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DEPARTMENT OF TRANSPORTATION

[4910-EX-P]

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2016-0175]

Qualification of Drivers; Exemption Applications; Implantable Cardioverter Defibrillators

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

ACTION: Notice of denials of exemption applications

SUMMARY: FMCSA announces its decision to deny applications from 11 individuals seeking exemptions from the Federal cardiovascular standard applicable to interstate truck and bus drivers and discusses the reasons for the denials. The Agency reviewed the medical information of each the individuals who applied for an implantable cardioverter defibrillator (ICD) exemption. Based on a review of the applications and following an opportunity for public comment, FMCSA has concluded that the 11 individuals in the notice did not demonstrate they could achieve a level of safety that is equivalent to, or greater than, the level of safety that would be obtained by complying with the regulation.

DATES: Denial letters were sent to each of the individuals listed in this notice on October 11, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief Medical Programs Division, 202-366-4001, U.S. Department of Transportation, FMCSA, 1200 New Jersey Avenue, S.E., Room W64-224, 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. 31136(e) and 31315, FMCSA may grant an exemption from the Federal Motor Carrier Safety Regulations for up to five years 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.” FMCSA can renew exemptions for up to an additional five years at the end of each five-year period.¹

On August 8, 2016, FMCSA published for public notice and comment, FMCSA 2016-0175, listing 11 individuals seeking exemptions for ICDs. Accordingly, the Agency has evaluated each applicant’s request to determine whether granting an exemption will achieve the required level of safety mandated by statute.

Evaluation Criteria- Cardiovascular Medical Standard and Advisory Criteria

The individuals included in this notice have requested an exemption from the provisions of 49 CFR 391.41(b)(4), which applies to drivers who operate CMVs in interstate commerce, as defined in 49 CFR 390.5. Section 391.41(b)(4) states that:

A person is physically qualified to drive a commercial motor vehicle if –

* * *

that person has no 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 [a temporary loss of consciousness due to a sudden decline in blood flow to the brain], dyspnea [shortness of breath], collapse, or congestive cardiac failure.

The FMCSA provides medical advisory criteria as recommendations for use by medical examiners in determining whether drivers with certain medical conditions and drivers who have undergone certain procedures and/or treatments should be certified to operate CMVs in interstate commerce in accordance with the various physical qualification standards in 49 CFR part 391, subpart E. The advisory criteria are currently set out in Appendix A to 49 CFR part 391. The advisory criteria for section 391.41(b)(4) provide, in part, that:

The term “has no current clinical diagnosis of” is specifically designed to encompass: “a clinical diagnosis of” (1) a current cardiovascular condition,

¹ 49 U.S.C. 31315(b), as amended by section 5206(a) of the FAST Act, Pub. L. 114-94, div. A, title V, 129 Stat. 1537 (Dec. 4, 2015).

or (2) a cardiovascular condition which has not fully stabilized regardless of the time limit. The term “known to be accompanied by” is designed to include a clinical diagnosis of a cardiovascular disease (1) which is accompanied by symptoms of syncope, dyspnea, collapse or congestive cardiac failure; and/or (2) which is likely to cause syncope, dyspnea, collapse, or congestive cardiac failure.

It is the intent of the Federal Motor Carrier Safety Regulations to render unqualified, a driver who has a current cardiovascular disease which is accompanied by and/or likely to cause symptoms of syncope, dyspnea, collapse, or congestive cardiac failure. However, the subjective decision of whether the nature and severity of an individual’s condition will likely cause symptoms of cardiovascular insufficiency is on an individual basis and qualification rests with the medical examiner and the motor carrier.

In the case of persons with ICDs, the underlying condition for which the ICD was implanted places the individual at high risk for syncope (a transient loss of consciousness) 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. See the Evidence Report on “Cardiovascular Disease and Commercial Motor Vehicle Driver Safety,” April 2007.² A focused research report entitled “Implantable Cardioverter Defibrillators and the Impact of a Shock on a Patient When Deployed,” completed for the FMCSA in December 2014, 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 and upholds the findings of the April 2007 report. Copies of the April 2007 report and the December 2014 report are included in the docket for this notice.

Discussion of Public Comments

On August 8, 2016, FMCSA published in a Federal Register Notice the names of 11 individuals seeking ICD exemption and requested public comment. The public comment period closed on September 7, 2016. A total of 29 commenters responded to the notice. Each

² Now available at http://ntl.bts.gov/lib/30000/30100/30123/Final_CVD_Evidence_Report_v2.pdf

of the comments was favorable towards the applicants continuing to drive CMV's with ICD's. Many commenters believed that the individuals seeking exemptions were safe drivers with safe professional work histories, and that their exemption request should be considered on an individual case basis based on merit. Several commenters expressed that individual driving records and experience should be factors in allowing persons with ICD's to operate CMVs.

FMCSA's Response

FMCSA acknowledges the commenters' concerns. The Agency reviews and considers each applicant's request individually. Based on the available medical literature cited above, however, 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.

Conclusion

FMCSA evaluated the 11 individual exemption requests on their merits, available data from Evidence Reports and Medical Expert Panel opinions on the impact of ICDs on Commercial Motor Vehicle driving, and the public comments received. The Agency has determined that the available medical literature and data does not support a conclusion that granting these exemptions would achieve a level of safety equivalent to or greater than the level of safety maintained without the exemptions. Each applicant has, prior to this notice, received a letter of final disposition on his/her exemption request. Those decision letters fully outlined the basis for the denial and constitute final Agency action. The list published today summarizes the Agency's recent denials as required under 49 U.S.C. 31315(b)(4).

The following 11 applicants are denied exemptions from the cardiovascular standard.

Charles R. Allen (MI)	James Goslee (MD)
William Blake (NH)	Richard Hacker (MD)
Roosevelt Tyrone Brown (SC)	Kathryn Kosse (AZ)
Kevin Coulter (CA)	Joseph Skrzyniarz, (MI)
John Dudar (CT)	Wylanne Deon Sanders (IL)
Timothy Godwin (NC)	

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Larry W. Minor
Associate Administrator for Policy

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