



DEPARTMENT OF TRANSPORTATION

[4910-EX-P]

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2006-24278; FMCSA-2006-25854; FMCSA 2008-0355; FMCSA 2010-0203; FMCSA-2011-0089]

Denial of Exemption Applications; Epilepsy and Seizure Disorders

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

ACTION: Notice of denial for exemptions from the provisions of 49 CFR 391.41(b)(8).

SUMMARY: FMCSA announces denial of applications from seven individuals for an exemption from the prohibition against persons with a clinical diagnosis of epilepsy or any other condition which is likely to cause a loss of consciousness or any loss of ability to operate a commercial motor vehicle (CMV), from operating CMVs in interstate commerce. Reasons for denial are listed after each name entry.

FOR FURTHER INFORMATION CONTACT: Elaine M. Papp, Director, Medical Programs Division, (202) 366-4001, fmcsamedical@dot.gov, FMCSA, Room W64-224, Department of Transportation, 1200 New Jersey Avenue, S.E., Washington, DC 20590-0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 31315 and 31136(e), FMCSA may grant an exemption for a 2-year period if it finds “such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption.” The statutes also allow the Agency to renew exemptions at the end of the 2-year period. The 7 individuals listed in this notice have recently requested an exemption from the epilepsy and seizure disorder standard in 49 CFR 391.41(b)(8), which applies to drivers who operate CMVs, as defined in 49 CFR 390.5,

in interstate commerce. Section 391.41(b)(8) states that a person is physically qualified to drive a CMV if that person has no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause the loss of consciousness or any loss of ability to control a commercial motor vehicle.

In order to make an evidence-based decision, FMCSA conducted a comprehensive review of scientific literature and convened a panel of medical experts in the field of neurology to evaluate key questions regarding seizure and anti-seizure medication related to the safe operation of a commercial motor vehicle. In reaching the determination to grant or deny exemption requests for individuals who have experienced a seizure, the Agency considered both current medical literature and information and the 2007 recommendations of the Agency's Medical Expert Panel (MEP). The Agency previously gathered evidence for decision-making concerning potential changes to the regulation, by conducting a comprehensive review of scientific literature that was compiled into a report entitled, "Evidence Report on Seizure Disorders and Commercial Vehicle Driving" (Evidence Report) [CD-ROM HD TL230.3 .E95 2007]. The Agency then convened an MEP in the field of neurology on May 14-15, 2007, to review: 49 CFR 391.41(b)(8) and the advisory criteria regarding individuals who have experienced a seizure; and the 2007 Evidence Report. The Evidence Report and the MEP recommendations are published on-line at <http://www.fmcsa.dot.gov/rules-regulations/topics/mep/mep-reports.htm>, under Seizure Disorders, and are in the docket for this notice.

MEP Criteria for Evaluation

On October 15, 2007, the MEP issued the following recommended criteria for evaluating whether an individual with epilepsy or a seizure disorder should be allowed to operate a CMV.¹ The MEP recommendations are included in an appendix at the end of this notice and in each of the previously published dockets.

Epilepsy diagnosis. If there is an epilepsy diagnosis, the applicant should be seizure-free for 8 years, on or off medication. If the individual is taking anti-seizure medication(s), the plan for medication should be stable for 2 years. Stable means no changes in medication, dosage, or frequency of medication administration. Recertification for drivers with an epilepsy diagnosis should be performed every year.

Single unprovoked seizure. If there is a single unprovoked seizure (i.e., there is no known trigger for the seizure), the individual should be seizure-free for 4 years, on or off medication. If the individual is taking anti-seizure medication(s), the plan for medication should be stable for 2 years. Stable means no changes in medication, dosage, or frequency of medication administration. Recertification for drivers with a single unprovoked seizure should be performed every 2 years.

Single provoked seizure. If there is a single provoked seizure (i.e., there is a known reason for the seizure), the Agency should consider specific criteria that fall into the following two categories: low-risk factors for recurrence and moderate-to-high risk factors for recurrence.

- Examples of low-risk factors for recurrence include seizures that were caused by a medication; by non-penetrating head injury with loss of consciousness less than or equal

¹ Engel, J., Fisher, R.S., Krauss, G.L., Krumholz, A., and Quigg, M.S., “Expert Panel Recommendations: Seizure Disorders and Commercial Motor Vehicle Driver Safety,” FMCSA, October 15, 2007.

to 30 minutes; by a brief loss of consciousness not likely to recur while driving; by metabolic derangement not likely to recur; and by alcohol or illicit drug withdrawal.

- Examples of moderate-to-high-risk factors for recurrence include seizures caused by non-penetrating head injury with loss of consciousness or amnesia greater than 30 minutes, or penetrating head injury; intracerebral hemorrhage associated with a stroke or trauma; infections; intracranial hemorrhage; post-operative complications from brain surgery with significant brain hemorrhage; brain tumor; or stroke.

The MEP report indicates individuals with moderate to high-risk conditions should not be certified. Drivers with a history of a single provoked seizure with low risk factors for recurrence should be recertified every year.

Medical Review Board Recommendations and Agency Decision

FMCSA presented the MEP's findings and the Evidence Report to the Medical Review Board (MRB) for consideration. The MRB reviewed and considered the 2007 "Seizure Disorders and Commercial Driver Safety" evidence report and the 2007 MEP recommendations. The MRB recommended maintaining the current advisory criteria, which provide that "drivers with a history of epilepsy/seizures off anti-seizure medication and seizure-free for 10 years may be qualified to drive a CMV in interstate commerce. Interstate drivers with a history of a single unprovoked seizure may be qualified to drive a CMV in interstate commerce if seizure-free and off anti-seizure medication for a 5 year period or more" [Advisory criteria to 49 CFR 391.43(f)].

The Agency acknowledges the MRB's position on the issue but believes relevant current medical evidence supports a less conservative approach. The medical advisory criteria for epilepsy and other seizure or loss of consciousness episodes was based on the 1988 "Conference

of Neurological Disorders and Commercial Driving” (NITS Accession No. PB89-158950/AS). A copy of the report can be found in the docket referenced in this notice.

The MRB’s recommendation treats all drivers who have experienced a seizure the same, regardless of individual medical conditions and circumstances. In addition, the recommendation to continue prohibiting drivers who are taking anti-seizure medication from operating a CMV in interstate commerce does not consider a driver’s actual seizure history and time since the last seizure. The Agency has decided to use the 2007 MEP recommendations as the basis for evaluating applications for an exemption from the seizure regulation on an individual, case-by-case basis. The disposition of applications announced in this notice applies the 2007 MEP recommendations.

Public Comments:

Patty Cantagallo, MD, expressed her concern that applicant John Morris had indications of alcohol abuse in his medical data. The Agency did not include Mr. Morris in the final disposition. Dr. Cantagallo also indicated uncertainty with applicant Anthony Besch having unresolved “nighttime seizures.” Mr. Besch was excluded from final disposition.

Denials and Reasons:

- The following drivers were listed previously in Federal Register Notice FMCSA–2006–24278:

Anthony Besch - We are unable to contact Mr. Besch by phone or through his former employer to ascertain his status.

Charles Gant - Mr. Gant’s records indicated that he had suffered transient ischemic attacks (stroke), not epilepsy.

John Morris-Mr. Morris’ file indicated that his seizure was induced by alcohol.

- The following driver was previously listed in Federal Register Notice FMCSA–2006–25854:

Daniel L. Pulse - Mr. Pulse may meet the criteria, but he has been unresponsive in attempts to certify the date of his last seizure and/or any anti-seizure medication he is taking.

- The following driver was previously listed in Federal Register FMCSA-2008-0355:

Travis Williams - Mr. Williams has a diagnosis of epilepsy, and his last seizure was in 2008. He will have been seizure-free for 8 years, as required by the MEP guidelines, in 2016. He may reapply at that time.

- The following driver was listed previously in Federal Register FMCSA 2010-0203:

Leo Lombardio - Mr. Lombardio had a loss of consciousness event related to a diagnosis of complex partial seizures in 2009. He does not meet the exemption criteria at this time.

- The following driver was listed previously in Federal Register FMCSA 2011-0089:

Richard Laqua -Mr. Laqua had a seizure in 2009 and does not currently meet the exemption criteria.

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T. F. Scott Darling, III
Chief Counsel

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