



[4910-EX-P]

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2019-0230]

Qualification of Drivers; Exemption Applications; Implantable Cardioverter Defibrillator (ICD)

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

ACTION: Notice of denials.

SUMMARY: FMCSA announces its decision to deny applications from five individuals treated with Implantable Cardioverter Defibrillators (ICDs) who requested an exemption from the Federal Motor Carrier Safety Regulations (FMCSRs) prohibiting operation of a commercial motor vehicle (CMV) in interstate commerce by persons with a current clinical diagnosis of myocardial infarction, angina pectoris, coronary insufficiency, thrombosis, or any other cardiovascular disease of a variety known to be accompanied by syncope (transient loss of consciousness), dyspnea (shortness of breath), collapse, or congestive heart failure.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366-4001, fmcsamedical@dot.gov, FMCSA, Department of Transportation, 1200 New Jersey Avenue, SE, Room W64-224, Washington, DC 20590-0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing materials in the docket, contact Docket Operations, (202) 366-9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Viewing Documents and Comments

To view comments, as well as any documents mentioned in this notice as being available in the docket, go to <http://www.regulations.gov/docket?D=FMCSA-2019-0230> and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12-140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue, SE, Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays.

B. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at www.dot.gov/privacy.

II. Background

On November 5, 2019, FMCSA published a *Federal Register* notice (84 FR 59672) announcing receipt of applications from six individuals treated with ICDs and requested comments from the public. These six individuals requested an exemption from 49 CFR 391.41(b)(4) which prohibits operation of a CMV in interstate commerce by persons with a current clinical diagnosis of myocardial infarction, angina pectoris, coronary insufficiency, thrombosis, or any other cardiovascular disease of a variety known to be accompanied by syncope, dyspnea, collapse, or congestive heart failure. The public comment period closed on December 5, 2019, and six comments were received.

FMCSA has evaluated the eligibility of these applicants and concluded that granting five of these six exemption requests would not provide a level of safety that would be

equivalent to, or greater than, the level of safety that would be obtained by complying with §391.41(b)(4). One individual's application was withdrawn. A summary of each applicant's medical history related to their ICD exemption request was discussed in the November 5, 2019, *Federal Register* notice and will not be repeated here.

The Agency's decision regarding these exemption applications is based on information from the Cardiovascular Medical Advisory Criteria, an April 2007, evidence report titled "Cardiovascular Disease and Commercial Motor Vehicle Driver Safety,"¹ and a December 2014, focused research report titled "Implantable Cardioverter Defibrillators and the Impact of a Shock in a Patient When Deployed." Copies of these reports are included in the docket.

FMCSA has published advisory criteria to assist medical examiners in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce.² The advisory criteria for §391.41(b)(4) indicates that coronary artery bypass surgery and pacemaker implantation are remedial procedures and thus, not medically disqualifying. Implantable cardioverter defibrillators are disqualifying due to risk of syncope.

III. Discussion of Comments

FMCSA received six comments in this proceeding. Five of the six comments were favorable towards the applicants continuing to drive CMV's with ICD's. The sixth comment was submitted by Mr. Corey Tugwell's cardiologist. His cardiologist's comments supported the withdrawal of Mr. Tugwell's exemption application.

¹ The reports are available on the internet at <https://rosap.ntl.bts.gov/view/dot/16462>; <https://rosap.ntl.bts.gov/view/dot/21199>

² These criteria may be found in 49 CFR part 391, APPENDIX A TO PART 391—MEDICAL ADVISORY CRITERIA, section D. *Cardiovascular: § 391.41(b)(4)*, paragraph 4, which is available on the internet at <https://www.gpo.gov/fdsys/pkg/CFR-2015-title49-vol5/pdf/CFR-2015-title49-vol5-part391-appA.pdf>.

In response to the comments, FMCSA believes that a driver with an ICD is at risk for incapacitation if the device discharges. This risk is combined with the risks associated with the underlying cardiovascular condition for which the ICD has been implanted as a primary or secondary preventive measure. Mr. Tugwell's application was withdrawn because an exemption is unnecessary. Mr. Tugwell was notified that he must still complete a medical certification examination by a certified medical examiner on the National Registry of Certified Medical Examiners to determine whether his underlying cardiovascular condition is stable, and if he meets the cardiovascular physical qualification standards (49 CFR 391.41(b)(4)) to receive a medical examiner's certificate.

IV. Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-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 Agency's decision regarding these exemption applications is based on an individualized assessment of each applicant's medical information, available medical and scientific data concerning ICDs, and any relevant public comments received.

In the case of persons with ICDs, the underlying condition for which the ICD was implanted places the individual at high risk for syncope or other unpredictable events known to result in gradual or sudden incapacitation. ICDs may discharge, which could result in loss of ability to safely control a CMV. The December 2014 focused research report discussed earlier upholds the findings of the April 2007 report and indicates that the available scientific

data on persons with ICDs and CMV driving does not support that persons with ICDs who operate CMVs are able to meet an equal or greater level of safety.

V. Conclusion

The Agency has determined that the available medical and scientific literature and research provides insufficient data to enable the Agency to conclude that granting these exemptions would achieve a level of safety equivalent to, or greater than, the level of safety maintained without the exemption. Therefore, the following five applicants have been denied exemptions from the physical qualification standards in § 391.41(b)(4):

Charles Huff (OH)	Brian J. Hullopetter (MN)
John Gittenmeier (MO)	Gaetano Letizia (NJ)
Thomas D. Worsley (VA)	

Each applicant has, prior to this notice, received a letter of final disposition regarding his/her exemption request. Those decision letters fully outlined the basis for the denial and constitute final action by the Agency. The list published today summarizes the Agency's recent denials as required under 49 U.S.C. 31315(b)(4).

Larry W. Minor,
Associate Administrator for Policy.