[4910-EX-P]

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2025-0038]

Qualification of Drivers; Exemption Applications; Implantable Cardioverter Defibrillators (ICDs)

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

ACTION: Notice of application for exemption; request for comments.

SUMMARY: FMCSA announces receipt of an application from one individual for an exemption from the prohibition in the Federal Motor Carrier Safety Regulations (FMCSRs) against operation of a commercial motor vehicle (CMV) 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. If granted, the exemption would enable the individual with an ICD to operate CMVs in interstate commerce.

DATES: Comments must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments identified by Docket No. FMCSA-2025-0038 using any of the following methods:

- Federal eRulemaking Portal: Go to www.regulations.gov, insert the docket number (FMCSA-2025-0038) in the keyword box and click “Search.” Next, sort the results by “Posted (Newer-Older),” choose the first notice listed, and click on the “Comment” button. Follow the online instructions for submitting comments.

- Mail: Dockets Operations; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Washington, DC 20590-0001.
- Hand Delivery: West Building Ground Floor, 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. Evangela Hollowell, Acting Chief, Medical Programs Division, FMCSA, DOT, 1200 New Jersey Avenue SE, Washington, DC 20590-0001, (202) 527-4750, fmcsamedical@dot.gov. 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 or submitting material to the docket, contact Dockets 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-2025-0038), 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

www.regulations.gov/docket/FMCSA-2025-0038. Next, choose the only notice listed, click the "Comment" 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 8½ by 11 inches, suitable for copying and electronic filing. FMCSA will consider all comments and material received during the comment period.

B. Confidential Business Information (CBI)

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to the notice contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to the notice, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission that constitutes CBI as "PROPIN" to indicate it contains proprietary information. FMCSA will treat such marked submissions as confidential under the Freedom of Information Act, and they will not be placed in the public docket of the notice. Submissions containing CBI should be sent to Brian Dahlin, Chief, Regulatory Evaluation Division, Office of Policy, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590-0001 or via email at brian.g.dahlin@dot.gov. At this time, you need not send a duplicate hardcopy of your electronic CBI submissions to FMCSA headquarters. Any comments FMCSA receives not specifically designated as CBI will be placed in the public docket for this notice.

C. Viewing Comments

To view comments go to www.regulations.gov. Insert the docket number (FMCSA-2025-0038) in the keyword box and click "Search." Next, choose the only notice listed, and click "Browse Comments." If you do not have access to the internet, you may view the docket online by visiting Dockets Operations on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590-0001, between 9 a.m. and 5 p.m. ET Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366-9317 or (202) 366-9826 before visiting Dockets Operations.

D. Privacy Act

In accordance with 49 U.S.C. 31315(b)(6), DOT solicits comments from the public on the exemption requests. DOT posts these comments, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice DOT/ALL-14 FDMS (Federal Docket Management System), which can be reviewed under the "Department Wide System of Records Notices" link at https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices. The comments are posted without edit and are searchable by the name of the submitter.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the Federal Register (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including the applicant's safety analysis. The Agency must provide an opportunity for public comment on the request.

The Agency reviews the application, safety analyses, and public comments submitted and determines whether granting the exemption would likely achieve a level of

safety equivalent to, or greater than, the level that would be achieved absent such exemption, pursuant to the standard set forth 49 U.S.C. 31315(b)(1). The Agency must publish its decision in the Federal Register (49 CFR 381.315(b)). If granted, the notice will identify the regulatory provision from which the applicant will be exempt, the effective period, and all terms and conditions of the exemption (49 CFR 381.315(c)(1)). If the exemption is denied, the notice will explain the reason for the denial (49 CFR 381.315(c)(2)). The exemption may be renewed (49 CFR 381.300(b)). FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

III. Background

The physical qualification standard for drivers regarding cardiovascular diseases and loss of consciousness provides that a person is physically qualified to drive a CMV 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, dyspnea, collapse, or congestive cardiac failure" (49 CFR 391.41(b)(4)). To assist in applying this standard, FMCSA publishes guidance for medical examiners (MEs) in the form of medical advisory criteria in Appendix A to 49 CFR part 391.[1] The advisory criteria for § 391.41(b)(4) indicates that ICDs are installed to address an ongoing underlying cardiovascular condition and that syncope or collapse is likely to occur as a result of both the underlying cardiovascular condition as well as when the ICDs discharge. Therefore, ICDs are medically disqualifying. In April 2007, FMCSA published an evidence report titled, "Cardiovascular Disease and Commercial Motor Vehicle Driver Safety," presenting findings regarding cardiovascular disease and CMV driver safety.[2] In December 2014, FMCSA published a research report

[1] 49 CFR part 391, App.A.II.C, available at https://www.ecfr.gov/current/title-49/subtitle-B/chapter-III/subchapter-B/part-391/appendix-Appendix%20A%20to%20Part%20391.
[2] "Evidence Report: Cardiovascular Disease" (Apr. 27, 2007), available at

titled, “Implantable Cardioverter Defibrillators and the Impact of a Shock in a Patient When Deployed,” that provided evidence regarding the potential impact of ICD deployment and how it may interfere with the safe operation of a CMV.[3]

The Agency considers the medical advisory criteria, the April 2007 evidence report, the December 2014 research report, the application, any public comments received, and the individual’s medical information in deciding whether to grant the exemption.

The individual listed in this notice has requested an exemption from 49 CFR 391.41(b)(4). Accordingly, the Agency will evaluate the qualifications of the applicant to determine whether granting the exemption will achieve the required level of safety mandated by statute.

IV. Qualifications of Applicant

Charles Pereira

Charles Pereira is a class CM commercial driver’s license holder in California. A January 17, 2025, letter from Mr. Pereira’s cardiologist reports that he had an ICD placed to treat ventricular fibrillation and ventricular tachycardia. His ICD was originally implanted in June 2010, and he received a shock from that device without loss of consciousness. Mr. Pereira’s ICD was replaced on December 12, 2022, and he has not received any shocks from the new device. Mr. Pereira’s cardiologist also reports his underlying heart condition is stable and that he has not experienced any symptoms concerning the device.

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https://doi.org/10.21949/1502991.

[3] “Implantable Cardio Defibrillators and the Impact of a Shock to the Patient when Deployed Research White Paper” (Dec. 17, 2014), available at https://www.fmcsa.dot.gov/sites/fmcsa.dot.gov/files/2021-06/Cardio%20Defibrillators%20White%20Paper_Final_508C.pdf.

V. Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315(b), FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. FMCSA will consider all comments received before the close of business on the closing date indicated under the DATES section of the notice.

Larry W. Minor,
Associate Administrator for Policy.

[FR Doc. 2025-13974 Filed: 7/23/2025 8:45 am; Publication Date: 7/24/2025]