



Docket No. FMCSA-2005-23151

## Comments of the American Diabetes Association

The American Diabetes Association (“Association”) submits these comments in response to the March 17, 2006 Advance Notice of Proposed Rulemaking by the Federal Motor Carrier Safety Administration (FMCSA) regarding its proposal to amend the medical qualifications standards contained in Part 391 of the Federal Motor Carrier Safety Regulations (FMCSRs) to allow the operation of commercial motor vehicles in interstate commerce by drivers with insulin-treated diabetes mellitus. The Association offers these comments on the thirteen areas identified by FMCSA for information and response.

### The American Diabetes Association

The Association is a nationwide, nonprofit, voluntary health organization founded in 1940. It consists of people with diabetes, health professionals who treat people with diabetes, research scientists, and other concerned individuals. With over 400,000 general members, over 17,000 health professional members and over 3 million contributors, the Association is the largest non-governmental organization that deals with the treatment and impact of diabetes. The Association establishes, reviews, and maintains the most authoritative and widely followed clinical practice recommendations, guidelines, and standards for the treatment of diabetes.<sup>1</sup> The Association also publishes the most authoritative professional journals concerning diabetes research and treatment.<sup>2</sup>

The mission of the Association is to prevent and cure diabetes and to improve the lives of all people affected by diabetes. This mission requires supporting a system that provides rigorous safety standards to protect commercial drivers with diabetes and the public, while not unduly denying people with diabetes the same rights granted to other Americans.

### Background

The Association has long advocated for FMCSA to adopt a program whereby each person with insulin-treated diabetes is afforded an individual assessment of his or her ability to be a commercial driver. Starting with the establishment of the Diabetes Exemption Program in 2003, important strides have been made to ensure that individuals with insulin-treated

---

<sup>1</sup> American Diabetes Association: Clinical Practice Recommendations 2006, *Diabetes Care* 29: Supp. 1 (2006).

<sup>2</sup> The Association publishes four professional journals with widespread circulation: (1) *Diabetes* (original scientific research about diabetes); (2) *Diabetes Care* (original human studies about diabetes treatment); (3) *Clinical Diabetes* (information about state-of-the-art care for people with diabetes); and (4) *Diabetes Spectrum* (review and original articles on clinical diabetes management).

diabetes are not unjustly barred from a career operating commercial motor vehicles. The Association supports revision to Part 391 of the FMCSRs to provide for individual assessment consistent with efforts made to date, but without the constraints of the unduly cumbersome exemption program currently in place. As discussed below, amending this regulation will go a long way toward eliminating the outdated and discriminatory blanket ban currently encompassed in the FMCSRs. The Association, however, is very concerned about FMCSA's decision to embark on an entirely new rule-making process. First, extensive effort and research went into developing the current exemption program. This process was thorough, but it was also incredibly time consuming – taking over seven years to complete the first time. Through this process a system for identifying which people with insulin-treated diabetes can safely driver commercial vehicles was established. The exemption process itself turned out to be too cumbersome to effectively provide for a nondiscriminatory means of assessment and, therefore, the process should be changed. However, the basic premise that people with insulin-treated diabetes can be safe commercial drivers following an individual assessment should not be questioned, and any new system should reflect the numerous advances in diabetes medicine and science made since the current regulatory blanket ban was adopted more than thirty-five years ago.

In addition, given the length of the prior proceeding, and the anticipated length of the current rulemaking process, it is imperative that while any rule-making process proceeds, FMCSA continues to both process applications from individuals who are applying for an exemption from current regulations through the Diabetes Exemption Program, and make improvements in the current exemption program so that those who apply can be effectively considered for exemptions.

### **Requests for Information and Comments**

FMCSA has identified for public comment thirteen areas for which it seeks input regarding possible amendment of its medical qualifications standards for drivers with insulin treated diabetes. The Association's comments will address each area in turn:

- (1) Currently, CMV drivers with ITDM must hold an exemption from the ITDM prohibition to operate in interstate commerce. What modifications to the ITDM prohibition in 49 C.F.R. 391.41 should FMCSA consider to enable such drivers to operate safely in interstate commerce without an exemption?*

The Association does not believe that every person with insulin-treated diabetes should qualify for a commercial drivers license (CDL), and supports a process for determining medical eligibility on an individual basis. Such a process should meet both safety concerns and principles of fairness and individual assessment. The Association supports amending Part 391 of the FMCSRs to eliminate the prohibition against insulin-treated individuals, and removing the decision of who may operate commercial motor vehicles (CMVs) from an exemption program to a system whereby physicians determine the medical qualification of individuals with diabetes. There are numerous problems with the current Diabetes Exemption Program that necessitate removing the eligibility determination from an exemption program, as well as many advantages to having physicians knowledgeable about diabetes make these determinations.

The Diabetes Exemption Program, as established on September 3, 2003 (68 Fed. Reg. 52441) and amended on November 8, 2005 (70 Fed. Reg. 67777), is time consuming and cumbersome.<sup>3</sup> While this should improve with the very recent addition of an application form for individuals to complete, the process is weighed down by a number of administrative issues, a lack of personnel at FMCSA to administer the exemption program, the burdensome nature of repeated requests for the same medical information and/or verification of various medical records, and requests for additional tests to be taken and submitted when FMCSA is unable to complete processing of applications in a timely manner.<sup>4</sup> The result is individuals waiting as long as eighteen months for a single exemption application to be processed. Such a system is useless to a driver who becomes unemployed when he or she cannot drive. The current system is also unduly expensive as it requires repeated medical appointments and testing. These delays and expenses could be effectively eliminated by having determinations on insulin-treated diabetes made by physicians knowledgeable about diabetes using standards established by FMCSA. The verification of examinations and tests could then be handled all in one office and at one time.

Federal transportation law and the FMCSRs currently provide that FMCSA must grant or deny an exemption request within 180 days after an exemption is requested.<sup>5</sup> In reality, however, the process takes much longer because FMCSA does not consider the period to begin until it receives a “complete” application, thus each time FMCSA requests additional information, it pushes the beginning of this 180-day period back further.<sup>6</sup> Moreover, FMCSA’s application states – contrary to the legislative requirements – that it allows for 180 days *after* it makes a preliminary decision to grant an exception.<sup>7</sup> The time it takes the

---

<sup>3</sup> Until very recently, there was no actual application form for individuals to complete, just a collection of letters from FMCSA, the physical qualifications standards in Part 391, the procedures for applying for an exemption generally in Part 381, and the September 3, 2003 Federal Register notice that applicants were forced to sort through in order to apply for a diabetes exemption. This created uncertainty about what information was needed to determine a person’s eligibility and caused many applicants to field numerous requests from FMCA to supply additional information to complete their applications.

<sup>4</sup> Even after FMCSA developed a more streamlined application and instructions, applicants continue to field requests to provide more information or to clarify information already provided. In some instances, the information sought had already been submitted by the applicant or his/her physician in the original application. In other instances, the information sought was not necessary to determine the individual’s suitability to hold an exemption (e.g., information about the applicant’s employer).

<sup>5</sup> See 49 U.S.C. § 31315(b)(5) (stating that applicants for exemptions are to be dealt with promptly, and emphasizing that “The Secretary shall grant or deny an exemption request after a thorough review of its safety implications, but in no case later than 180 days after the filing date of such request.”).

<sup>6</sup> See Qualification of Drivers; Exemption Applications; Diabetes, 68 Fed. Reg. 52441, 52443 (Sept. 3, 2003) (stating “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.”). FMCSA “recognizes that this potential six-month waiting period may seem burdensome” *Id.* at 52443.

<sup>7</sup> The application states: “It may take up to 180 days from the date a preliminary decision is made to grant an exemption until the exemption is granted. This time is required for evaluation of the completed application and to complete the *Federal Register* notice process” and that applicants should “note that additional medical information may be required depending on any medical conditions outlined in the application. Once the

agency to review each exemption request is time the applicant with diabetes spends in limbo waiting to learn his or her fate, and often losing his or her job. The Association discussed the economic hardship that grows from the long wait in its 2005 comments concerning the first four individuals identified to receive diabetes exemptions.<sup>8</sup> For the majority of applicants with diabetes, FMCSA's decision determines whether they can return to a driving career, as well as whether they will be able to retain the very health insurance coverage that helps them manage their diabetes. FMCSA has acknowledged this problem. In its March 16, 2006 press release announcing this advanced notice of proposed rulemaking, FMCSA stated that, "this can be a lengthy process because prior to granting an exemption the Agency is required to examine each applicant's medical circumstances and publish their names in the Federal Register for public comments."<sup>9</sup>

These delays are occurring despite the fact that FMCSA is not even following all of the statutory provisions for notice in the current exemption program. Section 31315 of title 49 of the United States Code on Transportation requires that FMCSA publish a notice of each exemption request in the Federal Register: "Upon receipt of an exemption request, the Secretary shall publish in the Federal Register a notice explaining the request that has been filed and shall give the public an opportunity to inspect the safety analysis and any other relevant information known to the Secretary and to comment on the request."<sup>10</sup> The agency has failed to meet this statutory requirement. Instead, FMCSA has published a notice only for those individuals who have been granted preliminary approval.<sup>11</sup> FMCSA states that because they "established eligibility criteria for use in determining whether the granting of a diabetes exemption would achieve the requisite level of safety, the Agency only publishes for public comment, the names of exemption applications that satisfy the eligibility requirements, based upon the information provided by the applicant . . . the Agency

---

application is complete, Federal Motor Carrier Safety Administration (FMCSA) will determine if the eligibility criteria have been met." "Exemption Application, Diabetes Standard" available at: <http://www.fmcsa.dot.gov/documents/safetyprograms/Diabetes/diabetes-exemption-package.pdf> (last visited April 28, 2006).

<sup>8</sup> See Comments of the American Diabetes Association, Docket No. FMCSA-2005-20721 (June 6, 2005) (stating that "failure to move expeditiously on applicants, the continued existence of the three-year rule, and the other unnecessary roadblocks discussed in this comment will continue to have a real impact on families across our country. As a result, unless changes are made, the Diabetes Exemption Program will be meaningless to most people with insulin-treated diabetes.").

<sup>9</sup> Press Release, Federal Motor Carrier Safety Administration, Advance Notice of Proposed Rulemaking (ANPRM) Concerning Truck and Bus Drivers with Insulin-Treated Diabetes Mellitus (Mar. 16, 2006) (on file with author).

<sup>10</sup> 49 U.S.C. § 31315(b)(4)(A).

<sup>11</sup> See, e.g., Qualification of Drivers; Exemption Applications; Diabetes, 70 Fed. Reg. 60875 (Oct. 19, 2005), Qualification of Drivers; Exemption Applications; Diabetes, 70 Fed. Reg. 75236 (Dec. 19, 2005), and Qualification of Drivers; Exemption Application from Thomas Deke; Diabetes, 71 Fed. Reg. 17558 (Apr. 6, 2006). The Association previously identified the problem with FMCSA's notice and comment efforts regarding the requirement to publish a notice in the Federal Register for each exemption requested, and providing the public an opportunity to inspect the relevant information and comment on the request. See Comments of the American Diabetes Association, Docket No. FMCSA-2005-20721 (June 6, 2005) (citing to 68 Fed. Reg. 52241 and the authority to issue exemptions).

periodically publishes the names of those individuals [who do not meet the requirements] to satisfy the statutory requirement for disclosing such information to the public.”<sup>12</sup> Individuals who do not meet the requirements are notified by letter. This, however, is contrary to the explicit dictates of federal law,<sup>13</sup> the FMCSRs,<sup>14</sup> and the Federal Register notice announcing the Diabetes Exemption Program.<sup>15</sup>

In the nearly three years that the Diabetes Exemption Program has been in place, hundreds of individuals have sought an exemption, yet, as of the date of the filing of this comment, only thirteen individuals have been granted exemptions by FMCSA.<sup>16</sup> Until very recently only four individuals had received exemptions. There are several reasons for such an alarmingly low number, but the Association believes that the cumbersome procedures of the exemption program itself are a major barrier to a fair and effective system for individual assessment.

*(2) How should FMCSA ensure that health care professionals who might be applying any revised standards do so in a consistent and appropriate manner which ensures both that the physical conditions of such drivers are adequate to enable them to operate safely and that the operation of CMVs is not deleterious to their health?*

#### Ensuring that health care providers appropriately apply revised standards

---

<sup>12</sup> Notice of final disposition, Qualification of Drivers; Exemption Applications; Diabetes, 71 Fed. Reg. 17157 (April 5, 2006).

<sup>13</sup> See 49 U.S.C. § 31315(b)(4)(A). Cf. “Exemption Application, Diabetes Standard” available at: <http://www.fmcsa.dot.gov/documents/safetyprograms/Diabetes/diabetes-exemption-package.pdf> (last visited April 28, 2006) (stating “If the applicant is eligible for an exemption, a notice must be published in the *Federal Register* requesting public comment on the application” and suggesting that only those applicants the agency deems eligible after an initial review are afforded the opportunity for public notice and comment).

<sup>14</sup> See 49 C.F.R. § 381.315(a) (“The Federal Motor Carrier Safety Administration will review your application and prepare, for the Administrator’s signature, a Federal Register notice requesting public comment on your application for an exemption.”).

<sup>15</sup> See Qualification of Drivers; Exemption Applications; Diabetes, 68 Fed. Reg. 52441, 52442 (Sept. 3, 2003) (stating “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.”).

<sup>16</sup> The agency published a Federal Register notice on June 2, 2006 regarding forty-seven other individuals, who must now wait additional time for the public to comment on their applications and for FMCSA to make its final determination. (It is unclear if this group has already received preliminary approval.) See Qualification of Drivers; Exemption Applications; Diabetes, 71 Fed. Reg. 32177 (June 2, 2006). According to federal law, these forty-seven individuals should have had their names published in the Federal Register when their requests for exemptions were received several months ago – not for the first time now when the agency is ready to make a decision.

There are two broad issues that health care providers should consider in determining the ability of an insulin-treated individual to safely operate a commercial motor vehicle: whether the individual has long-term complications of diabetes severe enough to adversely affect driving, and whether the individual is prone to severe hypoglycemia. Evidence of long-term complications that may indicate an individual is not medically qualified for commercial driving include (but are not limited to) severe diabetic peripheral neuropathy with an inability to feel the position of the foot on the pedals, and diabetic retinopathy with documented visual impairment (which would disqualify the individual from CMV operation under separate vision standards). The second issue – severe hypoglycemia – is best predicted by a physician knowledgeable about diabetes looking at a number of factors included in the current exemption program, including a review of blood glucose logs and history of hypoglycemia.<sup>17</sup> Further, the current Diabetes Exemption Program requires, and the Association would expect any new system to include, a requirement that the individual “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 that the individual “has the ability

---

<sup>17</sup> The comments of the National Transportation Safety Board (NTSB) state that “drivers may not take appropriate action even when they recognize the symptoms of hypoglycemia . . . and it is the very driver who does not recognize such events who presents the greatest risk to public safety.” Comments of the National Transportation Safety Board, Docket No. FMCSA-2005-23151 (June 9, 2006). NTSB misses the mark. Both the current Diabetes Exemption Program and the physician-based system the Association proposes require an extensive individual assessment of a driver’s diabetes health and ability to safely operate a commercial motor vehicle. Not only does the exemption program disqualify individuals with hypoglycemic unawareness, but the medical screening protocols that physicians use in evaluating insulin-treated drivers require a thorough review of daily blood glucose logs. Reviewing logs allows a physician to see if the individual has experienced a low blood glucose level that he or she did not detect.

Similarly, NTSB’s reliance on two accidents involving persons with diabetes (one fatal aviation accident and one tour bus operator accident) is misplaced. Beyond the fact that neither accident was shown to have been caused by hypoglycemia or other diabetes-related complications, both instances involved individuals who had failed to divulge their diabetes to federal regulators and therefore the operators had neither been screened before being licensed nor were they operating under any medically-appropriate diabetes protocols (such as frequent blood glucose monitoring or diabetes management education).

The 2000 Report to Congress addresses the issue of identifying those individuals who are at risk for severe hypoglycemia, stating:

The medical research, however, has shown that not all ITDM individuals are at significant risk for the incapacitation caused by hypoglycemia. Thus, to develop a program that meets the safety standard required, protocols are needed to screen and identify individuals at risk for severe hypoglycemia. The research reviewed indicates that screening can be conducted by examining an ITDM individual’s medical history for evidence of hypoglycemia episodes . . . a feasible program for qualifying ITDM individuals to operate CMVs should include protocols for screening on the history of severe hypoglycemia and hypoglycemia unawareness.

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) at 63. The Association expects that this aspect of the exemption program would be transferred to a new diabetes standard and/or physician guidelines.

and has demonstrated willingness to properly monitor and manage his/her diabetes.”<sup>18</sup> Patient education is critical to any system for certifying insulin-treated commercial drivers and health care professionals applying a revised diabetes standard should be required to address both the long term complications of diabetes and the patient’s likelihood of experiencing severe hypoglycemia.

It is important to meet all legitimate safety concerns, but to do so by implementing a more effective and efficient system of qualifying insulin-treated drivers. Such a system requires the vital expertise of doctors knowledgeable about diabetes. Accordingly, FMCSA should require physicians experienced in chronic disease management of diabetes to conduct the medical examination of insulin-treated commercial drivers with regard to diabetes-specific issues (with a member of the soon-to-be-developed National Registry of Certified Medical Examiners conducting the rest of the examination, as discussed more fully below).

In order for individuals with insulin-treated diabetes to operate CMVs without an exemption, the diabetes physicians certifying insulin-treated drivers must have medically current and appropriate diabetes guidelines to follow concerning CMV operation. The Association suggests transferring many of the safety and medical screening, operating, monitoring, and accountability provisions in the current Diabetes Exemption Program to guidelines to be used by such physicians in their review. However, some of these provisions are outdated or unnecessary and should be revisited during the development of physician guidelines:

1. *Blood glucose monitors.* It is not necessary for the physician to certify the make and model of the individual’s blood glucose monitoring device, as long as the meter has a memory and the physician is able to retrieve recent glucose measurements to be used to evaluate the individual’s diabetes health.<sup>19</sup>
2. *Physician administrative requirements.* It is overly burdensome and medically unnecessary to require that the physician evaluating the applicant provide all information on letterhead or with a notarized signature.<sup>20</sup>
3. *Quarterly reports.* It is unnecessary to require quarterly reporting from the physician to FMCSA that the individual’s blood glucose levels and glycosylated hemoglobin (A1C) are in an adequate range. Rather, the physician should be

---

<sup>18</sup> Qualification of Drivers; Exemption Applications; Diabetes, 68 Fed. Reg. 52441, 52444 (Sept. 3, 2003).

<sup>19</sup> The 2003 Federal Register notice announcing the Diabetes Exemption Program states that individuals who have been issued an exemption must submit certain information from their endocrinologist, including “the make and model of the glucose monitoring device with memory.” See *id.* at 52442.

<sup>20</sup> FMCSA’s application materials state that the endocrinologist must attach a copy of his/her “office letterhead with signature, date, medical license number, and state of issue.” “Exemption Application, Diabetes Standard” available at <http://www.fmcsa.dot.gov/documents/safetyprograms/Diabetes/diabetes-exemption-package.pdf> (last visited April 28, 2006). At least one applicant was required to have his endocrinologist’s information notarized before submitting it to FMCSA. See Comments of the American Diabetes Association, Docket No. FMCSA-2005-20721 (June 6, 2005) (describing the problems experienced by one applicant to include “requiring that he provide the serial number to his blood glucose meter on his endocrinologist’s letterhead and that every page of information sent be notarized.”).

charged with determining an individual schedule for follow up visits and reporting any problems that would make the individual unable to continue to drive safely during the licensing period.

4. *Employment information.* It is not necessary to collect information about the applicant's employer (as required on the current exemption application) since, as a result of SAFETEA-LU, prior commercial driving experience is not required to be eligible for an exemption.
5. *Driving record.* The requirement that the individual's driving record contain no involvement in an accident in which the applicant contributed to the cause of the accident is unrelated to that individual's ability to operate a CMV while using insulin, unless diabetes contributed to the accident, and should be eliminated from physician guidelines except to the extent diabetes is implicated or that such incidents are considered for all drivers.
6. *Blood glucose range.* The Association is concerned that FMCSA has misapplied criteria about blood glucose range in the current exemption program. The current exemption application states that "a CMV driver should not have large fluctuations in blood glucose levels. Drivers should maintain blood glucose levels between 100 to 400 mg/dl prior to and while driving a CMV."<sup>21</sup> This operational criterion was established to ensure that individuals *who have received an exemption* would not drive if their blood glucose was too low or too high *while driving*. Instead, FMCSA has included this range in its application materials, implying that an individual must always keep his or her blood glucose within this range in order to be qualified for an exemption. There is no legitimate medical reason to automatically disqualify individuals whose blood glucose logs show some readings below 100 mg/dl or above 400 mg/dl. This criteria should be eliminated from the current application and not be included in any new diabetes standard and/or guidelines. Rather, significant fluctuations in blood glucose should be considered by the diabetes physician when evaluating whether the individual is medically qualified to operate a CMV.

#### The effect of CMV operation on the health of drivers with diabetes

The Association notes that federal transportation law requires that FMCSA prescribe regulations on commercial motor vehicle safety. At a minimum, the regulations shall ensure that "the operation of commercial motor vehicles does not have a deleterious effect on the physical condition of the operators."<sup>22</sup> There is nothing about commercial driving that makes it a dangerous or inadvisable occupation for someone with insulin-treated diabetes as long as the individual is able to maintain his or her blood glucose within a safe range while driving – and an assessment of this is already needed to determine if the individual

---

<sup>21</sup> "Exemption Application, Diabetes Standard" available at:  
<http://www.fmcsa.dot.gov/documents/safetyprograms/Diabetes/diabetes-exemption-package.pdf>  
(last visited April 28, 2006).

<sup>22</sup> 49 U.S.C. § 31136(a)(4).

poses a safety risk. Thus, no additional assessment of the impact on the health of the driver, separate from the safety assessment described above, should be included in the criteria for individual assessment.

FMCSA should not require that individuals with insulin-treated diabetes manage their diabetes in a certain way in order to receive DOT certification. FMCSA's focus should be on ensuring that the individuals operating CMVs in interstate commerce are physically qualified to do so, and not whether it is medically advisable for a person with diabetes to follow a specific diabetes management regimen or to have a higher or lower A1C level.<sup>23</sup> Rather, that is a decision that, from a medical and legal standpoint, should be made by an individual and his or her physician based on how diabetes affects that person. Simply put, one size does not – and should not – fit all.

Further, FMCSA should not apply more stringent standards to individuals with diabetes than it does to other drivers that it regulates through its FMCSRs because of the presence of a diabetes diagnosis unless such standards are necessary to insure safety. As stated in the recently enacted Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU):

Insulin-treated individuals may not be held by the Secretary to a higher standard of physical qualification in order to operate a commercial motor vehicle in interstate commerce than other individuals applying to operate, or operating, a commercial motor vehicle in interstate commerce; except to the extent that limited operating, monitoring, and medical requirements are deemed medically necessary under regulations issued by the Secretary.<sup>24</sup>

---

<sup>23</sup> In addition, contrary to the assertion in the comments submitted by the National Transportation Safety Board (Docket No. FMCSA-2005-23151-48 at 2-3), it simply is not the case that a person with insulin-treated diabetes must choose between the immediate threat of incapacitating hypoglycemia and utilizing intensive diabetes management to lessen the possibility of long-term diabetes complications. Rather, as stated by the four world-renowned endocrinologists who comprised the FMCSA's own expert medical panel, "It is our expert opinion that, in part because of the many new diabetes management tools that are available, some people can be brought very close to normal levels of blood glucose without significant risk of hypoglycemia. Certainly most people can reach a goal of <7% [A1C] without this complication." Letter from Michael Brennan, George Grunberger, Edward Horton and Christopher Saudek, members of the Expert Medical Advisory Panel, to Annette Sandberg, Administrator, Federal Motor Carrier Safety Administration (Dec. 20, 2005) (available at Docket no. FMCSA-2001-9800). The advances in diabetes management that make this possible were discussed at length in the Association's 2001 comments which are attached as Exhibit A and incorporated in these comments. As we stated in 2001:

For the commercial operator with insulin-treated diabetes, the medical options available today versus twenty-five years ago are staggering. The 1980s and 1990s witnessed an explosion of advances in diabetes self-management techniques and tools that dramatically reduced the threat of an individual's incapacitation due to hypoglycemia. Advances in blood glucose monitors, insulin, injection devices, insulin pumps, and self-management education all greatly contribute to improved diabetes self-management.

Comments of the American Diabetes Association, Docket No. FMCSA-2001-9800 (Oct. 1, 2001).

<sup>24</sup> Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users § 4129, Pub. L. No. 109-59, 119 Stat. 1144 (Aug. 10, 2005).

Thus, the rules and regulations that FMCSA applies to all drivers to ensure their health and safety, including provisions for training and hours of duty, should be applied equally to people with diabetes.

*(3) FMCSA also requests public comments on the changes made in the current exemption program for CMV drivers with ITDM that were made by the November 8, 2005 Notice.*

SAFETEA-LU required that FMCSA revise the September 2003 rule establishing the Diabetes Exemption Program by doing two things: remove the requirement that individuals with insulin-treated diabetes have experience operating a commercial vehicle while using insulin; and require a minimum period of insulin use to demonstrate control of diabetes consistent with the findings of the Expert Medical Panel convened by FMCSA in 1999-2000 to study this issue.

The language in SAFETEA-LU that eliminated the requirement of three years of prior commercial driving experience while using insulin helped bring the Diabetes Exemption Program in line with the recommendations of FMCSA's experts. The "three year rule" was unsupported in medicine or law, and prevented the vast majority of people with diabetes from even applying for an exemption. From the outset it eliminated entire populations of otherwise qualified drivers because the driving experience itself was so difficult to attain. Because only some states allowed insulin-treated individuals to drive commercially, and because there are few employment opportunities comprising solely intrastate commercial driving, it was nearly impossible for individuals to gain the requisite experience. Most importantly, requiring that an individual have three years of commercial driving experience while using insulin was unnecessary to ensure that highway safety would not be compromised by issuing an exemption. The three year rule was not based on the current medical practice of diabetes management, and in fact, ran counter to the testimony of the Expert Medical Panel convened by FMCSA to study this issue. The 2000 Report to Congress<sup>25</sup> stated that the Panel discussed the need for a period of time to adjust to insulin use before commencing commercial driving, and recommended a one or two month period for a person to adjust to insulin use before seeking to obtain a commercial driver's license. The Panel allowed for an extension of this period if the treating physician deemed it necessary. The Panel determined that this minimum period of insulin use is what is medically necessary to establish control of diabetes, and consequently, safe operation of a commercial vehicle.

On November 8, 2005, FMCSA fulfilled the mandate of SAFETEA-LU by revising the exemption program to eliminate the draconian three-year rule. However, rather than implementing SAFETEA-LU as intended by Congress, FMCSA instead added an additional requirement effective immediately – and without the opportunity for public comment – that

---

<sup>25</sup> 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) (available at Docket No. FMCSA-2001-9800).

no one could obtain an exemption unless he or she has a glycosylated hemoglobin (A1C) in the range of 7% to 10%.<sup>26</sup>

An A1C test tells a person what his or her average blood glucose (sugar) level is over the past 2-3 months. It is a useful indicator of diabetes management **when used in conjunction with other assessment tools**, such as a review of daily blood glucose logs, but cannot be used standing alone to assess an individual's ability or inability to drive safely. Individuals with an A1C at the low end (below 7%) have very well managed diabetes. These levels are often seen in people with mild diabetes or in people who take very good control of their diabetes, and do not in themselves predict hypoglycemia. High A1C indicates a relatively high blood glucose, the main symptoms of which – excess thirst and urination – do not impair driving.

In fact, FMCSA's Expert Medical Panel considered whether potential drivers should be required to have a certain A1C level, and specifically rejected this idea. In their letter to Administrator Sandberg and posted on the public docket, FMCSA's experts said that "a set A1C range doesn't best identify those people who can be the safest drivers."<sup>27</sup> The group further stated that:

The new minimum level of 7% that has been established is affirmatively harmful to individuals with diabetes. As endocrinologists, our goal is for our patients to have A1Cs below 7% in order to prevent or delay the devastating long-term complications of diabetes . . . the goal for the individual patient is an A1C as close to normal for people without diabetes (<6%) as possible, without significant hypoglycemia . . . It is our expert opinion that, in part because of the many new diabetes management tools that are available, some people can be brought very close to normal levels of blood glucose without significant risk of hypoglycemia. Certainly, most people can reach a goal of <7% without this complication. Such people would make excellent, safe commercial drivers and we can indeed identify these people using other screening criteria in the diabetes exemption program . . . We cannot over-emphasize that requiring A1C >7% goes contrary to everything we have been trying to accomplish over the last couple of decades. This is simply the wrong message for our patients and the wrong message to increase safety on our roads.<sup>28</sup>

---

<sup>26</sup> See Qualification of Drivers; Eligibility Criteria and Applications; Diabetes Exemption, 70 Fed. Reg. 67777, 67780 (Nov. 8, 2005) (stating that "FMCSA has determined that the appropriate measure of HgA1C to demonstrate stable control of diabetes while using insulin is in the range of 7% and 10%" and "FMCSA will now require submission with the application of only one HgA1C result within the range of  $\geq 7\%$  and  $\leq 10\%$  to meet the minimum period of insulin use requirements.").

<sup>27</sup> Letter from Michael Brennan, George Grunberger, Edward Horton and Christopher Saudek, members of the Expert Medical Advisory Panel, to Annette Sandberg, Administrator, Federal Motor Carrier Safety Administration (Dec. 20, 2005) (available at docket no. FMCSA-2001-9800).

<sup>28</sup> *Id.*

The Association strongly disagrees with the A1C range established by FMCSA in its November 8, 2005 notice. The Association generally recommends people with diabetes try to keep their A1C level below 7%. This is not necessary for safe driving, but in order to lessen the chances of developing the long-term complications of diabetes.<sup>29</sup> Yet, anyone who meets this goal would, per the November 8, 2005 notice, be automatically disqualified from commercial driving. FMCSA seems to claim that this range is needed to prevent incapacitating low blood glucose levels. That is not what FMCSA's own experts – or any expert in diabetes management – would say.<sup>30</sup> Rather, the over fifty safety measures in the Diabetes Exemption Program, including providing A1C data as a one of the measures considered, are more than sufficient to determine which people who use insulin are qualified to be safe commercial drivers.<sup>31</sup>

FMCSA subsequently stated in the application form for those seeking diabetes exemptions that, “applicants with A1c test levels <7% are eligible for an exemption if they have no history of severe hypoglycemic episodes.”<sup>32</sup> The agency further explained in its response to its Expert Medical Panel:

The A1C range that we referenced in our November 2005 notice of changes to the exemption program is not used as an absolute standard for determining the eligibility of applicants for diabetes exemptions. The range we referenced is for use by endocrinologists in making an individual determination whether the treating physician believes it is appropriate to recommend that the driver be granted a diabetes exemption.<sup>33</sup>

While the Association is pleased to see FMCSA acknowledge that individuals with an A1C below 7% may be qualified to operate CMVs, this statement does not go far enough. The exemption program specifically defines disqualifying severe hypoglycemic reactions – to include seizure, loss of consciousness, a reaction requiring assistance of another person, or a period of impaired cognitive function that occurred without warning – and thus it is unnecessary to have any further requirement or suggestion of what FMCSA believes is the “acceptable range.” Doing so essentially requires that an individual obtain an exemption within an exemption simply because he or she has achieved the level of blood glucose

---

<sup>29</sup> See *id.* (stating that “an A1C above 7, while not ideal for long-term health, does not mean that an individual is not a safe driver. While very high A1C readings do raise a concern, we do not support a specific upper cutoff. Rather . . . A1C results should be reviewed with daily blood glucose readings and an assessment made that takes into account the numerous other screening guidelines that are a part of the diabetes exemption program.”).

<sup>30</sup> See *id.*

<sup>31</sup> See *id.* (discussing the role of an individual's A1C and stating that “this information, taken together with the numerous other screening, operation, and monitoring procedures that we recommended (and that are a part of the diabetes exemption program), established a safe system to select drivers with insulin treated diabetes.”).

<sup>32</sup> See “Exemption Application, Diabetes Standard” available at: <http://www.fmcsa.dot.gov/documents/safetyprograms/Diabetes/diabetes-exemption-package.pdf> (last visited Apr. 28, 2006).

<sup>33</sup> Letter from Annette M. Sandberg, Administrator, Federal Motor Carrier Safety Administration, to Michael Brennan, M.D. (Mar. 24, 2006) (on file with author).

control that all diabetes health authorities recommend. FMCSA should not continue to use this medically unjustified criterion in *any* form or for *any* purpose and should revise its public documents and application materials to remove any reference to what is an acceptable A1C range. Further, no such range should be included in any revision to the physical qualification standards or implementing physician guidelines.

*(4) Should FMCSA allow medical examiners to assume responsibility for making an individual determination of the ITDM driver's ability to manage this health condition, or should the agency require the physician responsible for treating the driver's ITDM to certify the driver meets the revised diabetes standard?*

As discussed above in response to question 2, the Association believes that a physician knowledgeable in diabetes should be involved in the decision as to whether an individual with insulin-treated diabetes is medically qualified to operate a CMV. Endocrinologists and other physicians who regularly care for patients with diabetes have specialized knowledge of the disease and treatment regimens. The input of these physicians is essential to assess an individual's diabetes management and determine whether CMV operation is safe and practicable in accordance with the revised standard and accompanying diabetes guidelines.

FMCSA has indicated its plan to establish a National Registry of Certified Medical Examiners (hereafter "National Registry"), a group of medical individuals who will undergo specific training and certification on the licensing of interstate commercial drivers.<sup>34</sup> Under FMCSA's proposal, all individuals seeking DOT certification will need to be examined by a medical examiner on the agency's registry. The Association supports FMCSA's plan to improve the certification process by allowing only trained individuals to make determinations regarding fitness to drive. Individuals with diabetes should be required to undergo the same process (requiring certification by a medical examiner on the National Registry), with the exception that the diabetes patient should first be certified by a physician experienced in chronic disease management of diabetes.

*(5) Should the agency revise the medical certificate to be issued by the medical examiner to a driver with ITDM to include certification from the "treating physician" in addition to the medical examiner?*

The Association supports a two-step certification process whereby a diabetes physician certifies that the individual with insulin-treated diabetes meets the revised diabetes standard, and the National Registry medical examiner completes the certification process with regard to all other aspects not related to diabetes. Under this scenario, the individual with insulin-treated diabetes will first see a diabetes physician to receive a sign off on whether he or she meets the diabetes standard and will bring this part of the certification to

---

<sup>34</sup> See National Registry of Certified Medical Examiners, 71 Fed. Reg. 28912 (May 18, 2006) (stating "the program would be comprised, in part, of a training and testing program that would result in a public registry of certified medical examiners who are authorized to conduct medical examinations of interstate commercial motor vehicle drivers and determine their physical qualifications to operate in interstate commerce . . . . Once the program is implemented, FMCSA would accept only medical examinations conducted by medical examiners listed on the Registry. The NRCME program would require training using a standardized curriculum, a certification test, and procedures to maintain the quality of the program in accordance with national accreditation standards.").

the National Registry medical examiner. Requiring that a diabetes physician first evaluate an individual with insulin-treated diabetes ensures that only those medically qualified individuals – those who meet the revised diabetes standard – are permitted to operate commercial vehicles. This new system will guarantee that individuals with insulin-treated diabetes are individually assessed – a goal of the current Diabetes Exemption Program that has become frustrated by the burdensome administrative requirements.

*(6) Each medical examiner has discretion to set the expiration date on a driver's medical certificate so that it is valid for any period up to 24 months, based on the examiner's determination of how often a driver needs to be re-examined, such as for a specific health condition (e.g. hypertension). What should the Federal standard maximum period of medical certification be for drivers with ITDM?*

The Association feels that the standard maximum period of medical certification for drivers with insulin-treated diabetes should be equal to other drivers who do not have diabetes. Insulin-treated drivers should be able to hold a medical certificate for up to 24 months, unless their diabetes physician identifies a diabetes-specific issue or the medical examiner identifies some other specific health condition affecting commercial driving that requires more frequent consultation. This would be consistent with the current Diabetes Exemption Program, which allows individuals to be granted exemptions for a two-year period.

*(7) What changes in health condition of drivers with ITDM (e.g., hypoglycemia-induced incidents) should be reported? What changes in crash/incident data (e.g., each crash) should be reported? Who should be responsible for such reports? To whom should these reports be submitted?*

The Association believes that in addition to any reporting requirements applicable to all drivers, any case of severe hypoglycemia (as defined in the revised standards), any motor vehicle accident caused by diabetes, or any significant change in diabetes health status (e.g., incapacitating retinopathy or neuropathy) should be reported. An individual who is involved in a motor vehicle accident should make every attempt to have his or her blood glucose checked and recorded.

Under the current Diabetes Exemption Program, exemption recipients are required to report “all episodes of severe hypoglycemia, significant complications, or inability to manage diabetes” as well as to report “any involvement in an accident or any other adverse event whether or not they are related to an episode of hypoglycemia.” The onus for reporting these things falls squarely on the person granted the exemption rather than the physician, although the physician should learn of these events during the annual evaluation and may include them on reports to FMCSA. Taking the determination of driver qualification out of an exemption program would not change this reporting requirement, as both the individual and his or her physician would be required to report any disqualifying events. This should be done under the same scheme applied to other drivers who have health problems that arise during the two-year certification period.

The Association proposes requiring physician or self-reporting of any incident related to diabetes to the state licensing authority, but eliminating the need to report any involvement in an accident or other adverse event to FMCSA. As required by the FMCSRs, individuals

shall report any convictions for motor vehicle offenses other than parking violations to the state that issued the commercial driver's license, as well as to the employer, within 30 days.<sup>35</sup> Diabetes-related incidents should be reported to the state licensing authority in the same manner as other potentially disqualifying events.

(8) *A number of States offer exemption, waiver, or grandfather programs for drivers with ITDM. Other States do not allow drivers with ITDM to operate without an exception/exemption. Would States that prohibit drivers with ITDM from operating CMVs continue to do so or would States adopt rules comparable with the new Federal standard? How many drivers with ITDM are currently operating commercially in these States? If these States have any evidence as to whether ITDM drivers operating CMVs are as safe, safer, or less safe than non-insulin treated diabetic drivers or non-diabetic drivers, FMCSA would like these States to provide such evidence or identify any sources where FMCSA may obtain such evidence. Also please describe any analysis that has been done on these ITDM drivers, and any special oversight that States conduct.*

Pursuant to the Americans with Disabilities Act<sup>36</sup> and the Rehabilitation Act of 1973,<sup>37</sup> a state may no longer maintain a system of blanket exclusion of all drivers with insulin-treated diabetes mellitus. Such a system was only lawful in prior years because of the federal government's ability to in essence "trump" federal anti-disability discrimination law in instances where another federal law or regulation conflicted with the anti-discrimination proscription.<sup>38</sup> Federal provisions changed to an individual assessment system in 2003, therefore, states must either adopt FMCSA's scheme or adopt another system for individual assessment that meets the standards established by federal anti-disability discrimination law.<sup>39</sup>

---

<sup>35</sup> 49 C.F.R. § 383.31.

<sup>36</sup> 42 U.S.C. § 12101-12213.

<sup>37</sup> 29 U.S.C. § 791-794.

<sup>38</sup> See 29 C.F.R. §1630.15(e) (stating that "it may be a defense to a charge of discrimination under this part that a challenged action is required or necessitated by another Federal law or regulation, or that another Federal law or regulation prohibits an action (including the provision of a particular reasonable accommodation) that would otherwise be required by this part.").

<sup>39</sup> See, e.g., *Kapche v. City of San Antonio*, 304 F.3d 493 (5th Cir. 2002) (acknowledging that *Sutton v. United Airlines*, 527 U.S. 471 (1999) mandates individualized inquiries under the Americans with Disabilities Act and holding that "an individualized assessment of Kapche's present ability to safely perform the essential functions of an SAPD police officer is required."). The court in *Kapche* also referenced the advances in diabetes science and medicine that allowed individuals with insulin-treated diabetes to safely drive and to perform safety-sensitive jobs. The court stated, "we briefly note that Kapche presented evidence of such medical advancements as portable glucose monitors, routine hemoglobin testing, improved insulin delivery systems, and improved insulin . . . Kapche also pointed to changes in various federal employment 'protocols,' which now require persons with diabetes be considered on a case by case basis." *Id.* at 500. See also *Branham v. Snow*, 392 F.3d 896, 903 (7th Cir. 2004) (stating "the determination whether a particular person with an impairment is substantially limited must be individualized."). The *Branham* court made it clear that "an individualized inquiry into each plaintiff's condition remains the rule in cases under the Rehabilitation Act and the ADA." *Id.*

The Association's 2001 comments on the proposed diabetes exemption program (attached as Exhibit A and incorporated in these comments) emphasized the safety of state waiver programs for insulin-treated commercial drivers.<sup>40</sup> At the time we included information about the Oregon waiver program:

Oregon reported that their commercial drivers with insulin-treated diabetes are safer than commercial drivers as a whole. The preventable accident rate per million miles traveled was 0.59 for commercial drivers with insulin-treated diabetes as opposed to 0.75 for all commercial drivers.<sup>41</sup>

The Association is not aware of any problems with the states' diabetes waiver programs since our 2001 comments.

*(9) Should new and emerging therapies for treatment of diabetes mellitus be considered in reviewing and revising the current standard? If so, how? If a revised FMCSA standard for drivers with ITDM is established, how would new and emerging therapies, particularly injectable medications (e.g., incretin mimetics) and continuous subcutaneous insulin infusion therapy, affect the implementation of a new standard?*

Physician guidelines to implement the new diabetes standard should specify a short adjustment period (e.g., two weeks) during which individuals must refrain from driving after "new and emerging therapies" are initiated if there is a reasonable basis to conclude that the particular therapy could negatively impact susceptibility to hypoglycemia. A list of such therapies should be made and updated periodically, on advice of the FMCSA Diabetes Panel. The list should only include therapies that affect insulin delivery, not those involved with monitoring glucose. Continuous subcutaneous insulin infusion therapy – a.k.a. "insulin pumps" – is not a new and emerging therapy (and has been a part of modern diabetes management since long before the establishment of the Diabetes Exemption Program in 2003) and should not be treated any differently than insulin taken in any other manner (e.g., syringe, pen), as the determination of what method of insulin administration is best for an individual should be left to the individual and his or her treating physician.

*(10) What quantitative data are there on safety performance of drivers with ITDM? Do these studies link efficacy of medication and therapy with risk and incidence of crashes in commercial and non-commercial motor vehicles? If so, how?*

It is essential to keep in mind that FMCSA has already extensively studied the safety of commercial driving by individuals with insulin-treated diabetes, and found that "there was no significant difference in the accident rates for ITDM drivers and the comparisons" and that "a more direct comparison . . . shows that the ITDM group has an accident rate lower than

---

<sup>40</sup> See Comments of the American Diabetes Association, Docket No. FMCSA-2001-9800 (Oct. 1, 2001) (stating that "some states have noted that drivers with insulin-treated diabetes are sometimes safer than other commercial operators.").

<sup>41</sup> *Id.*

the national rate.”<sup>42</sup> This FMCSA study examined data from individuals who were driving commercial vehicles in interstate commerce pursuant to the grandfather provision from the prior Federal Highway Administration waiver program, as well as drivers working in intrastate commerce pursuant to state waiver programs, and concluded that “the variety of evidence in this study reveals a compelling picture. Almost without exception, all results point to the driving safety of CMV operators with ITDM.”<sup>43</sup> The 2000 Report to Congress also stated that FMCSA’s “most recent risk assessment showed that a reasonably large sample of individuals with ITDM are presently operating CMVs at a safety level not significantly different than a sample of non-diabetic drivers. Moreover . . . drivers with ITDM can operate CMVs at a level of safety that is consistent with the national norm for safety . . . it is possible to screen individuals with ITDM and have them safely operate CMVs.”<sup>44</sup>

The Association has not identified any studies that link increased efficacy of medication and therapy with risk and incidence of crashes in commercial motor vehicles, and re-emphasizes the conclusions and distinctions noted in our 2002 comments (attached as Exhibit B and incorporated in these comments).<sup>45</sup> In those comments, we noted that reliance on certain studies (particularly the original findings of the Diabetes Control and Complications Trial (DCCT), the United Kingdom Prospective Diabetes Study (UKPDS) and a study published in the American Medical Association by Clarke et al.) was misplaced and outdated. Since the data was gathered for the DCCT and UKPDS, diabetes management has progressed such that these studies cannot be relied upon to restrict commercial driving of individuals with insulin-treated diabetes. Insulin regimens have changed (to include very rapid acting insulin), blood glucose monitoring systems have improved, insulin delivery systems have advanced, and the role of patient education has improved to allow patients to better understand the warning signs of hypoglycemia and how to take action to prevent impairment that could affect driving.

Further limiting the usefulness of these studies is the fact that their subjects were drawn from the general population of people with diabetes instead of a pool of professional CMV drivers operating under strict protocols; they were often conducted in a controlled environment (in which subjects knew from the outset that they were at no personal risk for continuing to drive under artificial conditions of hypoglycemia); and they do not assess the relative risk of insulin use and commercial driving (e.g., when compared with other medical conditions and the use of even over-the-counter medications). Accordingly, such studies cannot form the basis of further restrictions on this population of commercial drivers. In fact, many of the studies, including several by Daniel Cox and his team from the University of

---

<sup>42</sup> Federal Motor Carrier Safety Administration, *A Study of the Risk Associated with the Operation of Commercial Motor Vehicles by Drivers with Insulin-Treated Diabetes Mellitus* (FMCSA-PPD-02-001) (2001).

<sup>43</sup> *Id.* at 48. This report also discussed two Canadian studies conducted on a group of 1,307 truck drivers (some with medical conditions and some without) that concluded that “drivers with diabetes did not have significantly more severe accidents than those without the condition.” *Id.* at 14.

<sup>44</sup> 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) (available at Docket No. FMCSA-2001-9800).

<sup>45</sup> Additional Comments of the American Diabetes Association, Docket No. FMCSA-2001-9800 (Feb. 4, 2002).

Virginia, themselves caution against using the results of their studies to limit or restrict commercial driving by individuals with insulin-treated diabetes.

After exhaustive study, the conclusion has been – correctly – reached that safe commercial driving and insulin-treated diabetes are not exclusive. The Association urges FMCSA not to revisit this conclusion, but rather, to refine the process of individually assessing and certifying medically qualified insulin-treated drivers by developing a system that retains the safety of the current system but that provides for a practical method to achieve individual assessment.

*(11) How many individuals with ITDM are likely to enter the motor carrier occupation if the current medical standards are changed to allow them to drive in interstate commerce?*

The Association does not have empirical data to answer this question, but believes that despite the progress made in recent years with the inception of the Diabetes Exemption Program, current regulations discourage many qualified individuals with insulin-treated diabetes from pursuing a career operating commercial motor vehicles. The Association has received inquiries from hundreds of individuals regarding commercial driving, the vast majority of whom are affected by the physical qualification rules regarding insulin-treated diabetes. As stated above, the Diabetes Exemption Program has allowed an extremely small number of individuals with insulin-treated diabetes to drive CMVs but comes with the consequence of many months waiting for a decision by FMCSA – time most drivers cannot afford to spend out of work, without pay or health insurance coverage. It is the Association’s experience, gained from speaking with many drivers facing the need to obtain an exemption because of insulin use, that a large number of qualified individuals do not even apply for exemptions because of the problems associated with, and the uncertainty that accompanies, the current burdensome process.

The number of people with diabetes is growing at an alarming rate. There are now more than 21 million people with diabetes in the United States,<sup>46</sup> the vast majority of whom have type 2 diabetes. Diabetes affects all parts of the population, including commercial drivers. FMCSA has already seen a large increase in the number of individuals applying for a diabetes exemption since passage of SAFETEA-LU last summer, numbers which have overwhelmed the agency’s resources and ability to process exemption applications in a timely manner.<sup>47</sup> Thus, unless significant additional resources are provided to FMCSA, the current exemption program does not have the means to fulfill its own requirements. Moreover, for the reasons set out in this comment, an exemption program is not the best method of assessing individuals with ITDM for safe commercial driving.

---

<sup>46</sup> See Centers for Disease Control and Prevention, National Diabetes Fact Sheet (Oct. 2005).

<sup>47</sup> See Qualification of Drivers; Eligibility Criteria and Applications; Diabetes Exemption, 70 Fed. Reg. 67777 (Nov. 8, 2005) (stating that “in the 2003 Notice, FMCSA estimated that approximately 700 applications for exemption would be filed annually . . . The number of applications actually filed has been substantially less. However, with the changes made in the exemption program by this revised Notice, the number of applications could increase substantially, and may approximate, at least initially, the level estimated in 2003.”).

- (12) *The TEA-21 Report to Congress discusses occupational and health risks and challenges for individuals with ITDM who operate CMVs. Are there additional occupational and health risks and challenges the TEA-21 Report to Congress did not discuss? Are there additional attributes of this occupation, which may make it particularly difficult for such drivers to manage their condition? Are these attributes characteristic of certain segments of the industry? Should individuals with ITDM be restricted to operating only in certain segments of the industry (e.g., driving locally or short-haul, but not long haul)?*

There is nothing specifically about commercial driving that is deleterious to the health of individuals with diabetes. There is no medical basis for restricting commercial driving to local or short-haul operation for drivers with insulin-treated diabetes. Medically qualified commercial drivers with insulin-treated diabetes are able to perform all aspects of their jobs while simultaneously managing their diabetes according to the treatment regimen developed by their physicians. As we noted in our previous comments, the science of diabetes management has advanced to such a point that individuals have flexibility in their eating and medication schedules and are not tied to one particular regimen. Commercial drivers with ITDM do not require operational restrictions in order to avoid debilitating hypoglycemia.<sup>48</sup>

- (13) *What are the potential operational stressors and physical impacts associated with CMV driving that may adversely impact a CMV operator with ITDM? Please provide references or available peer-reviewed research data.*

There are certain operational stressors and physical impacts associated with CMV driving that affect all drivers, regardless of whether the individual has diabetes. As we noted in previous comments:

An individual with insulin-treated diabetes who is otherwise qualified does not have those same operational limits [as does an individual with a vision impairment]. Under the proposed protocol, such a driver will only be behind the wheel when his or her blood glucose level is within a safe range. There is no difference between that individual's physical abilities – including how that individual perceives the road and other vehicles – and any other commercial driver. Except for the monitoring and maintenance requirements in the proposed protocol . . . the operation of a commercial vehicle for an individual with insulin-treated diabetes is no different than for anyone else.<sup>49</sup>

The Association does not feel there are any factors that justify limiting or restricting commercial vehicle operation by physically qualified individuals with insulin-treated diabetes

---

<sup>48</sup> NTSB states in their comments that there must be “strict operational limits to ensure regular meals,” an assertion that demonstrates a lack of understanding about of the science and medicine of current diabetes management. See Comments of the National Transportation Safety Board, Docket No. FMCSA-2005-23151-48 (June 9, 2006) With the advent of different types of insulin, it is no longer true that all individuals with diabetes must eat at a certain time in order to prevent hypoglycemia.

<sup>49</sup> Comments of the American Diabetes Association, Docket No. FMCSA-2001-9800 (Oct. 1, 2001).

who wish to pursue a career driving as long as they meet the revised diabetes standard and/or physician guidelines.

### **Comments on Rulemaking and Analyses and Notices**

In addition to the thirteen areas identified above for comment, FMCSA also noted that it seeks comments on two additional issues to help guide its analysis for potential proposed rulemaking:

- (1) The costs and benefits of potentially effective and reasonably feasible alternatives to the current regulations, including improving the current regulation and reasonably viable non-regulatory actions; and
- (2) Any preliminary impact assessments of these regulatory and non-regulatory alternatives on the health of CMV drivers with ITDM.

The Association stresses that changing the current process from an exemption program to a regulatory scheme that allows for individual assessment and certification of medically qualified individuals with diabetes will have a significant positive impact on the lives of individuals with diabetes, their families, employers, and the economy by adding to the pool of safe, productive, experienced drivers. Throughout these comments, the Association has noted the potential benefits of such as system from both a medical and a practical perspective, as well as the provisions of the current system that should and should not be retained in a new regulatory scheme. A far inferior alternative would be to maintain the current exemption program but with the changes proposed in this comment and with sufficient staffing at FMCSA to meet the program's own requirements for application processing. Further, the Association reiterates what we stated above in response question 2: there is nothing about commercial driving that makes it a dangerous or inadvisable occupation for someone with insulin-treated diabetes as long as the individual is able to maintain his or her blood glucose within a safe range while driving.

The American Diabetes Association appreciates the opportunity to comment on proposed changes to the system for individual assessment of potential commercial drivers with insulin-treated diabetes and would be happy to provide any additional information or assistance as reexamination of the current process continues.

Contact information: Shereen Arent  
(703) 299-5519  
[sarent@diabetes.org](mailto:sarent@diabetes.org)

# EXHIBIT A

**Comments of the American Diabetes Association  
Docket No. FMCSA-2001-9800  
October 1, 2001**

The American Diabetes Association (“Association”) submits this comment in response to the notice by the Federal Motor Carrier Safety Administration (FMCSA) of its proposal to issue exemptions from the blanket prohibition against individuals who use insulin to treat their diabetes currently contained in Part 391 of the Federal Motor Carrier Safety Regulations (FMCSRs). This regulation governs the medical qualifications for drivers of commercial motor vehicles (CMVs) in interstate commerce, and makes it impossible for anyone who controls their diabetes with insulin to obtain a commercial driver’s license (CDL) for interstate operations.

## **Introduction**

The Association began its fight against this blanket prohibition in the 1980’s by filing a petition for rulemaking to amend the driver qualification standards in Part 391. In the 1990’s, Congress recognized that this blanket prohibition may not be necessary given advances in medicine, technology, and diabetes care. In the Transportation Equity Act for the 21<sup>st</sup> Century, Congress directed the U.S. Department of Transportation (DOT) to evaluate the feasibility of replacing the blanket prohibition with a screening protocol to allow individual assessment of applicants who use insulin to control their diabetes. If DOT determined that such a screening protocol was feasible and safe, it was required to initiate a rulemaking to end the blanket prohibition. The current proposal to issue exemptions arose from the DOT’s determination that a screening protocol was feasible and safe.

The Association generally applauds FMCSA for advancing a proposal to end the current blanket ban that prevents anyone with insulin-treated diabetes from meeting the medical standards necessary to operate a commercial motor vehicle in interstate commerce and therefore obtain a CDL. This proposal and change in policy is long overdue, and will implement a methodology for individual assessment of applicants.

“Blanket bans”— such as this one – were generally created when diabetes was far less understood, and before the discovery of the many effective medical treatments and supplies available for diabetes management today. In light of these advancements, a blanket policy is not consistent with the national interest because it causes unnecessary economic disruption, is not required for highway safety, and is discriminatory.

The Association does not believe that every person with insulin-treated diabetes should automatically qualify for a CDL. Rather, the Association strongly supports replacing the blanket ban with a medically sound protocol for individual assessment that maximizes both safety and employment opportunities for people with diabetes. Such a protocol should be stringent – to ensure safety – but its requirements should be firmly based upon medical and scientific knowledge.

Accordingly, the Association supports most aspects of the proposed protocol including the very stringent assessment to determine if a person is medically qualified to drive a commercial motor vehicle, the specific requirements for monitoring and driving, and the ongoing need for intense medical monitoring. The proposed program, however, fails to achieve the goal of setting up a practicable protocol for individual assessment by unnecessarily including a requirement that applicants must have driven a commercial motor vehicle while using insulin for the three years immediately preceding an application.

In addition, the change from a blanket ban to an individual assessment should take the form of a rulemaking to change the driver qualification standards themselves, rather than through an exemption program. This is consistent with the legislative mandate by Congress on this issue. This also is warranted by the data in the FMCSA's Report to Congress on this issue,<sup>1</sup> and is necessary for consistency with our Nation's civil rights laws.

A workable protocol based on current medical science would benefit people with diabetes through increased employment opportunities and benefit industry through an increased labor supply. It would be safe, and it would be fair.

### **The American Diabetes Association**

The Association is a nationwide, nonprofit, voluntary health organization founded in 1940. It consists of people with diabetes, health professionals who treat people with diabetes, research scientists, and other concerned individuals. With over 400,000 general members, over 17,000 health professional members and over 3 million contributors, the Association is the largest non-governmental organization that deals with the treatment and impact of diabetes. The Association establishes, reviews, and maintains the most authoritative and widely followed clinical practice recommendations, guidelines, and standards for the treatment of diabetes.<sup>2</sup> The Association also publishes the most authoritative professional journals concerning diabetes research and treatment.<sup>3</sup>

The mission of the Association is to prevent and cure diabetes and to improve the lives of all people affected by diabetes. This mission requires supporting a system that provides rigorous safety standards to protect commercial drivers with diabetes and the public, while not unduly denying people with diabetes the same rights granted to other Americans.

---

<sup>1</sup> 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 21<sup>st</sup> Century (July 2000) (hereafter "Report to Congress").

<sup>2</sup> American Diabetes Association: Clinical Practice Recommendations 2001, *Diabetes Care* 24: Supp. 1 (2001).

<sup>3</sup> The Association publishes five professional journals with widespread circulation: (1) *Diabetes* (original scientific research about diabetes); (2) *Diabetes Care* (original human studies about diabetes treatment); (3) *Clinical Diabetes* (information about state-of-the-art care for people with diabetes); (4) *Diabetes Reviews* (invited reviews on selected topics for research-oriented health professionals); and (5) *Diabetes Spectrum* (review and original articles on clinical diabetes management).

## **The Disease of Diabetes**

The Association's position on the proposed rule is based on current medical knowledge and treatment of the disease of diabetes. Diabetes is an incurable disease that affects the way the body uses food. It causes glucose (sugar) levels in the blood to be too high. In type 1 diabetes, the pancreas stops making insulin. In type 2 diabetes, the body makes some insulin, but either makes too little or has trouble using the insulin, or both. Insulin allows glucose to move from the bloodstream into the cells where it becomes the source of the energy needed for all of life's activities.

People with diabetes regulate their blood glucose levels through awareness of body signals, self-administration of blood tests, and self-administration of medication and food. All people with type 1 diabetes and about half of those with type 2 diabetes must administer insulin either through injections or through wearing an insulin pump. Taking insulin in this manner can result in blood glucose levels that are too low, a condition known as hypoglycemia.

The major concern for a driver who takes insulin is that his or her blood glucose level will become so low that it impairs the ability to drive. While this complication of diabetes occurs in a small minority of people, it does not occur in the vast majority of people who take insulin. Accordingly, federal law should not automatically prohibit anyone with insulin-treated diabetes from operating a commercial motor vehicle in interstate commerce. Rather, each person with insulin-treated diabetes should be evaluated based upon a workable individual assessment that emphasizes safety.

## **Advances in Medical Care and Treatment of Diabetes Render the Blanket Ban a Relic**

For the commercial operator with insulin-treated diabetes, the medical options available today versus twenty-five years ago are staggering. The 1980s and 1990s witnessed an explosion of advances in diabetes self-management techniques and tools that dramatically reduced the threat of an individual's incapacitation due to hypoglycemia. Advances in blood glucose monitors, insulin, injection devices, insulin pumps, and self-management education all greatly contribute to improved diabetes self-management.

In the 1970s, visual strips estimated the glucose level in the urine of the patient by comparing the color of the test strip to a color chart. These strips were not only inconvenient but also inaccurate. Urine glucose levels are not comparable to blood glucose levels and usually will grossly underestimate the latter.

In the early 1980s, the invention of new visual strips allowed individuals to determine their glucose level by using a blood sample. With the introduction of blood glucose meters in the mid-1980s, people with diabetes could, for the first time, accurately and immediately test their blood glucose levels in real time. In less than a minute, a blood glucose meter can give an exact measurement in milliliters of glucose in the blood by automatically reading the test strip. A blood glucose reading allows a person with diabetes to evaluate his or her situation and take the necessary steps to maintain the desired glucose level. Because the modern blood glucose

meter can give a precise reading, it is particularly effective in reducing the likelihood of hypoglycemia.

During the last decade meter technology has raced forward. Today's meters offer a number of features that make them even more valuable tools in diabetes self-management. Today, meters are portable and can be as small as a pen or credit card weighing between one to eight ounces. Many of the meters have memories that can record values such as time and date of test results, insulin dosages, one-to four-week averages, and even diet and exercise recordings. Some meters allow the user to download values into a computer. Some meters even act as an alarm clock with multiple settings while others come equipped with a modem. While the many features available for blood glucose meters serve to enhance a person's control of diabetes, the critical element is that a person with diabetes can now know his or her exact glucose level at any minute of the day. In addition, these advances allow physicians to accurately assess their patient's level of control by looking at the actual readings a patient has obtained on his/her meter. This data makes it possible for physicians to accurately assess an individual's risk for problems that might impair his or her ability to operate a commercial motor vehicle.

Advances in insulin have also taken place in the last ten years, including the development of insulin analogs that reduce the risk of hypoglycemia. In 1996, the FDA approved new, rapid-acting insulin called Lispro. Lispro begins working very soon after it is injected; therefore, Lispro may be injected 15 minutes before a meal instead of an hour as is customary. This allows the Lispro-user to eat meals on a less rigid schedule than with other forms of insulin. In addition, Lispro is cleared from the blood after two to five hours compared to twelve or more hours with other insulins. Since it leaves the bloodstream more quickly, Lispro reduces the chances of hypoglycemia several hours after a meal.

Advances in the injection of insulin have also promoted healthier people with diabetes. People used to reuse steel needles until sharp, disposable needles became more readily available in the mid 1980's. Today, injection devices are available that look like a writing pen and carry several doses of insulin. A variety of other injection methods are available today including automatic, button and jet injectors. In addition, the rise in popularity of insulin pumps has taken out much of the human error in maintaining healthy lives. Many people prefer to use insulin pumps over multiple injections because the pumps offer a continuous system of insulin delivery. This, in turn, offers better glucose control and a more flexible lifestyle.

Outside of the supplies available to people with insulin-treated diabetes, the training available has also continued to improve. In the recent past, few insurance companies reimbursed for self-management education and training for people with diabetes. The result was that fewer people with diabetes monitored their glucose effectively and even fewer received extensive education on how to manage their disease. This has changed. Today, forty-six states and the District of Columbia require state regulated insurers to reimburse for supplies, equipment, and self-management education – covering over four million people with diabetes. The 1997 Balanced Budget Act passed by Congress included a Medicare benefit for self-management education. As a result, the number of people with diabetes who receive education is now rapidly increasing.

In summary, the many advances in diabetes supplies and self-management education in the last thirty years have contributed to a much healthier, dynamic population with diabetes. Unfortunately, because of the inclusion of the three-year rule (which will be discussed in more detail later), the proposed rule operates on the assumption that people with diabetes lack the ability to manage their disease and, consequently, to minimize the possibility of hypoglycemia. Any protocol for individual assessment would be a disservice to medical science, people with diabetes, and industry, if it did not reflect the latest advances in medical science and treatment for people with diabetes.

### **Previous Experiences Prove Drivers with Insulin-Treated Diabetes Are Safe**

Commercial drivers with insulin-treated diabetes have proven that they can operate commercial motor vehicles safely. States have achieved great success in licensing commercial drivers who have insulin-treated diabetes for operation in intrastate commerce. Moreover, DOT's waiver program for individuals with insulin-treated diabetes, which enabled applicants to qualify for operation in interstate commerce in the early to mid 1990's, also provides strong support for overturning the "blanket-ban" in Part 391.

The Association canvassed all 50 states to determine the status of intrastate commercial driving programs for insulin-treated individuals. Approximately forty states allow some people with insulin-treated diabetes to operate commercial vehicles in intrastate commerce. These states have not reported any problems with drivers with insulin-treated diabetes. Contrary to the proposed federal regulation, in most states there is absolutely no requirement that the applicant for a waiver have a set amount of commercial driving experience while using insulin in order to qualify for a waiver. Nevertheless, the programs have produced safe drivers.

In fact, some states have noted that drivers with insulin-treated diabetes are sometimes safer than other commercial operators. For example, in Kansas, the Transportation Manager for the Kansas Corporation Commission wrote, "[We] are very satisfied with the [diabetes] waiver program... We are not aware of any accidents in which our waiver drivers have been involved. We believe these waiver drivers quite possibly are more careful than the average drivers."<sup>4</sup>

Oregon reported that their commercial drivers with insulin-treated diabetes are safer than commercial drivers as a whole. The preventable accident rate per million miles traveled was 0.59 for commercial drivers with insulin-treated diabetes as opposed to 0.75 for all commercial drivers. Even more telling is the applicability of Oregon's experience to interstate driving. Distances traveled within the state can match or exceed distances traveled in interstate commercial transport. For example, road mileage sometimes exceeds 550 miles, a distance is greater than a trip from Baltimore, Maryland to Detroit, Michigan, which includes travel in five states. Many large states such as Montana, Idaho, Oregon, Wyoming, New York and Pennsylvania also license qualified drivers with insulin-treated diabetes. Given the large size of these states, many of the trips drivers make are as strenuous, if not

---

<sup>4</sup> The Secretary of Transportation in Kansas is E. Dean Carlson, the former Administrator of the FHWA during at least part of the federal diabetes waiver program.

more demanding, than some interstate trucking routes. Yet, none of these states report problems with drivers with insulin-treated diabetes.

The successful federal experience with commercial drivers with insulin-treated diabetes provides even more support for overturning the blanket-ban. In 1993, the Federal Highway Administration embarked on an effort to evaluate the safety of commercial drivers with insulin-treated diabetes. In 1996, the FHWA released the results of the waiver programs:

The data have shown that the driving performance of this group of waived drivers was and continues to be better than the driving performance of all CMV drivers collectively... (Federal Register, Monday, January 8, 1996)

At the conclusion of the program, the accident rate for drivers with diabetes in situations in which one vehicle was towed from the scene was 0.783. The national rate was 0.911. The accident rate for the group with diabetes was lower than the national rate and *none* of the accidents involving the drivers with diabetes was attributed to the driver's diabetes.

The FHWA subsequently granted grandfather rights to the drivers allowing them to continue to operate across state lines. Before the FHWA took this action, the agency received hundreds of positive comments regarding the diabetes program. A letter from the New Jersey Department of Transportation in support of grandfathering the drivers summarize the success of the program:

Our experience with these drivers is that, with high awareness of their unique circumstances, they are both especially careful as drivers and notably responsive to the requirements placed on them.

The experiences of the states demonstrates that people with insulin-treated diabetes can be safe operators of commercial vehicles, and should not unduly be denied economic opportunities.

### **A Strong, Workable Protocol Supports Safety**

The Association does not believe that people with diabetes should be automatically deemed fit for the rigors that accompany operating a commercial motor vehicle. Rather, the Association supports a stringent federal protocol that ensures that those people who drive commercial vehicles are medically fit, that they adhere to a rigorous protocol to monitor their disease while operating a commercial motor vehicle, and that they follow tough accountability measures to ensure compliance. The Association believes, with one notable exception that will be described later, that the proposed protocol is medically sound. By establishing very strict eligibility criteria, the Administration is ensuring a high-threshold for safe and serious candidates.

The Association supports the medical screening criteria in the proposed protocol to the extent that it is based on medical science. Among other criteria, the protocol would automatically disqualify any candidate who has had a recurrence of hypoglycemic reactions resulting in impaired cognitive functions or loss of consciousness, any candidate who has

not passed a full medical examination, or any candidate whose endocrinologist does not believe that individual is fit for the rigors of commercial driving.

The Association also supports the special conditions and requirements on the actual operation of a commercial motor vehicle by individuals with insulin-treated diabetes, including the requirements to test blood glucose levels frequently and only drive if levels are within a designated range. By ensuring that commercial drivers with insulin-treated diabetes follow a strict regimen to manage their disease, both their health and the public safety area served.

Similarly, the Association supports the stringent monitoring provisions that require ongoing medical evaluations including providing records of all daily glucose measurements. The Association has long believed that ongoing self-management training and education is the cornerstone of healthy living for all people with insulin-treated diabetes, and is pleased that the proposed rule includes these provisions in the protocol.

### **The Devastating Three-Year Requirement**

Unfortunately, the proposed rule would provide little practical benefit to people with diabetes because of the provision mandating that, in order even to apply for an exemption from the blanket prohibition, an applicant must have spent the previous three years operating a commercial vehicle while using insulin to treat his or her diabetes. Under the proposed rule, there are only two ways a person with insulin-treated diabetes would even be able to *be considered* for an exemption:

1. The person has hidden his or her use of insulin for three years and unlawfully operated a commercial motor vehicle for that same period of time; or
2. The person has been able to find and hold a job driving a commercial vehicle in intrastate commerce for three years by residing in one of the states that permits an individual with insulin-treated diabetes to obtain an intrastate CDL, meeting the particular qualification standards of that state, and finding an employer willing and able to provide a commercial driving position strictly limited to intrastate commerce.

Currently, about forty states allow some people with insulin-treated diabetes to drive commercial vehicles in intrastate commerce with various limitations depending upon the state. These state “waiver” programs are, however, an extremely poor mechanism for a person to meet the proposed three-year requirement. First, a significant number of states don’t have a waiver program, subsequently limiting the proposed rule’s benefit based on random geography. Second, even if an individual does live in a state with a waiver program, it is quite possible that he or she may not meet the state’s unique eligibility requirements, as there are no uniform standards and the criteria for participation varies dramatically from state to state. Some waiver programs are limited to “grandfather” provisions that automatically exclude anyone who was not licensed as of a certain date, many times as far back as the mid-1980’s. Perhaps most significantly, “intrastate commerce” – as an economic event – is a very rare commercial driving opportunity in today’s business world. Most routes take a driver through multiple states. And, even for those drivers who stay

within their home state, the goods or people being transported are usually beginning or continuing an interstate movement. Thus, even operations solely within one state almost always constitute interstate commerce and trigger the FMCSRs. Finally, were the states to follow the leadership of the federal government and adopt the federal standard with its three-year requirement, there would be no way for individuals to obtain the required commercial driving experience in a legal manner. This is a very real and critical problem, which will render the federal protocol illusory relief. The bottom line is that most people who use insulin – and who would indeed be safe commercial drivers – will never be able to meet the three-year requirement.

The Association has heard from hundreds of individuals and families affected by the blanket ban. Sadly, most of these people would not be eligible for the proposed exemption program. Consider these examples:

- A truck driver with an impeccable safety record and who has lived with diabetes for many years is forced to relinquish his or her commercial driver's license upon commencing insulin therapy.

This is often someone who has supported his or her family through truck driving for many years, and does not have other employment options. Such drivers immediately lose their livelihood and can never even hope to re-enter their profession unless they find a way to lawfully drive a commercial vehicle in intrastate commerce for three years under a state waiver program. Literally, the Nation's most highly decorated truck driver with thirty years experience and over 2 million accident free miles could be fired from his or her job. This result does not change even if that highly decorated driver demonstrates control of his or her disease and meets the medical standards set forth by the FMCSA's medical panel. Such a result is patently unfair.

Sadly, we are aware of many people with type 2 diabetes who, when forced to make this Hobson's choice, ignore the advice of their doctors and put their long range health at great risk by refusing to go on insulin therapy. This dynamic decreases rather than increases highway safety.

- A truck driver who is newly diagnosed with type 1 diabetes is forced to immediately terminate his or her employment.

Again, this would be true no matter how much experience that person has as a commercial driver.

- A person who has had well-controlled insulin-treated diabetes for many years and who wants to pursue a position in interstate trucking would likely never be eligible for a commercial driver's license

This would be true even if that person had been able to perform other physically demanding jobs without experiencing any problems. Thus, someone who has

done police work or construction while using insulin, and experienced absolutely no problems, would be barred from commercial driving.

The inclusion of a three-year requirement eliminates entire populations of otherwise eligible drivers and renders almost negligible the benefit of the proposed rule to people with insulin-treated diabetes. And, it is a requirement that is unrelated to the individual's disease, to the individual's control of diabetes, and to the individual's ability to stand on the same footing as any other applicant who is otherwise qualified to drive a commercial motor vehicle. The reality of the situation is that proposed protocol continues the blanket ban against most of the individuals who would be the safest applicants: those individuals who have lived and worked as commercial truck drivers for years with diabetes and whose treatment regime now includes insulin; and those who have lived with insulin-treated diabetes for years without experiencing the problems the protocol seeks to screen out. If the three-year rule were necessary to assure safety the fact that it excluded most people who use insulin would have to be acceptable. The simple, overriding fact is that the three-year rule is not supported by legitimate concerns for safety.<sup>5</sup>

### **Recommendations of the Expert Medical Panel Ignored**

The FMCSA's Report to Congress provides no basis for the three-year rule. Rather, the requirement runs counter to the testimony of the Expert Medical Advisory Panel convened by FMCSA to study this issue. The Report states that the Expert Medical Advisory Panel discussed the need for a period of time to adjust to insulin use before commencing commercial driving. FMCSA's experts recommended a one or two month period for a person to adjust to insulin use before seeking to obtain a CDL (one month for someone with type 2 diabetes who is converting to insulin use; two months for a person who is newly diagnosed with type 1 diabetes). This period could be extended by the treating physician, if necessary. The four highly acclaimed physicians who served as the FMCSA's Expert Medical Panel have submitted a comment on the proposed exemption program stating their objections to the proposed three-year requirement.

The Association, as the country's preeminent medical association in the area of diabetes, agrees with FMCSA's Expert Medical Panel that the proposed three-year requirement is not rooted in the modern medical practice of treating diabetes. There is simply no medical evidence to support this draconian provision, one that will make individual assessment

---

<sup>5</sup> The proposed exemption for individuals with insulin-treated diabetes should not be treated in the same manner as the current exemption for individuals with vision impairments. Even if an individual with a vision impairment is otherwise qualified under the FMCSRs, that individual has operational limitations every minute behind the wheel that might impact that person's perception of the road and other vehicles. On the other hand, an individual with insulin-treated diabetes who is otherwise qualified does not have those same operational limitations. Under the proposed protocol, such a driver will only be behind the wheel when his or her blood glucose level is within a safe range. There is no difference between that individual's physical abilities – including how that individual perceives the road and other vehicles – and any other commercial driver. Except for the monitoring and maintenance requirements in the proposed protocol, which the Association supports, the operation of a commercial motor vehicle for an individual with insulin-treated diabetes is no different than for anyone else.

meaningless for most of the people with diabetes who – according to medical science – are safe, reliable drivers.

### **Exemption Program Provides Limited Protections**

The Association is very disappointed that the proposed protocol is designed to be implemented through an exemption program. Rather, the medical qualification standards should themselves be changed to eliminate the current blanket ban and replace it with individual assessment utilizing the protocol discussed above. This approach is consistent with the legislative mandate by Congress, and consistent with current civil rights laws.

Another exemption program would be redundant. The Department of Transportation has been studying – and receiving advice from its own expert panels recommending change in this area – since the mid-1980's. The federal government and the vast majority of states have successfully experimented with allowing a limited number of drivers with insulin-treated diabetes to operate commercial vehicles.

The proposed exemption program will face a number of hurdles that a change in the regulation itself would not. Such a program risks repeating the fate of the successful but short-lived 1993 Federal Highway Administration Diabetes Waiver Program that was prematurely terminated due to legal proceedings on a different FHWA exemption program. Moreover, an exemption program may not protect qualified drivers who use insulin from discrimination by individual employers – making the program of limited use. This is particularly true in light of the Supreme Court decision in *Albertsons, Inc. v. Kirkingberg*, 527 U.S. 555 (1999) where the Court permitted an employer to ignore a waiver granted under the DOT's former vision waiver program. While there may be a number of ways to attempt to distinguish an exemption program based on the record established by FMCSA here from the vision waiver program at issue in *Kirkingberg*, nevertheless, an exemption program would spawn potentially successful court challenges. In reality, such a program would also result in much more discrimination that never reaches the point of litigation.

Blanket bans are antithetical to purpose of the Americans with Disability Act and certainly to the emphasis on individual assessment in the Supreme Court's decisions in the *Sutton* trilogy. (*Sutton v. United Airline, Inc.*, 527 U.S. 471 (1999); *Murphy v. United Parcel Service, Inc.* 527 U.S. 516 (1999); *Albertsons, Inc. v. Kirkingberg*, 527 U.S. 555 (1999)) As such, they should not continue to be the general regulatory standard when, as here, the Department of Transportation has determined that individual assessment is feasible.

Blanket bans send a message to the employers throughout the country: it is acceptable to judge a person based on the disease he or she has, rather than upon what that individual can or cannot do. In this case, the impact is widespread since – in addition to its direct impact on commercial drivers – the Department of Transportation standard is looked to as a guide by employers throughout the country. Thus, while not legally applicable to areas other than commercial driving, the Department's blanket prohibition is often adopted by employers to limit the opportunities of people with diabetes in positions ranging from mechanics, to factory workers, to sales positions requiring driving.

Because of the dramatic impact that this proposed protocol would have both on potential commercial drivers and on thousands of people in professions beyond the commercial motor vehicle industry, the Association strongly urges the Administration to change the driver qualification standards themselves. Such a change in the regulation will firmly establish that the federal government believes individual assessment is the legally correct course in evaluating people with diabetes.

### **Conclusion**

With the exception of the two essential issues noted above, the Association supports the proposed protocol. The Department of Transportation has spent a good deal of time studying this issue and developing this protocol. The Association urges the Department not to let these many good efforts be in vain by proposing a protocol that fails to allow people who are medically safe drivers to pursue careers as commercial drivers.

The Association stands ready to work with FMCSA to support a practicable and workable protocol to end discrimination against individuals with insulin-treated diabetes. Please contact the Association if any additional information or data is needed by the FMCSA or if the Association can provide its assistance in any manner.

Contact Information: Shereen Arent  
telephone: 703-299-5519  
e-mail: [sarent@diabetes.org](mailto:sarent@diabetes.org)

# EXHIBIT B

**Additional Comments of the American Diabetes Association  
Docket No. FMCSA-2001-9800  
February 4, 2002**

The American Diabetes Association (“Association”) submits these additional comments in response to the January 3, 2002 notice by the Federal Motor Carrier Safety Administration (FMCSA) to reopen the public comment period on its proposal to issue exemptions from the blanket prohibition against individuals who use insulin to treat their diabetes currently contained in Part 391 of the Federal Motor Carrier Safety Regulations. This regulation governs the medical qualifications for drivers of commercial motor vehicles (CMVs) in interstate commerce, and currently makes it impossible for anyone who controls their diabetes with insulin to obtain a commercial driver’s license (CDL) for interstate operations.

During the original comment period, which lasted from July 31, 2001, to October 1, 2001, the Association submitted extensive comments. With the comment period having been reopened on January 3, 2002, this document is intended to supplement the Association’s original comments.

## **Background**

In general, the Association applauds FMCSA for advancing a proposal to end the current blanket ban that prevents anyone with insulin-treated diabetes from obtaining a CDL. The Association does not believe that every person with insulin-treated diabetes should automatically qualify for a CDL, and supports most aspects of the proposed protocol including almost all of the very stringent assessment to determine if a person is medically qualified to drive a commercial motor vehicle, the specific requirements for monitoring and driving, and the ongoing need for intense medical monitoring. At the same time, the Association very strongly believes that the proposed program fails to achieve the goal of setting up a practicable protocol for individual assessment by unnecessarily including a requirement that applicants must have driven a commercial motor vehicle while using insulin for the three years immediately preceding an application.<sup>1</sup>

## **The Original Comment Period**

The original comment period closed on October 1, 2001. The Association was pleased to see overwhelming and broad support for eliminating the blanket prohibition, as well as significant opposition to the three-year rule. The diversity of the respondents expressing

---

<sup>1</sup> The Association’s opposition to the three-year requirement encompasses the requirement that an applicant possess “a valid intrastate CDL or a license (non-CDL) to operate a CMV” in order to qualify for this exemption program, found in the Applicant Information supporting documentation section (1), as well the requirement in section (2) regarding actual operation of a commercial motor vehicle – as the former requirement is merely a subset of the latter. Together these requirements prevent the vast majority of applicants who would be safe drivers from being qualified for this exemption program. Both provisions should be eliminated.

their support for eliminating the blanket ban is quite notable. Submissions in support of an individual assessment and/or expressing concern with the proposed three-year requirement came from private citizens, industry associations, unions, Members of Congress, state Department of Motor Vehicles administrators, and government agencies including the Department of Justice and the Equal Employment Opportunity Commission.

By the Association's analysis, to date the Department of Transportation (DOT) received comments from nearly 300 individuals or organizations. Among this group of comments, only 10 (about 3%) expressed opposition to the rule. Significantly, nearly two-thirds of the comments (195) expressed opposition to the proposed three-year rule. Based on the comments received to date, it is clear that the general public supports an individual assessment of people with insulin-treated diabetes who wish to obtain a CDL to operate in interstate commerce.

### **The Expert Medical Panel Letter**

It has been the Association's contention that the three-year rule is not based on the current medical practice of diabetes management. Therefore, it is important to note the inclusion of a letter that was submitted to the public docket by the four physicians who were selected by the Department of Transportation to serve on the Medical Advisory Panel as part of the agency's 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 21<sup>st</sup> Century (July 2000) (hereafter, "Report to Congress"). In their comment, the physicians who served on the agency's own Medical Advisory Panel outlined their objections to the three-year rule, noting that the "three year requirement is simply unsupported by the science of diabetes management and control." The physicians wrote:

As members of the Expert Medical Panel, we specifically discussed the minimum period of insulin use for a commercial driver before being qualified to drive. As indicated on p. 43 of the Report, we agreed that a period of one month would be sufficient for a driver with type 2 diabetes who was converting to insulin use, and a period of two months would be sufficient for a person who is newly diagnosed with type 1 diabetes.

### **Medically Unnecessary Requirement Causes Undue Economic Hardship**

The current blanket prohibition causes economic hardship by creating job loss once a commercial motor vehicle operator with diabetes commences insulin use. The Association has heard from its members about a common situation: a seasoned driver with type 2 diabetes who has established a livelihood driving a commercial vehicle in interstate commerce is advised to go on insulin by his or her physician. The driver then faces a choice: go on insulin and lose your job, or don't go on insulin.

Unfortunately, the proposed protocol would do nothing to alleviate the economic hardship created by this situation. Few such drivers will have employers that have intrastate driving opportunities available – even if the employer were willing to assign the driver to those operations for three years. Thus, the three-year rule ensures that people in this situation will face job loss.

As a result, the medically unnecessary three-year requirement will make the availability of an individual assessment meaningless. The Association believes that a better alternative exists in the recommendations of the physicians on the Expert Medical Panel: a one or two month period where an individual would adjust to insulin use. A one or two month adjustment period would be medically sound and would give those commercial operators who can pass the rest of the strict criteria in the proposed protocol the opportunity to continue to earn a livelihood. Failure to provide a reasonable, medically sound adjustment period would only unnecessarily promulgate economic hardship and disruption.

### **Opposition to the Proposed Exemption Program is Not Based on Current Medical Management of Diabetes**

The Association notes that while there was very little opposition in the public docket to the basic concept of moving from the existing blanket-ban to an individual assessment, those comments opposing individual assessment of drivers with insulin-treated diabetes are filled with inaccuracies and outdated information.

Opposition to the proposed exemption program has two facets: concerns with the studies used or not used by FMCSA, and cynical generalizations about people with diabetes. This opposition bases its opinions on fear and conjecture and ignores scientific advances and data collected by the FMCSA.

#### **DCCT, UKPDS, and Clarke Study Misapplied**

The risk attendant to allowing individuals who use insulin to drive commercial vehicles is specifically related to the risk of hypoglycemia occurring during the act of driving with a resultant motor vehicle accident. The reality is that hypoglycemia in patients with insulin-treated diabetes is rare, predictable, and preventable. Opposition to allowing individual assessment of commercial drivers who use insulin is based on limited data from two studies initiated in the early 1980's, the Diabetes Control and Complications Trial (DCCT) and United Kingdom Prospective Diabetes Study (UKPDS), and a misapplication of the Clarke et al. study from the Journal of the American Medical Association.<sup>2</sup>

---

<sup>2</sup> Clarke W, Cox D, Gonder-Frederick L, Kovatchev B: Hypoglycemia and the Decision to Drive a Motor Vehicle by Persons with Diabetes. *Journal of the American Medical Association* 282:750-54 (1999).

The DCCT and UKPDS were pivotal studies in type 1 and type 2 diabetes, respectively, examining the role of tight glycemic control. In the process of striving for intensified glucose control, both studies identified incidence and prevalence rates for hypoglycemia and risk factors for their occurrence. However, in light of the many advances in diabetes management that have occurred since the time of these studies, the data gleaned from these reports by those opposing individual assessment do not provide evidence of anticipated rates of hypoglycemia today – even for those potential drivers who strive for tight glycemic control.

Several initial observations help to put the data on hypoglycemia in these studies into the proper context. Rather than forming the final word on the risk of hypoglycemia in individuals with type 1 diabetes, the initial results of the DCCT, identifying a three-fold increase of severe hypoglycemia in the intensively treated group, were themselves used to identify risk factors that, once taken into account, resulted in a subsequent reduction of risk of severe hypoglycemia in the final results of the DCCT.<sup>3</sup> In addition, the vast majority of potential drivers who use insulin would have type 2 diabetes, as 90 percent of all people with diabetes in the United States have this form of the disease. Major episodes of hypoglycemia are far less common in this patient population. Even in those individuals intensively treated with insulin in the UKPDS, fewer than 5% of individuals experienced a single major hypoglycemic episode in a single year.

Moreover, the science of diabetes management has advanced significantly since the time of these studies, with major advances in the types of insulin available, the methods of insulin delivery, the means of self-monitoring blood glucose levels, and training available to improve self-assessment of hypoglycemia.

The DCCT and UKPDS were initiated with insulin regimens based upon the types of insulin available at the time, including animal source (beef, pork) insulins and extremely long acting Ultralente insulin, which has a notorious history of unpredictability and hypoglycemia. Newer more predictable insulin preparations – which have been shown to significantly reduce the risk of hypoglycemia – have replaced the preparations that were used at the time of these studies. Very rapid acting insulin (Insulin Lispro and Insulin Aspart) begins to work within 10 minutes of injection, as opposed to the traditional short acting regular insulin which requires injection 30 to 60 minutes prior to eating. Thus, under the prior insulin regimen, a driver would have had to stop, take insulin, continue driving while the insulin took effect, and then stop to eat. Today, a driver stops, takes insulin, eats immediately, and the insulin action is available while needed to store the ingested calories then is gone when the food has been absorbed. Insulins available at the time of these studies, on the other hand, continued to work for 4 to 6 hours after injection – long after food absorption had been completed. This

---

<sup>3</sup> Diabetes Control and Complications Trial Research Group: Epidemiology of Severe Hypoglycemia in the Diabetes Control and Complications Trial. *Am J Med* 90:450-459 (1991).

theoretical benefit has translated into clinical reductions in severe and nocturnal<sup>4</sup> hypoglycemia events in patients with diabetes. A 47% reduction in nocturnal reactions and severe hypoglycemia was noted with the use of Insulin Lispro as compared with regular human insulin in subjects with type 1 diabetes despite use in subjects with a history of severe hypoglycemia.<sup>5</sup> Comparable data were noted in subjects with type 2 diabetes new to insulin therapy who experienced a 24% reduction in prevalence of nocturnal hypoglycemia in those treated with Lispro.<sup>6</sup> Similar findings have been demonstrated with insulin Aspart in both European and American trials.<sup>7</sup>

Of particular interest, investigators found the use of Ultralente insulin (the formulation utilized in UKPDS) to be associated with an increased risk of hypoglycemia.<sup>8</sup> Not only has the availability of very rapid acting insulin reduced the risk and occurrence of hypoglycemia, but new long-acting insulin preparations have minimized hypoglycemia risk as well. In type 1 diabetes, all hypoglycemia was reduced by 43% and severe hypoglycemia by 40% with insulin Glargine as compared to intermediate-acting NPH insulin.<sup>9</sup> A fifty percent reduction in nocturnal hypoglycemia was found in patients with type 2 diabetes treated with insulin Glargine as opposed to NPH insulin.<sup>10</sup>

Thus, the UKPDS and DCCT provided important baseline information on risks and predictability of hypoglycemia in patients who choose to seek very tight control, but newer

---

<sup>4</sup> Incidence of nocturnal hypoglycemia is relevant because it tracks a long period of time in which the patient does not eat, as might be the case of a long haul driver.

<sup>5</sup> Ferguson SC, Strachan MW, Janes JM, Frier BW: Severe Hypoglycaemia in Patients with Type 1 Diabetes and Impaired Awareness of Hypoglycaemia: A Comparative Study of Insulin Lispro and Regular Human Insulin. *Diabetes Metabolism Research Review* 17(4):285-91 (July – Aug 2001).

<sup>6</sup> Bastyr EJ III, Huang Y, Brunelle RL, Vignati, L, Cox DJ, Kotsanos JG: Factors Associated with Nocturnal Hypoglycaemia Among Patients with Type 2 Diabetes New to Insulin Therapy: Experience with Insulin Lispro. *Diabetes, Obesity and Metabolism* 2:39-46 (2000).

<sup>7</sup> Raskin P, Guthrie RA, Leiter L, Riis A, Jovanovic L: Use of Insulin Aspart, a Fast-Acting Insulin Analog, as the Mealtime Insulin in the Management of Patients with Type 1 Diabetes. *Diabetes Care* 2000 23: 583-588; and Heller S, Colagiuri S, Vaaler S, Wolffenbuttel B, Koelendorf K, Friberg H, Windfeld K, Sondergaard K, Linholm A: Reduced Hypoglycemia with Insulin Aspart: A Double-Blind Randomized, Crossover Trial in Type 1 Diabetic Patients. *Diabetes* 50(Supplement 2): A137 (2001) (abstract).

<sup>8</sup> Bastyr EJ III, Huang Y, Brunelle RL, Vignati, L, Cox DJ, Kotsanos JG: Factors Associated with Nocturnal Hypoglycaemia Among Patients with Type 2 Diabetes New to Insulin Therapy: Experience with Insulin Lispro. *Diabetes, Obesity and Metabolism* 2:39-46 (2000).

<sup>9</sup> Ratner R, Hirsch E, Neifing J, Garg S, Mecca T, Wilson C: Less Hypoglycemia with Insulin Glargine in Intensive Insulin Therapy for Type 1 Diabetes. *Diabetes Care* 23:639 (2000).

<sup>10</sup> Yki-Jarvinen H, Dressler A, Zeimen M: Less Nocturnal Hypoglycemia and Better Post-Dinner Glucose Control with Bedtime Insulin Glargine Compared with Bedtime NPH Insulin During Insulin Combination Therapy in Type 2 Diabetes. *Diabetes Care* 23:1130-36 (2000).

insulin preparations have resulted in marked reductions in hypoglycemia incidence and prevalence even among this population.

In addition to the improvements in insulin, newer and far more rapid and sophisticated blood glucose monitoring systems – unavailable at the time of DCCT and UKPDS – facilitate successful patient monitoring of glucose status. New glucose monitoring systems can easily fit in a pocket, utilize miniscule quantities of blood, and provide accurate results in as short as five seconds. At the time of DCCT, blood glucose monitoring required volumes of blood more than ten times greater, took two minutes to obtain a value, and required either visual interpretation of estimated glucose or use of a bulky meter.

Newer developments in blood glucose monitoring include the approval and availability of two separate continuous glucose monitoring devices. The Minimed CGMS provides continuous glucose measurements over a three-day period of time. The Cygnus Glucowatch is worn on the wrist like a watch and provides continuous monitoring for a twelve-hour period. With these systems no interruption of daily activities is required for glucose determinations. These systems also include intrinsic alarms for hypoglycemia but, even more interestingly, will alarm for rapidly falling glucose even before hypoglycemia is reached.

Insulin delivery systems have also improved. During the last five years, technology has advanced to the point where insulin can be delivered without syringes and refrigerated insulin, as previously required. Insulin is now widely available in pens that fit in a shirt pocket, so that the patient can simply set the dosage and push the button to inject the insulin. Not only is this system more convenient, it virtually eliminates the errors that were common with the old system where the patient had to use a syringe to carefully draw out the correct dosage from the refrigerated vial. In addition, many patients are turning to pump therapy as an alternative to traditional injections of insulin. With insulin pump therapy, a device the size of a beeper continuously delivers a small amount of insulin via a small opening just under the skin of the abdomen. Pump therapy is personalized to an individual's own needs and adjusts for dietary changes.

In addition, patient education has improved allowing patients to better understand the warning signs of hypoglycemia and how to take action prior to any impairment.<sup>11</sup> Such training is an integral part of the proposed protocol.

Thus, data taking into account the important medical advances since the time when data was gathered for the DCCT and UKPDS demonstrate the fallacy of using the initial results from these studies to justify continuing a blanket prohibition of commercial drivers who use insulin. Moreover, the subjects of these studies were drawn from the general population of people with diabetes; they did not have to pass the strict assessment, driving, and medical monitoring requirements that would be imposed on commercial drivers under the proposed program.

---

<sup>11</sup> Clement S: Diabetes Self-Management Education. *Diabetes Care* 18:1204-13 (1995).

Similar problems are attendant in using the Clarke study to oppose lifting the blanket ban on commercial drivers who use insulin. Use of this study, as a gauge for whether or not there should be an exemption program for commercial operators, particularly one that has a strictly defined protocol with accountability mechanisms, is misleading at best.

Proponents of using the Clarke study to deny individual evaluation to drivers who use insulin fail to consider that:

- None of the participants in the Clarke study were given a thorough medical screening by an endocrinologist who certified that the applicant both had been educated in diabetes management and had the ability and demonstrated willingness to properly monitor and manage his or her diabetes, as would be participants in the proposed exemption program.
- None of the participants in the Clarke study had to follow a protocol to regularly monitor their blood glucose while operating a vehicle, as in the proposed exemption program.
- None of the participants in the Clarke study had to submit to long-term accountability measures, including ongoing education in diabetes management and hypoglycemia awareness, as in the proposed exemption program.
- None of the participants in the Clarke study were professional drivers, as would be every participant the proposed exemption program.

In sum, using the Clarke study to corroborate a position against the proposed exemption program is fallacious because it extrapolates a conclusion for one population (medically-screened commercial drivers with insulin-treated diabetes subject to operational guidelines and accountability measures) from the actions of a very different population (the general public with type 1 diabetes).

The argument that Clarke's driving simulator study is applicable is also specious because of the conditions under which data was obtained. Individuals enrolled in the study were quite aware that they were at no personal risk for continuing to drive under artificial conditions of hypoglycemia. None of those citing this study can demonstrate translation of this laboratory observation to real life.

In fact, the Clarke study itself cautions against the type of conclusions that were reached by those opposing individual assessment of commercial drivers with insulin-treated diabetes:

These data should not be construed to mean that individuals with type 1 diabetes should not be permitted to drive or that their privilege to drive should be restricted. Indeed, the frequency of motor vehicle crashes is not known to be higher among drivers with type 1 diabetes.

The study goes on to suggest that drivers should measure their blood glucose level and raise potentially low levels prior to driving, should always carry rapid-acting glucose with them, and should obtain diabetes management education – all integral parts of the protocol proposed by FMCSA.

### FMCSA Study Provides Key Data

While those opposing lifting the blanket ban are left to base their position on outdated or inapplicable data, the data from *A Study of the Risk Associated with the Operation of Commercial Motor Vehicles by Drivers with Insulin-Treated Diabetes Mellitus* (Federal Motor Carrier Safety Administration 2001) (hereafter, “FMCSA Study”) looked at the applicable population, current drivers with insulin-treated diabetes, doing the applicable task, commercial driving.<sup>12</sup> Using sound principals of statistical analysis the results found no statistical difference in accident rate among drivers with diabetes as compared to the general population. Assessing all available data, the FMCSA Study found “there was no significant difference in the accident rates for ITDM drivers and the comparisons.” The study goes on to note: “A more direct comparison to the [General Estimates System]<sup>13</sup> shows that the ITDM group has an accident rate lower than the national rate.”

The bottom line is clear:

The variety of evidence in this study reveals a compelling picture. Almost without exception, all results point to the driving safety of CMV operators with ITDM.

### State Experience and Other Waiver Programs Should Not Be Dismissed

Significantly, most of those who oppose ending the blanket ban in interstate commerce do not oppose allowing drivers with insulin-treated diabetes to operate in intrastate commerce. This admission follows from the fact that they are unable to cite any adverse state experiences with intrastate waiver programs for drivers with insulin-treated diabetes. Rather, those opposing an individual assessment of drivers with insulin-treated diabetes in interstate commerce are forced to argue that this positive experience in states across the country is irrelevant.

---

<sup>12</sup> The study population contained drivers who were driving commercial vehicles in interstate commerce pursuant to the grandfather provision from the prior Federal Highway Administration waiver program as well as drivers working in intrastate commerce pursuant to state waiver programs. It bears noting that because the proposed FMCSA protocol contains more rigorous screening, driving, and monitoring mechanisms than the study population, those driving pursuant to the proposed protocol would constitute an even safer group of drivers.

<sup>13</sup> The General Estimates System is operated by the National Highway Traffic Safety Administration and is a survey of police accident reports.

The Association strongly disagrees with those who dismiss the experience of intrastate operators as irrelevant to interstate commercial operations. Distances traveled within Oregon, for example, can match or exceed distances traveled in interstate commercial transport. Road mileage sometimes exceeds 500 miles, a distance which is about the same as a trip from Baltimore, Maryland to Detroit, Michigan, which includes travel in five states. Oregon reported that their commercial drivers with insulin-treated diabetes are safer than commercial drivers as a whole. The preventable accident rate per million miles traveled was 0.59 for commercial drivers with insulin-treated diabetes as opposed to 0.75 for all commercial drivers. In fact, many other large states also license qualified commercial drivers with insulin-treated diabetes, but none of these states report problems with commercial drivers with insulin-treated diabetes.<sup>14</sup>

### *Cynical Views of People with Diabetes*

The experience of the states, combined with the federal waiver programs in both commercial motor vehicles and aviation, demonstrates that fears about people with insulin-treated diabetes are rooted in misconceptions and outdated medical science. The Association has made it a priority to fight misinformation about diabetes and discriminatory views of people with diabetes, and, as such, is concerned about the cynical generalizations about people with diabetes found in several comments in the public docket.

The negative assertions regarding insulin-treated commercial drivers are wholly based on conjecture. According to these few comments, people with insulin-treated diabetes who are, or would be, commercial drivers:

- Cannot comply with the “rigors...and inherent danger of interstate driving.”
- Are unable to adjust their food and insulin intake to account for unexpected exertion.
- Lack the ability to “determine which foods are appropriate for their dietary needs, or accurate serving amounts.”
- “...will do their best to hide any [hypoglycemic] episodes.”

---

<sup>14</sup> The current system also perpetuates geographic discrimination by prohibiting drivers in many parts of the East Coast from doing even short haul driving which, because of the size of states and the proximity of major cities to nearby states, often encompasses travel through several jurisdictions. For example, a half-hour trip in the Metropolitan Washington, DC area can include travel in three jurisdictions.

- Will “choose to erase hypoglycemic blood sugar measurements if they feel their employment would be threatened by [the records from their blood glucose monitor].”<sup>15</sup>
- “...with low blood sugar would often decide to drive anyway because of job demands.”
- Would actually attempt to check their blood glucose levels while driving a commercial vehicle as opposed to pulling over at a rest stop and doing this procedure – which takes less than a minute to perform.

These generalizations assume the worst about people with insulin-treated diabetes.<sup>16</sup> They assume drivers with diabetes have no incentive to maintain safety for themselves and for others on the road. Such remarks also fail to take into account the explosion of advances in diabetes self-management techniques and tools over the last 15 years. The fact is that there are many people with insulin-treated diabetes who are more than capable of handling the responsibilities of commercial driving and other physically demanding occupations. For many people with insulin-treated diabetes, the only barriers they face on the job are those imposed by people and organizations that base their actions on stereotypes and misconceptions about diabetes management today.

### **Exemption Program Provides Limited Protections**

The Association believes the change from a blanket ban to an individual assessment should take the form a change in the driver qualification standards themselves, rather than through an exemption program. This is consistent with the legislative mandate by Congress on this issue. It also is warranted by the data in the FMCSA’s Report to Congress on this issue, and is necessary for consistency with our Nation’s civil rights laws. The proposed protocol would have a dramatic impact both on potential commercial drivers and on thousands of people in professions beyond the commercial motor vehicle industry, and the Association strongly urges the Department of Transportation to change the driver qualification standards themselves.

### **Conclusion**

---

<sup>15</sup> Contrary to such assertions, standard blood glucose meters do not erase information, even if actions such as removing the battery are taken. Moreover, the proposed FMCSA protocol *requires* drivers to submit this information to their physicians on a quarterly basis.

<sup>16</sup> Similarly, one comment assumes the worst about employers arguing that “It seems unlikely that . . . employers would let [insulin-treated drivers] take all the time necessary to check, recheck, and take corrective measures.” The Americans with Disabilities Act would require such easily accomplished accommodations. Moreover, the Association believes most employers would be quite willing to accommodate their employees’ needs. In fact, one comment submitted to the docket was from a company that was willing to pay a fine rather than terminate one of its drivers with insulin-treated diabetes because the company knew how valuable and capable the driver was.

With the major exceptions of the three-year requirement and the decision to pursue an exemption program rather than a change in the regulation, the Association supports the proposed protocol and commends the Department of Transportation for their efforts on this issue. The Association urges the Department to make modifications to ensure that the proposed protocol is based on current medical practice and structured in a manner that will allow people to take advantage of it.

The Association reiterates its desire to work with FMCSA and provide any assistance necessary to support a practicable and workable protocol to end discrimination against individuals with insulin-treated diabetes.

Contact Information: Shereen Arent  
telephone: 703-299-5519  
e-mail: [sarent@diabetes.org](mailto:sarent@diabetes.org)