[4910-EX-P]

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2019-0167]

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 four 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-2019-0167 and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting Docket Operations 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.transportation.dot.gov/privacy.

II. Background

On October 1, 2019 FMCSA published a *Federal Register* notice (84 FR 52163) announcing receipt of applications from four individuals treated with ICDs and requesting comments from the public. These four individuals requested an exemption from 49 CFR 391.41(b)(4) that 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 October 31, 2019 and three comments were received.

FMCSA has evaluated the eligibility of these applicants and concluded that granting these exemptions 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). A summary of each applicant's medical history related to their ICD exemption request was discussed in the October 1, 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 further supported in 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 three comments in this proceeding. Of the three comments received, two were duplicate comments from an anonymous commenter. The anonymous commenter supports all three individuals being granted an exemption based on the documentation that they have provided, that they have improved cardiac statuses, and that their ICDs have never deployed. The commenter states that individuals with epilepsy and diabetes are able to get

[1] The April 2007 Evidence report is available on the internet at https://rosap.ntl.bts.gov/view/dot/16462;
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[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.

approved for exemptions despite their condition and treatment. This commenter states that the Agency should do more research and make exemption decisions on a case-by-case basis. Mr. Christopher Oakland, an applicant, commented in support of FMCSA granting exemptions for 1 year to individuals who provide medical documentation from a qualified healthcare provider, that the individual is stable, the individual has no documented symptoms of syncope, dyspnea, collapse or congestive heart failure as stated in the cardiovascular standard, and the ICD has not administered therapy. Mr. Oakland commented that he submitted a total of three letters and that two of the three letters are from two different electrocardiologists. He further commented that the *Federal Register* notice posted that he submitted only two letters.

In response to the first commenter, FMCSA reviews and considers each request received for an ICD exemption individually to determine whether the applicant is able to meet a level of safety equivalent to, or greater than, the level achieved without an exemption. While the individuals' underlying cardiac conditions may demonstrate levels of improvement, their medical treatment plans also rely on the ICD device. The device, though it may not have deployed since implantation, may unpredictably deploy at a future date to deliver therapy. Based on the available medical and scientific data concerning ICDs, FMCSA finds that the applicants have an ongoing risk for incapacitation if the device discharges in response to cardiovascular symptoms. This risk for incapacitation does not meet an equal or greater level of safety that would be achieved absent an exemption. Concerning the comments on the need for additional research, FMCSA has processes and procedures in place to consider new research and existing research so that the Agency's determinations are evidence-based.

Mr. Oakland contacted the Agency prior to the close of the comment period to confirm that he submitted a total of three letters, one from his cardiologist, and letters from two

separate electrophysiologists. Mr. Oakland was informed that the statement in the *Federal Register* regarding the submission of two letters was an oversight, and confirmed that the content of each of the electrophysiologists' letters was considered prior to the date that the *Federal Register* notice was published.

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 the public comments received.

ICDs are electronic devices that treat cardiac arrest, ventricular fibrillation, and ventricular tachycardia, through the delivery of rapid pacing stimuli or shock therapy. ICDs treat but do not prevent arrhythmias. Therefore, the individual remains at risk for syncope or loss of consciousness. The underlying conditions for which the ICD was implanted therefore places these individuals at high risk for syncope or other unpredictable events know to result in gradual or sudden incapacitation. In addition, ICDs may discharge, which could result in loss of ability to safely control a CMV. The December 2014 focused research report referenced previously upholds the findings of the April 2007 report and indicates that the available scientific data on individuals with ICDs and CMV driving does not support that individuals with ICDs who operate CMVs are able to meet an equal or greater level of safety. FMCSA's individual assessment of the exemption applications and the public comments does

not provide any basis for departing from its general views on the risks posed by individual with an underlying cardiovascular condition that requires the implantation of an ICD to control.

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 referenced previously 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, even when considered with the individual assessment of each application, 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 four applicants have been denied exemptions from the physical qualification standards in § 391.41(b)(4):

Christopher Cloud (GA)	Joby Doucet (LA)
Robert D. Forbes (NY)	Christopher Oakland (RI)

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).

Issued on: January 23, 2020

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Larry W. Minor,
Associate Administrator for Policy.

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