#### **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

#### 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.<sup>2</sup> 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.

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

https://www.gpo.gov/fdsys/pkg/CFR-2015-title49-vol5/pdf/CFR-2015-title49-vol5-part391-appA.pdf.

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

<sup>&</sup>lt;sup>2</sup> 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

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. Hullopeter (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.

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#### **DEPARTMENT OF TRANSPORTATION**

## Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2020-0046]

## Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

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

**ACTION:** Notice of applications for exemption; request for comments.

**SUMMARY:** FMCSA announces receipt of applications from seven individuals for an exemption from the prohibition in the Federal Motor Carrier Safety Regulations (FMCSRs) against persons with a clinical diagnosis of epilepsy or any other condition that is likely to cause a loss of consciousness or any loss of ability to control a commercial motor vehicle (CMV) to drive in interstate commerce. If granted, the exemptions would enable these individuals who have had one or more seizures and are

taking anti-seizure medication to operate CMVs in interstate commerce.

**DATES:** Comments must be received on or before May 7, 2020.

ADDRESSES: You may submit comments identified by the Federal Docket Operations Docket No. FMCSA-2020-0046 using any of the following methods:

- Federal eRulemaking Portal: Go to http://www.regulations.gov/docket?D=FMCSA-2020-0046. Follow the online instructions for submitting comments.
- *Mail:* Docket Operations; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- Hand Delivery: West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal Holidays.
  - Fax: (202) 493-2251.

To avoid duplication, please use only one of these four methods. See the "Public Participation" portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

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 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Operations, (202) 366–9826.

## SUPPLEMENTARY INFORMATION:

#### I. Public Participation

#### A. Submitting Comments

If you submit a comment, please include the docket number for this notice (Docket No. FMCSA-2020-0046), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to http://www.regulations.gov/

docket?D=FMCSA-2020-0046. Click on the "Comment Now!" button and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than  $8\frac{1}{2}$  by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period.

## B. 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-2020-0046 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 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.

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## II. Background

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 statute also allows the Agency to renew exemptions at the end of the 5-year period. FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

The seven individuals listed in this notice have requested an exemption from the epilepsy and seizure disorders prohibition in 49 CFR 391.41(b)(8). Accordingly, the Agency will evaluate