highway and Auto Safety (AHAS), the Insurance Institute for Highway Safety (IIHS), Philip A. Shelton, M.D., and Mr. Bernard Gustavsen, one of the waived drivers, opposed the NPRM. The comments of the AHAS and IIHS addressed the reliability and accuracy of the FHWA’s risk assessment, use of the General Estimate System (GES) as a comparison group, existing scientific evidence of the increased crash risk of drivers with diabetes and vision-impairments and other factors which, they contend, support their position that the FHWA should not grant grandfather rights to the drivers holding a valid Federal vision or diabetes waiver on March 31, 1996. Dr. Shelton, chairman of the Medical Advisory Board of the Department of Motor Vehicles of the State of Connecticut, believed that the FHWA’s NPRM, as proposed, was without merit and created a privileged class of drivers. Mr. Gustavsen stated that he opposed the waiver program and believed that all rules and regulations prior to the waiver should remain enforced and be carried out to the fullest degree; however, it is not clear whether Mr. Gustavsen understands that, without his waiver of the current vision standard or grandfather rights after March 31, 1996, he would not qualify to operate a CMV in interstate commerce. These comments are more fully discussed below.

Discussion of the Comments

A. In Favor

The Disabilities Law Project, a non-profit law firm representing individuals with disabilities including several waived drivers, believed that unsafe drivers have been effectively screened out of the waiver program and that the good driving performance of these remaining drivers as well as the proposed medical monitoring requirements will ensure the continued safe driving of this group of drivers. Furthermore, this firm believes that the FHWA’s proposed actions are consistent with national policy as expressed in the Rehabilitation Act of 1973 and the Americans with Disabilities Act to facilitate the employment of qualified individuals with disabilities.

The NPTC, a national association representing more than 1100 companies that utilize proprietary trucks in their business activities, believed the FHWA’s proposal will be an important step in the FHWA’s overall efforts to establish performance-based standards. It cited the drivers safe driving performance and emphasized the need to continue the medical monitoring. The NPTC believed “the conditions FHWA has put into place will effectively screen out any unsafe drivers and safeguard the operation of CMVs.”

Eglis K. Bogdanovics, M.D., a practicing endocrinologist and board member of the American Diabetes Association (Connecticut Affiliate) commented as a member of the Medical Advisory Board of the Department of Motor Vehicles of the State of Connecticut in support of the NPRM. Dr. Bogdanovics stated that he was not surprised by the safe performance of the diabetes drivers, and cited the waiver program data to support his belief that motivated insulin-treated diabetics can “scrupulously avoid hypoglycemia” and operate CMVs safely.

The AOA strongly supported the FHWA’s proposal to allow the drivers in the vision waiver program to continue operating CMVs in interstate commerce after March 31, 1996; however, they were silent on whether waived drivers in the diabetes program should be allowed to continue driving. The AOA believed that an examination by an ophthalmologist or optometrist as part of the medical requirements for operating under the proposed grandfather provision was appropriate.

The AAMVA commented in support of the NPRM, but expressed some reservations concerning the drivers in the diabetes waiver program. Specifically, AAMVA was concerned about the potential effects of hypoglycemia on CMV drivers. The American Diabetes Association, in earlier comments to FHWA docket MC-87-17, noted that mild hypoglycemia resulting in minor cognitive effects is not an immediately threatening emergency, although it should be addressed immediately by ingesting glucose. The FHWA believes that such ingestion can occur quickly and without stopping the vehicle. Therefore, it is requiring that the diabetic drivers carry a source of rapidly absorbable glucose while driving. Individuals with severe hypoglycemic reactions or hypoglycemic unawareness were excluded from participating in the program. The FHWA believes that today’s medical technology for screening individuals for severe hypoglycemia and the proposed medical monitoring requirements, including an annual examination by an endocrinologist, ensure that such individuals will be detected and removed from the pool of diabetic drivers operating under § 391.43.
a large number of independent owner-operators and professional drivers at both the Federal and State level, urged the FHWA to allow the waived drivers to continue to operate in interstate commerce, stating that the drivers "have earned the privilege... as evidenced by their safety record." The OOIDA also believed that the medical monitoring requirements were sound and that the affected drivers would not object to these requirements in order to continue driving after March 31, 1996. The IBT, IUOE, and the EEOC, like OOIDA, supported the FHWA's proposal to allow the waived drivers to operate in interstate commerce after March 31, 1996, but they also urged the FHWA to move beyond this proposed action and change the physical qualification requirements to allow individual assessments of a driver's ability to safely operate a CMV in interstate commerce. They cited the good driving performance of the waived drivers and, therefore, concluded that the drivers were not a high risk group. 

The ATA, a national trade association representing the trucking industry, commented in opposition to the broad issuance of waivers, but stated it would support a case-by-case evaluation that considered the merits of individual waived drivers. Notwithstanding the safe performance of the drivers in the waiver program, the FHWA's decision to allow this group of vision and diabetes waived drivers to operate CMVs in interstate commerce has been and continues to be based on the individual assessment of each driver's compliance with the waiver program conditions, including driving performance and medical requirements. Initially, to determine eligibility for participation in the waiver program, individual determinations were made on the basis of complete data submitted. Each driver's application was individually examined, any missing information was required to be furnished, and each driver was measured against the waiver standards to assure that all the conditions were met. Recognizing that this group of waived drivers could potentially include some subpar drivers who individually would present an unacceptable risk, the FHWA took steps to identify and remove such drivers. The FHWA's monitoring systems, which have been in effect since the inception of the programs, were later enhanced to more promptly identify subpar performers among the waived group to ensure that safety was maintained. The FHWA's periodic verification of the waived drivers' reported accidents and citations through each driver's State motor vehicle record (MVR) was increased to monthly monitoring. Additionally, medical reports from the waived drivers have been reviewed and verified. Therefore, the FHWA has determined that the 2326 drivers in the vision impaired group and an annual physical qualification examination and certification in addition to an annual eye examination for the vision impaired drivers and an annual examination by an endocrinologist for diabetic drivers as an extra precaution to ensure the continued safe operation of these drivers.

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to § 391.43 and the medical examinations by the appropriate medical specialists be sent directly to the FHWA to be included in a database of waived drivers, (2) that information concerning the driver's activities at the time of an insulin reaction (hypoglycemia) be reported, (3) FHWA notification to each driver 45 days in advance of the expiration of the current physical qualification certificate, and (4) the medical examiner to provide copies of the required certifications to the employer and driver. Although the ATA considered the monitoring conditions for operating under the proposed grandfather provisions to be the foundation for an appropriate monitoring program, the FHWA believes its proposed monitoring program, regarding medical requirements and performance, is an extra precaution that enlarges the current system of safeguards in place for all CMV drivers in the general population. All of the drivers who will be operating under this grandfather provision will be subject to State or Federal enforcement or licensing sanctions and, in most cases, to the penalty provisions of the commercial drivers' license regulations (49 CFR Part 383). Furthermore, the FMCSRs currently require the medical examiner to provide a copy of the medical certificate to the motor carrier. In addition, the FMCSRs do not preclude employing motor carriers, the first level enforcers under the regulatory scheme for the FMCSRs, from imposing additional requirements to ensure that their drivers meet the requirements under § 391.41. Many motor carriers obtain copies of the completed medical examination form to keep on file while others will require certification by a medical examiner of their choice even though the driver has a current medical examiner’s certificate. Some employers require both. The provisions in § 391.64 will not preclude motor carriers or other employers from obtaining additional information on employees who will be operating under this grandfather provision.

Furthermore, the FHWA believes that merging the medical determination process with the CDL process will provide further scrutiny of the performance of all commercial drivers. Therefore, the FHWA has determined that the monitoring conditions, as outlined in the NPRM, are more than adequate to ensure the continued safe operation of these drivers when viewed in the framework of the safeguards in place for monitoring all commercial drivers. The proposed monitoring conditions will provide safeguards for employers while not imposing an undue burden on the grandfathered drivers.

The ATA expressed concern over potential changes to the medical certificate as a result of this action and in light of additional changes that may be forthcoming as a result of the FHWA’s plans for revising the medical examination form. Although the FHWA finds it necessary to change the medical certificate to verify that a driver is qualified to operate a CMV by operation under § 391.64, the FHWA is sensitive to ATA’s concern regarding an adequate lead time for informational changes to forms and to the ATA’s economic concerns as a result of having to discard large inventories of current forms. Therefore, the FHWA will allow the current medical certificate form to be used until existing stocks are exhausted or until one year from the effective date of the change, whichever comes first, provided that medical examiners using existing forms make appropriate handwritten notations of the required information on such forms.

The ATA’s comments included a recommendation for a final report on the FHWA’s waiver programs. The FHWA will prepare a final report of its efforts in this area and will give consideration to the ATA’s suggestions for information to be addressed in the report. The report will be placed in the docket.

The ATA raised several issues concerning the risk assessment used by the FHWA to justify granting grandfather rights to the waived drivers after March 31, 1996. We believe that the ATA comments contain a misunderstanding of the data presented in the Risk Assessment Report. It stated that “in assessing the accident rate of drivers in the vision waiver program, it is reported that their rate was below that of the general commercial vehicle driver population except for the period January to June 1994.” The ATA is erroneously combining statements from two different tables. The NPRM did state that the accident rate of these drivers were below that of the general commercial vehicle driver population rate. That statement applied to Tables 1 and 2 in the Risk Assessment Report which reported the rates for cumulative periods of time from the beginning of the program. The accident rate given for January to June 1994 (Table 4) was presented in the context of data to be used for a trend analysis of independent time periods and no comparison was made for that data relative to the general driver population. The statement of the higher rate for that period was made in the context that it represented a departure from the accident trend across time. Even with this departure, the overall accident trend was not increasing and, in fact, showed a decreasing trend.

The ATA also stated that there was a failure to analyze the accident experience of the drivers in the two groups, vision and diabetes, in the same manner. It is true that the accident rates of the two groups were viewed in a different manner relative to the national rate, but this was done because the numbers of drivers in the two groups were so disparate (over 2,000 in the vision group versus slightly more than 100 in the diabetes group) that the same method of analysis could not appropriately be used for both. In the vision group, confidence intervals were used to relate that group’s accident rate to the national rate. This was done because the number of drivers was of sufficient size that the error of estimate for the accident rate would not be so large as to allow the rate to get too much above the national rate before safety concerns were raised. In the diabetes group, confidence intervals were not calculated because the small numbers in the diabetes group provide an error of estimate for their accident rate which is larger and, as a result, it was determined that the actual rate without confidence intervals would be compared to the national rate. When the diabetes group’s rate became larger than the national rate, a more detailed scrutiny of the drivers was made. If the lower level of the confidence interval for the vision group’s rate had become larger than the national rate, a similar type of scrutiny would have been done for that group. An overall approach of this type is accepted practice to protect patients in clinical trials that investigate the therapeutic use of pharmaceutical products.

The ATA and the AAMVA commented on the proposed requirement that the endocrinologist certify that the driver is free of insulin reactions (less than one documented, symptomatic hypoglycemic reaction per month). The AAMVA misinterpreted this requirement by incorrectly interpreting hypoglycemia to mean that one hypoglycemic reaction per month
would be allowed, including severe hypoglycemic reactions. This was not the FHWA's intent. The FHWA continues to believe that individuals with severe hypoglycemia and hypoglycemia unawareness should be excluded from operating CMVs. At the same time, the FHWA believes that mild hypoglycemia is not an immediately threatening emergency, although it must be addressed within a few minutes by ingesting glucose. The reference, "less than one documented, symptomatic hypoglycemic reaction per month," was intended to provide guidelines to the endocrinologist and medical examiner for evaluating the status of the driver's diabetic condition for the preceding 12 months. This reference was included because the FHWA was anticipating the question, "What is meant by free of insulin reactions?" To clarify this issue, the FHWA believes that an individual is free of insulin reactions if he or she does not have severe hypoglycemia (i.e., episodes of altered consciousness requiring the assistance of another person to regain control) or hypoglycemia unawareness (i.e., the inability to recognize the early symptoms of hypoglycemia), and has less than one documented, symptomatic hypoglycemic reaction per month. Any one episode or a series of documented, symptomatic hypoglycemia reactions should be evaluated in terms of the individual's overall diabetic condition, and whether the individual, as a result of such reactions, is likely to experience any diminution in driving ability. The FHWA believes that the more frequent medical evaluation and self-monitoring requirements for operating under § 391.64 will ensure that the drivers operating under this grandfather provision who develop severe hypoglycemia or hypoglycemia unawareness will be identified and promptly removed from the pool of drivers.

B. In Opposition

The AHAS voiced strong opposition to the FHWA proposal to grant grandfather rights to the drivers in the vision and diabetes waiver program after March 21, 1996. In addition to rearguing the position it took in the court proceedings, the AHAS criticized the proposal to grandfather these drivers asserting that the FHWA relied on a monitoring program that it characterized as lacking precision and containing inaccuracies and inconsistencies. The AHAS stated that the comparison of Table 1 and Table 2 in the FHWA Risk Assessment (October 12, 1995) shows a number of incongruities and that it is difficult to perform cross-table comparisons.

These two tables in the Assessment were not intended to be compared. As is stated in the text of the assessment (page 2), Table 1 is a compilation of data presented in the various monitoring reports developed throughout the course of the program. The rates presented in that table represent all drivers who were in the program at the time of the particular monitoring report. Table 2, on the other hand, is a re-examination of the accident data for only those drivers who are still in the program as of October 1995 (as was stated in the text). Given that this is a re-examination of those drivers in October 1995, it is possible to retrospectively restructure the dates of accident rate presentation with information available at that later date. Since the tables were not intended for comparison, given that they are based on different sets of drivers at different time periods with different retrospective perspectives, the appearance of apparent inconsistencies is not surprising. This misapplication is, unfortunately, exacerbated by some typographical errors. In Table 1, the National Accident Rate for the June 1994 comparison should be 2.40 instead of 2.422. In addition, in Table 2, the year of the national accident rate for the June 1994 comparison should be 1992 rather than 1993.

Other apparent inconsistencies identified by AHAS are explained on the basis of how data are reported to GES and to the waiver program. For example, the AHAS stated that the national accident rate used for June 1993 (the 1991 rate of 2.13) is different from that used just two months later for August 1993 (the 1992 rate of 2.40). The use of different rates is related to the availability of data from GES. The results of the GES data acquisition process for any year usually become available in late summer or early fall for the subsequent year. The 1992 GES data were not available in June 1993 but became available by August 1993. The AHAS also pointed out that, for June 1994, the smaller number of drivers in Table 2 had a larger number of accidents (293) than the number of drivers in Table 1 for that date (292). This is explained by the nature of delays in reporting. The accidents reported in June 1994 in Table 1 are for the complete reporting period prior to that date. The data reported in Table 2 is taken from complete data reported as of October 1995.

The AHAS has also observed that the drivers remaining in the program (Table 2) have persistently higher accident rates than those shown when the program had fuller participation. The fuller program data presented in the past contains drivers whose waivers were subsequently revoked for a variety of reasons, only one of which was prompted by the driver having an accident with a citation. Having an accident with a citation is a relatively rare event, and the preponderance of revocations occurs for reporting problems, such as failure to report medical evaluations, mileage, violations, and other required data. When these individuals are removed from the program, their vehicle miles traveled (VMT) are also removed from reports but, unless they also had accidents, there is no reduction in the overall number of accidents reported. Therefore, the accident rates per million VMT will naturally increase. Even with this increase, however, the accident rates of those remaining in the vision waiver group are still considerably lower than the national rate.

The AHAS has made several statements alluding to the inadequacy of the study design in the diabetes waiver program. The AHAS claimed that the inadequacies of the design undermine the ability of the FHWA to draw inferences from the results. The AHAS' understanding of the activities surrounding the diabetic waiver is inexact. The FHWA is not presently conducting a study to generalize the feasibility of issuing waivers to diabetic drivers. No inferences about a waiver program will be drawn from these results. No research study has been in place since the U.S. Court of Appeals' decision, cited above, regarding the waiver programs. Since that time, the program has focused on the monitoring of the drivers. This means that the procedures of inferential research do not apply in this circumstance. In its place, monitoring is conducted on multiple levels: in group monitoring to compare the waived drivers' accident rates to the national accident rate as a warning device, and thereafter, on a case-by-case basis if the group monitoring indicates this is necessary.

Since the FHWA changed the focus of the waiver program, the AHAS's comments concerning the study design have been resolved. For example, given that no inference is drawn, the size of the sample is irrelevant. Also, when the FHWA detects that the group accident rate in a monitoring report exceeds the national rate, it is not contrary to study methodology to use a case-by-case review, because the monitoring effort is not a study. Moving to a case review is a prudent step in the monitoring process. It is the same process as that
used in clinical trials to protect patient safety.

The AHAS stated that the conduct of case reviews is not a valid means of conducting statistical analysis. In the context explained above, this claim is clearly not relevant since the focus of the data presentation in the diabetes monitoring report was comparative and not a statistical analysis with such facets as confidence intervals.

The AHAS also stated that case-by-case evaluations are entirely subjective since they are not based on such methods as accident reconstruction. The contrast offered here is hardly valid because accident reconstruction also has subjective components and is therefore not entirely objective. In like manner, the case level analysis conducted by the FHWA is not entirely subjective. The analysis at that level seeks to determine if the reporting police officer has issued a citation indicating that the driver may be at fault. The analysis also examines the accident report to determine if there is any evidence of driving behavior that could potentially indicate a hypoglycemic event, such as crossing the median, swerving, or driving off the road. In the cases where medical attention is given to the waivered driver, reports on glucose levels are obtained. Therefore, both methods involved some analytical decision making based on evidence.

The AHAS stated that the FHWA does not review GES data to eliminate accidents in which the truck driver was at fault. It is true that the FHWA did not do this, however, the FHWA did not compare the at-fault accident rate of the diabetic group to the GES data. A comparison was made for accidents when one vehicle was towed from the scene. This rate for the diabetes group was 0.783. It was pointed out by the Insurance Institute for Highway Safety that the rate should be compared with the national rate for tow away accidents, which was estimated by the University of Michigan’s Transportation Research Institute (UMTRI) to be 0.911. In this case, the diabetes group’s rate is lower than the national rate (0.783 vs 0.911).

The AHAS stated that there is a problem in the reporting process which involves a lag-time in revealing accidents in the diabetes waiver program. The FHWA recognizes that there is a lag in reporting accidents in the monitoring report, but notes that there is no lag in examining accidents as they are reported to the FHWA. The lag in reporting in the monitoring report is due to the delay in the reporting of vehicles less than 10 tons. Since the initial focus of the monitoring report is to compare the group accident rate to the national rate, it is necessary to have complete mileage data to construct the group accident rate. The accidents that are combined with relevant mileage must be from the same period of time, and mileage data reports lag behind the accident reports. Accidents must be reported within 15 days of their occurrence. Since accidents occur at random times, it is not possible to have mileage reported concurrently with accidents. However, since the accidents are usually reported first, they are examined to determine if action should be taken relative to a particular accident.

The AHAS commented on its previous objection to the diabetes waiver program that pointed out the safety dangers inherent in a plan that relies on close monitoring. The FHWA is aware that an individual under close or tight control has a greater propensity for episodes of hypoglycemia than an individual under less rigid control. However, as the FHWA stated in an earlier notice (58 FR 40690), it is not mandating tight control for the drivers who will be operating under §391.64. As already mentioned, individuals with severe hypoglycemia or hypoglycemia unawareness were excluded from participating in the diabetes waiver study program. Such individuals will continue to be promptly identified, found unqualified, and removed from this pool of drivers by virtue of the more frequent medical evaluation and self-monitoring conditions for operating under §391.64.

The IHHS, in its comments opposing the FHWA’s NPRM, stated that “evidence continues to mount concerning the increased crash risk of drivers with diabetes.” To support this, it submitted three studies (Dionne et al., 1995; Koepsell et al. 1994; Cox et al. 1993) which are addressed below. While these studies are well-performed and their results are clearly defensible, a closer scrutiny suggests that they may not be as conclusive relative to the waiver group as IHHS implies. For example, the Dionne (1995) study seems to show that diabetic drivers of straight trucks have a 2.4 relative risk of accidents when compared to healthy drivers. Taken in isolation, this result is compelling. But viewed in the broader context of the study, it is less conclusive relative to FHWA’s waiver program. In particular, this study also examined diabetic drivers of articulated trucks, and there was no significant relative risk for that group. The authors of the study state that it is difficult to explain why diabetic drivers of straight trucks show an elevated risk while this result does not hold for articulated trucks. They speculate that the different results may be due to company owners being more rigorous in their selection of drivers for articulated trucks or that the results are due to different levels of disease severity in the two groups of diabetic drivers.

This study does not distinguish between diabetic drivers who are treated with insulin and those who are not. The authors also do not report the number of diabetic drivers in relation to truck type. In addition to not examining the interactive effects of disease severity, the potential moderating effects of other factors (e.g., age and driving behavior) are not analyzed. Thus, while the results are significant in the context of straight trucks, the overall lack of specificity strongly suggests that this outcome is preliminary and not directly applicable to the waiver group.

Koepsell et al. (1994) reported that they found more than a two-fold risk of crashes among diabetic drivers who were 65 years of age or older. This would be consistent with the degenerative nature of the disease relative to aging. However, the average age of the drivers in the diabetes waiver group is slightly over 43 with less than one percent (0.85%) 65 or older. That study, therefore, is not directly relevant for the present group of drivers.

Cox et al. (1993) reported that in a group of 25 Type I diabetics on a driving simulator, driving performance was significantly disrupted under conditions of moderate hypoglycemia. However, it seems reasonable that these study conditions, i.e. testing conducted under fasting conditions and IV insertions in the arms of individuals being tested, would in and of themselves, affect overall performance. The limited relevance of these study findings to the drivers in the FHWA waiver programs is best represented by the Cox Study conclusion itself: “Because we used a simulator, it is not clear to what extent these data can be extrapolated to an individual’s actual driving performance.”

Regarding the crash risk of drivers with vision impairments, the IHHS cited the Rogers and Janke study of California heavy vehicle operators with vision impairments. This was a 1987 study conducted at the request of the FHWA. While the study findings for this visually impaired group showed that both their accident and conviction rates, adjusted for age, were significantly and substantially higher than those for visually non-impaired drivers, the authors concluded that the “evidence does not strongly suggest a need for compendious in substantiating the federal standard, given the lack of good data on
possible exposure differences.” Although not cited by the IIHS, McKnight et al. (1985) concluded in their study of monocular and binocular truck drivers that an individual’s style of driving was a more predictive measure of accident involvement than was visual status. They found that monocular drivers showed deficiencies on a number of clinical visual measures, but no differences were found between monocular and binocular drivers in tasks of actual driving performance (i.e., information interpretation, hazard detection, visual search, lane keeping, clearance judgment, and gap judgment).

The IIHS claimed that there are a number of fallacies in the reasoning that lead to the FHWA proposal. As a first fallacy, it claimed that the FHWA’s reasoning is based on a relatively clean individual driving record predicting future low crash risk. The IIHS indicated that this reasoning is faulty because a study of crashes in California showed that two-thirds of the crashes in one year involved drivers who had no accidents in the preceding three years. Although this is a cogent result for individual drivers, it is not reflective of the analysis conducted by the FHWA in making the determination to grandfather this group of drivers. The FHWA has determined that the current group, and only this group of drivers, as a group, does not present an increased risk on the road. That is, individuals may have unpredictable variability in accident behavior across time but groups are not necessarily that labile. Groups can have stable behavior across time but groups are not necessarily predictable.

The FHWA believes that stable behavior gives a group the best focus for this validity. Groups can have this as the chief potential weakness with their results (U.S. General Accounting Office, “Cross Design Synthesis; A New Strategy for Medical Effectiveness Research,” March 1992, GAO/PEMD–92–18). It is believed that external validity is of primary concern in the decision to allow this group of drivers to continue in their professions and, as a result, GES is the best focus for this validity.

Another fallacy alleged by the IIHS involves the FHWA’s statement that most waivered drivers are not at fault in their crash involvement. It stated that the problem concerns the subjective nature of fault determination. The IIHS is correct in this finding and in its claim that a waivered driver, while not at fault, may lack the opportunity to react quickly. However, the IIHS’ claim is not germane here, given the behavior of the vision waiver group. Their accident rate, even with the foregoing possibility, is still lower than the national rate.

The IIHS is correct in its assertion that the FHWA has improperly characterized the GES data. The FHWA was incorrect to state that accidents are not included in GES unless one vehicle was towed from the accident scene. The diabetes waiver group accident rate of .783 under towed vehicle condition should not have been compared to the national rate of 2.39. The IIHS was correct in stating that the 0.783 rate should have been compared to the more appropriate rate (towaway crashes) calculated by UMTRI which was 0.911. However, 0.783 is still smaller than 0.911 and the rate ratio involving these two (.783/.911=0.859) is less than one. For this particular group of drivers, this piece of evidence suggests they are certainly not less safe than the average CMV driver.

The IIHS stated that a limitation of the program was the methods used to determine crash involvement by traffic violation citations. The IIHS stated that self-reporting of crashes and violations is problematic and the primary source of verification, motor vehicle records, is less than complete. It is true that self-reporting can be problematic and requires some form of verification. At present, the FHWA verifies the waivered drivers’ accident and violation reports in three ways. In some cases, the FHWA is able to obtain driver histories by querying the Commercial Driver License Information System (CDLIS). The CDLIS is a component of the national CDL program which has as one of its procedures the requirement that States communicate the relevant accident and violation information for out-of-State drivers to the State of their license.

The IIHS’ comments that jurisdictions “are not forwarding all the convictions to the primary licensing” jurisdiction is an acknowledged traffic record problem. However, for CDL drivers this is now an issue subject to State compliance requirements. It is being addressed as part of the overall effectiveness of the CDL program. There are a number of efforts underway addressing the issue of convicting jurisdiction reporting to the licensing jurisdiction, including efforts among various police organizations and courts regarding the requirements of the CDL
The FHWA has documented the safe driving performance over a six-year period for the vision waived drivers and over a five-year period for diabetes waived drivers and determined that this group of waived drivers will be allowed to continue driving in interstate commerce after March 31, 1996, based on continuous and sustained safe performance as a group. The underlying basis for this action is the performance data gathered to date and risk analysis performed on this data that show that the continued operation of both waived groups of drivers, who total 2326 as of March 1, 1996, will be consistent with the public interest and safe operation of CMVs. Prior to being admitted into the study, the waiver applicants had to demonstrate a three-year period of safe driving performance (i.e., no chargeable accidents and no more than one serious traffic violation). Since the program began, the data have shown that the driving performance of this group of waived drivers is better than the driving performance of all CMV drivers collectively, based on data obtained from the General Estimates Service (GES). Moreover, each driver in the vision and diabetes waiver programs has been closely monitored, in many cases for three years or more, and the poorest performers have been eliminated. Coupled with their 3-year good driving record preceding the waivers, the continued good driving during the waiver program has earned these drivers individually partial exemption from §§ 391.41(b)(10) and 391.41(b)(3), respectively.

In addition, the FHWA believes that the continued employment of individuals with demonstrated safe driving records is in the public interest by allowing these individuals to gain employment in occupations of their choice, by promoting economic viability and furthering national policy and legislative goals articulated in both the Rehabilitation Act of 1973 and the Americans with Disabilities Act of 1992.

Therefore, the FHWA hereby amends 49 CFR part 391 to grant grandfather rights to all drivers holding a valid Federal vision or diabetes waiver on March 31, 1996. Under the grandfather provision, the FHWA will allow only those drivers who have been granted temporary waivers to participate in the Federal vision and diabetes waiver programs, numbering 2326 as of March 1, 1996, to continue to operate in interstate commerce beyond March 31, 1996, subject to certain operating conditions. This action will provide relief to these drivers who, notwithstanding the demonstrated abilities of the group, would otherwise not be permitted to operate a CMV in interstate commerce. These grandfather provisions are conditional, in order to ensure the continued safe operation of these drivers. In addition to the conditions regarding medical requirements discussed below, the FHWA will monitor the performance of these drivers through periodic checks.

Medical Requirements for Operating Under This Grandfather Provision

The FHWA recognizes that any person's medical or physical condition may deteriorate over time. Consequently, the FHWA will require a physical examination every year under § 391.43, instead of every 2 years as is required of other drivers, as an extra precaution to ensure the continued safe operation of these drivers. Under this provision, the waived drivers, like all other interstate drivers, must be otherwise physically qualified pursuant to § 391.41 of the FMCSRs.

In addition, in this final rule, the FHWA requires the grandfathered vision impaired drivers to obtain an annual vision examination by an ophthalmologist or optometrist, indicating that they have been examined within the past two months and that the driver is free of insulin reactions; (3) has the ability and capacity to properly monitor and manage his/her diabetes; (4) does not have a diabetic condition that would adversely affect his or her ability to operate a CMV. An individual is free of insulin reactions if he or she does not have severe hypoglycemia (i.e., episodes of altered consciousness requiring the assistance of another person to regain control) or hypoglycemia unawareness (i.e., the inability to recognize the early symptoms of hypoglycemia), and has less than one documented, symptomatic hypoglycemic reaction per month. These drivers will be required to carry a source of rapidly absorbable glucose and continue to monitor their blood glucose using a portable glucose monitoring device equipped with a computerized memory one hour prior to driving and approximately every four hours while driving. Upon request, the driver must submit his or her blood glucose logs to the endocrinologist and/or the medical examiner or when otherwise directed by an authorized agent of the FHWA. A copy of the endocrinologist’s report must be submitted to the medical examiner at the time of the annual physical qualification examination under part 391 of the FMCSRs.

This final rule requires this group of drivers to carry a medical certificate stating: “Medically qualified by operation of 49 CFR 391.64.” Drivers who do not provide a copy of the required information from the ophthalmologist/optometrist or the endocrinologist to the medical examiner at the time of their annual physical qualification examinations cannot be recertified to continue driving a CMV in interstate commerce under this grandfather provision.

Technical Amendment

In this final rule, the FHWA also relocates the provision in part 391 granting limited exemptions for intracity zone drivers. The current provision, required under the Motor Carrier Act of 1988 (49 U.S.C. 31136(f)), is codified as paragraph (d) of 49 CFR 391.2, General Exemptions. This action redesignates the provision, without any substantive change, as § 391.62, where it is more properly included in subpart G, Limited Exemptions. Paragraph (d)(5)(i) of 49 CFR 391.2 is also being deleted as superfluous.

Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

The FHWA has determined that this final rule is not a significant regulatory action under Executive Order 12866 or under the regulatory policies and procedures of the DOT. It is anticipated that the economic impact of this rule will be minimal because of its limited application and the small number of
affected drivers. Moreover, this action will not have any permanent effect on any existing safety standard. It will merely continue the status quo by grandfathering some 2,300 drivers who have been operating safely for substantial periods of time. Therefore, a full regulatory evaluation is not required.

The FHWA finds that this final rule is exempt from the 30-day delayed effective date requirement of U.S.C. 553(d) because it "grants or recognizes an exemption or relieves a restriction." Without this action, CMV drivers in the agency’s diabetes and vision waiver studies would no longer be qualified to operate in interstate commerce after March 31, 1996, the date on which these programs would otherwise end. This final rule enables these drivers to continue operations, subject to certain operating and monitoring conditions, granting an exemption to the vision and diabetes standards of 49 C.F.R. §391.41 that would otherwise soon apply to these drivers.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act, 5 U.S.C. 601–612, the FHWA has evaluated the effects of this final rule on small entities. The FHWA believes that this action will not have a significant economic impact on a substantial number of small entities because this action is directed solely at a limited number and narrowly defined population of CMV drivers operating in interstate commerce. This action will not cause a major increase in costs or prices and, therefore, will not have a significant effect on the Nation’s economy.

Executive Order 12612 (Federalism Assessment)

This rulemaking will amend 49 CFR part 391 pertaining to the qualification of CMV drivers. This action will allow CMV drivers who currently hold waivers from the Federal vision and diabetes requirements to continue operating in interstate commerce after March 31, 1996. This rulemaking has been analyzed in accordance with the principles and criteria contained in Executive Order 12612. Nothing in this rulemaking will directly preempt any State law or regulation. This rulemaking will not limit the policymaking discretion of the States. Therefore, the FHWA has determined that this rulemaking does not have sufficient federalism implications to warrant the preparation of a separate Federalism Assessment.

Executive Order 12372 (Intergovernmental Review)

Catalog of Federal Domestic Assistance Program Number 20.217, Motor Carrier Safety. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.

Paperwork Reduction Act


Regulation Identification Number

A regulation identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

List of Subjects in 49 CFR Part 391

Driver qualifications, Highway safety, Motor carriers, Reporting and recordkeeping requirements, Safety, Transportation.

Issued on: March 20, 1996.

Rodney E. Slater,
Federal Highway Administration.

In consideration of the foregoing, the FHWA amends title 49, CFR, subtitle B, chapter III, part 391 as set forth below:

PART 391—QUALIFICATIONS OF DRIVERS

1. The authority citation for part 391 continues to read as follows:


§391.2 [Redesignated as §391.62]

2. Part 391 is amended by redesignating §391.2 as §391.62 and revising it to read as follows:

§391.62 Limited exemptions for intra-city zone drivers.

The provisions of §§391.11(b)(1) and 391.41(b)(1) through (b)(11) do not apply to a person who:

(a) Was otherwise qualified to operate and operated a commercial motor vehicle in a municipality or exempt intracity zone thereof throughout the one-year period ending November 18, 1988;
(b) Meets all the other requirements of this section;
(c) Operates wholly within the exempt intracity zone (as defined in 49 CFR §390.5);

(d) Does not operate a vehicle used in the transportation of hazardous materials in a quantity requiring placarding under regulations issued by the Secretary under 49 U.S.C. chapter 51.; and

(e) Has a medical or physical condition which:

(1) Would have prevented such person from operating a commercial motor vehicle under the Federal Motor Carrier Safety Regulations contained in this subchapter;
(2) Existed on July 1, 1988, or at the time of the first required physical examination after that date; and

(3) The examining physician has determined this condition has not substantially worsened since July 1, 1988, or at the time of the first required physical examination after that date.

3. Section 391.64 is added to read as follows:

§391.64 Grandfathering for certain drivers participating in vision and diabetes waiver study programs.

(a) The provisions of §391.41(b)(3) do not apply to a driver who was a participant in good standing on March 31, 1996, in a waiver study program concerning the operation of commercial motor vehicles by insulin-controlled diabetic drivers; provided:

(1) The driver is physically examined every year, including an examination by a board-certified/eligible endocrinologist attesting to the fact that the driver is:

(i) Otherwise qualified under §391.41;

(ii) Free of insulin reactions (an individual is free of insulin reactions if that individual does not have severe hypoglycemia or hypoglycemia unawareness, and has less than one documented, symptomatic hypoglycemic reaction per month);

(iii) Able to and has demonstrated willingness to properly monitor and manage his/her diabetes; and

(iv) Not likely to suffer any diminution in driving ability due to his/her diabetic condition.

(2) The driver agrees to and complies with the following conditions:

(i) A source of rapidly absorbable glucose shall be carried at all times while driving;

(ii) Blood glucose levels shall be self-monitored one hour prior to driving and at least once every four hours while driving or on duty prior to driving using a portable glucose monitoring device equipped with a computerized memory;

(iii) Submit blood glucose logs to the endocrinologist or medical examiner at the annual examination or when otherwise directed by an authorized agent of the FHWA;
(iv) Provide a copy of the endocrinologist's report to the medical examiner at the time of the annual medical examination; and

(v) Provide a copy of the annual medical certification to the employer for retention in the driver's qualification file and retain a copy of the certification on his/her person while driving for presentation to a duly authorized Federal, State or local enforcement official.

(b) The provisions of §391.41(b)(10) do not apply to a driver who was a participant in good standing on March 31, 1996, in a waiver study program concerning the operation of commercial motor vehicles by drivers with visual impairment in one eye; provided:

(1) The driver is physically examined every year, including an examination by an ophthalmologist or optometrist attesting to the fact that the driver:

(i) Is otherwise qualified under §391.41; and

(ii) Continues to measure at least 20/40 (Snellen) in the better eye.

(2) The driver provides a copy of the ophthalmologist or optometrist report to the medical examiner at the time of the annual medical examination.

(3) The driver provides a copy of the annual medical certification to the employer for retention in the driver's qualification file and retains a copy of the certification on his/her person while driving for presentation to a duly authorized federal, state or local enforcement official.

3. Section 391.43 is amended by redesignating paragraphs (e), (f) and (g) as paragraphs (f), (g) and (h), respectively; by adding a new paragraph (e); by revising the text preceding the Instructions in newly designated paragraph (f) and the text preceding the Certificate in newly designated paragraph (h); and by amending the medical examiner's certificate form at the end of newly designated paragraph (h) by adding a new listing after the words "______ Qualified only when wearing a hearing aid" to read as follows:

§391.43 Medical examination; certificate of physical examination.

(e) Any driver operating under a limited exemption authorized by §391.64 shall furnish the medical examiner with a copy of the annual medical findings of the endocrinologist, ophthalmologist or optometrist, as required under that section. If the medical examiner finds the driver qualified under the limited exemption in §391.64, such fact shall be noted on the Medical Examiner's Certificate.

(f) The medical examination shall be performed, and its results shall be recorded, substantially in accordance with the following instructions and examination form. Existing forms may be used until current printed supplies are depleted or until March 31, 1997.

(h) The medical examiner's certificate shall be in accordance with the following form. Existing forms may be used until current printed supplies are depleted or until March 31, 1997, provided that the medical examiner writes down in pen and ink any applicable information contained in the following form: MEDICAL EXAMINER'S CERTIFICATE

4. In §391.45, paragraph (b)(2) is revised to read as follows:

§391.45 Persons who must be medically examined and certified.

(b) * * *

(2) Any driver authorized to operate a commercial motor vehicle only with an exempt intracity zone pursuant to §391.62, or only by operation of the exemption in §391.64, if such driver has not been medically examined and certified as qualified to drive in such zone during the preceding 12 months; and

* * * * *

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