



DEPARTMENT OF TRANSPORTATION

[4910-EX-P]

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2005-23151]

Agency Information Collection Activities; Information Collection Revision

Request - Medical Qualification Requirements, OMB Control Number 2126-0006

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

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FMCSA announces that it is considering submitting the Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for its review and approval and invites public comment on a revision to the Information Collection (IC) titled *Medical Qualification Requirements*, covered by OMB Control Number 2126-0006, which is currently due to expire on August 31, 2018. This revision is due to the Agency's anticipation of a final rule to revise its regulations to eliminate the blanket prohibition against insulin-dependent diabetic individuals' operation of commercial motor vehicles (CMV) in interstate commerce. The final rule is based on the Agency's 2015 Notice of Proposed Rulemaking (NPRM) and subsequent announcement of the availability of recommendations provided by FMCSA's Medical Review Board (MRB) after an analysis of the comments received in response to the NPRM. Based on the MRB's analysis of the comments and their recommendations, FMCSA is considering replacing the previously proposed written notification from the treating clinician (TC) with a form titled *Insulin-Treated Diabetes Mellitus Assessment Form* to be completed by the TC and provided to the certified medical examiner (certified ME). This form could

be required for CMV drivers treated with insulin for diabetes who wish to drive in interstate commerce. FMCSA invites public comment on the proposed IC revision and the form that it is being considered.

DATES: We must receive your comments on or before **[INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION OF THIS NOTICE IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments identified by Federal Docket Management System (FDMS) Docket Number FMCSA-2005-23151 using any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the online instructions for submitting comments.
- Fax: 1-202-493-2251.
- Mail: Docket Services; U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building, Ground Floor, Room W12-140, Washington, DC 20590-0001.
- Hand Delivery or Courier: U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building, Ground Floor, Room W12-140, Washington, DC, between 9 a.m. and 5 p.m. e.t., Monday through Friday, except Federal holidays.

Instructions: All submissions must include the Agency name and docket number. For detailed instructions on submitting comments and additional information on the exemption process, see the Public Participation heading below. Note that all comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>, and follow the online instructions for accessing the dockets, or go to the street address listed above.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement for the Federal Docket Management System published in the Federal Register on January 17, 2008 (73 FR 3316), or you may visit <http://edocket.access.gpo.gov/2008/pdfE8-794.pdf>.

Public Participation: The Federal eRulemaking Portal is available 24 hours each day, 365 days each year. You can obtain electronic submission and retrieval help and guidelines under the "help" section of the Federal eRulemaking Portal Web site. If you want us to notify you that we received your comments, please include a self-addressed, stamped envelope or postcard, or print the acknowledgement page that appears after submitting comments online. Comments received after the comment closing date will be included in the docket and will be considered to the extent practicable.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, U.S. Department of Transportation, Federal Motor Carrier Safety Administration, West Building 6th Floor, 1200 New Jersey Avenue, SE., Washington, DC 20590. Telephone: 202-366-4001; email FMCSAmedical.@dot.gov.

SUPPLEMENTARY INFORMATION:

Background:

The primary mission of FMCSA is to reduce crashes, injuries, and fatalities involving large trucks and buses. The Secretary of Transportation has delegated to FMCSA its responsibility under 49 U.S.C. §§ 31136, 31149 and 31502 to prescribe regulations that ensure that CMVs are operated safely. As part of this mission, the Agency's Medical Programs Division works to ensure that CMV drivers engaged in interstate commerce are physically qualified and able to safely perform their work.

Information used to determine and certify driver medical fitness must be collected for our highways to be safe. FMCSA is the Federal government agency authorized to require the collection of this information and the authorizing regulations are located at 49 CFR 390-399. FMCSA is required by statute to establish standards for the physical qualifications of drivers who operate CMVs in interstate commerce for non-excepted industries (49 U.S.C. 31136(a)(3), 31149(c)(1)(A)(i), and 31502(b)). The regulations relevant to this collection are outlined in the Federal Motor Carrier Safety Regulations (FMCSRs) at 49 CFR 390-399. The FMCSRs at 49 CFR § 391.41 set forth the physical qualification standards that interstate CMV drivers who are subject to part 391 must meet, with the exception of drivers operating vehicles transporting migrant workers (who must meet the physical qualification standards set forth in 49 CFR § 398.3). The FMCSRs covering driver physical qualification records are found at 49 CFR § 391.43, which specify that a medical examination be performed on CMV drivers subject to part 391 who operate in interstate commerce. The results of the examination must be recorded in accordance with the requirements set forth in that section.

Section 391.41(b)(3) states that a person is physically qualified to drive a CMV if that person has no established medical history or clinical diagnosis of diabetes mellitus

currently requiring insulin for control. As such, drivers with insulin-treated diabetes mellitus (ITDM) are currently prohibited from driving CMVs in interstate commerce unless they obtain an exemption from FMCSA.

On May 4, 2015 (80 FR 25260), FMCSA published a NPRM proposing to revise § 391.41(b)(3) to permit drivers with stable, well controlled ITDM to be qualified to operate CMVs in interstate commerce who meet the proposed new requirements of §§ 391.45 and 391.46. The proposal would enable drivers with ITDM to obtain a Medical Examiner's Certificate (MEC), Form MCSA-5876, from a certified ME at least annually to operate a CMV in interstate commerce if the TC provides documentation to the certified ME that the condition is stable and well controlled.

To assist in the development of the final rule, FMCSA requested that the MRB, under MRB Task 15-1, review and analyze all comments from medical professionals, labor and industry, and trade associations, and identify factors the Agency should consider when making decisions about the next steps in the diabetes rulemaking. In July 2015, the MRB deliberated on these public comments for purposes of offering recommendations to the Agency on this topic.

In September of 2015, the MRB provided several detailed recommendations in a final report of Task 15-1 to the Agency. In the report, the MRB recommended that FMCSA develop a questionnaire for the TC to send to the certified ME. See Recommendation II E, "FMCSA Drivers With Insulin Treated Diabetes Mellitus Assessment Form." In September 2016, the Agency published a Federal Register notice announcing the availability of and requesting comments on the MRB's Task 15-1 recommendations. The MRB's final report for Task 15-1 and the Federal Register notice

are available in the docket for this rulemaking (in addition to being available on the Agency's public website).

The Agency evaluated the MRB's recommendations, as well as public comments, and is considering the use of an assessment form titled *Insulin-Treated Diabetes Mellitus Assessment Form*. The Agency may modify the form and the information that would be collected in response to any comments received in response to this notice. The addition of this requirement will add 33,616 annual burden hours and \$2,823,744 annual salary costs. However, eliminating the Diabetes Exemption Program as proposed in the NPRM will result in 2,219 less annual burden hours and \$68,645 less annual salary costs. Therefore, the final rule would provide a net increase of 31,397 in annual burden hours and \$2,755,099 in salary costs from the proposed updated annual burden hours and costs. The form that is being considered would include the following information collected by the TC:

CMV Driver Information

1. Name
2. DOB
3. Information about the driver's use of insulin;
 - a. Whether the driver is newly diagnosed or an established insulin user
 - b. Date insulin use began
 - c. Whether or not the driver has been on a stable insulin regimen for three months prior
4. Information about the driver's use of blood glucose self-monitoring records

- a. Whether or not the driver provided documentation of ongoing self-monitoring of blood glucose measured with an electronic glucometer for at least the preceding three months
 - b. Number of times per day the driver is testing their blood glucose
 - c. Whether or not the driver is compliant with glucose monitoring based on his/her specific treatment plan
5. Information about insulin management and diabetes control
- a. Whether or not the driver has experienced any severe hypoglycemic episodes within the preceding three months
 - b. Whether or not the driver has experienced any severe hypoglycemic episodes in the absence of warning symptoms in the preceding three months
 - c. Whether or not the driver has had his/her HbA1C measured intermittently over the last 12 months with the most recent measure within the preceding three months accompanied by a copy of the most recent laboratory results.
6. Information about diabetes complications
- a. Whether or not the driver has any signs of diabetes complications or target organ damage that impairs the driver's ability to safely operate a CMV
7. Information about progressive eye diseases
- a. Date of last comprehensive dilated eye examination
 - b. Whether or not the driver has been diagnosed with Stage 3 or 4 diabetic retinopathy

- c. Whether or not the driver has been diagnosed with any other progressive eye disease(s)

8. Any comments provided by the TC

TC Information

1. Certification that they are the treating clinician for the driver and that the driver maintains a stable insulin regimen and stable control of his/her insulin-treated diabetes mellitus.
2. Date
3. Name
4. Signature
5. Telephone Number
6. Email address
7. Street Address
8. City, State, and Zip Code

The public interest in, and the right to have, safe highways requires the assurance that drivers of CMVs can safely perform the increased physical and mental demands of their duties. FMCSA's medical standards provide this assurance by requiring drivers to be examined and medically certified as physically and mentally qualified to drive a CMV.

Therefore, the information collected on this assessment form could assist the certified ME in determining if the driver with ITDM that is being examined is medically qualified under 49 CFR § 391.41 to operate a CMV, and to ensure that there are no

medical conditions that could adversely affect his or her ability to drive safely or cause incapacitation constituting a risk to the public.

The use of this form could allow the certified ME to have communication with TCs so that the certified ME fully understands whether the driver with ITDM that is being examined has stable, well-controlled diabetes. This information will assist the ME in determining whether insulin treatment or any medical complications of diabetes will impact a driver's ability to safely operate a CMV. Therefore, FMCSA expects that 100 percent of drivers who are treated with insulin and intend to operate a CMV in interstate commerce will have the form completed by their TC.

TCs would be able to fax or scan and email the form to the certified ME. Consistent with OMB's commitment to minimizing respondents' recordkeeping and paperwork burdens, and the increased use of secure electronic modes of communication, the Agency anticipates that approximately 25 percent of the *Insulin-Treated Diabetes Mellitus Assessment Forms* would be transmitted electronically.

The information collected from the *Insulin-Treated Diabetes Mellitus Assessment Form* provided to the certified ME will become part of the CMV driver's record maintained for at least three years by the certified ME. Therefore, the information will not be available to the public. The FMCSRs covering driver physical qualification records are found at 49 CFR § 391.43, which specify that a medical examination be performed on CMV drivers subject to part 391, subpart E who operate in interstate commerce. The results of the examination shall be recorded in accordance with the requirements set forth in that section.

Title: Medical Qualification Requirements

OMB Control Number: 2126-0006.

Type of Request: Revised collection.

Respondents: Treating Clinicians (i.e., healthcare professional who manages and prescribes insulin for treatment of a driver's diabetes mellitus as authorized by the healthcare professional's applicable State licensing board)

Estimated Number of Respondents: 252,117 treating clinicians

Estimated Time per Response: 8 minutes

Expiration Date: 8/31/2018

Frequency of Response: Required

Estimated Total Annual Burden: 33,616 hours

PUBLIC COMMENTS INVITED: You are asked to comment on any aspect of this information collection, including: (1) whether the proposed collection is necessary for the performance of FMCSA's functions; (2) the accuracy of the estimated burden; (3) ways for FMCSA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize or include your comments in the request for OMB's clearance of this information collection.

Issued under the authority of 49 CFR 1.87 on: July 20, 2017

G. Kelly Regal
Associate Administrator for Office of
Research and Information Technology
and Chief Information Officer

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