**DEPARTMENT OF TRANSPORTATION** **[4910-EX-P]**

**Federal Motor Carrier Safety Administration**

**[Docket No. FMCSA-2015-0180]**

**Agency Information Collection Activities; New Information Collection Request: 391.41 CMV Driver Medication Form**

**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 its plan to submit 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 the approval of a new ICR titled, *391.41 CMV Driver Medication Form*. This ICR is voluntary and may be utilized by medical examiners (MEs) responsible for issuing Medical Examiner's Certificates (MECs) to commercial motor vehicle (CMV) drivers. MEs that choose to use this ICR will do so in an effort to communicate with treating healthcare professionals who are responsible for prescribing certain medications, so that the ME fully understands the reasons the medications have been prescribed. The information obtained by the ME when utilizing this ICR will assist the ME in determining if the driver is medically qualified under 49 CFR § 391.41 and to ensure that there are no disqualifying medical conditions or underlying medical conditions and prescribed medications that could adversely affect their safe driving ability or cause incapacitation constituting a risk to the public.

**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-2015-0180 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, 20590-0001.
- Hand Delivery or Courier: West Building, Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., 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: 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.

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:** Charles A. Horan III, Director, Office of Carrier, Driver, and Vehicle, Safety Standards, U.S. Department of Transportation, Federal Motor Carrier Safety Administration, West Building 6th Floor, 1200 New Jersey Avenue, SE., Washington, DC 20590. Telephone: 202-366-2362; email charles.horan@dot.gov.

**SUPPLEMENTARY INFORMATION:**

**Background:** The primary mission of the Federal Motor Carrier Safety Administration (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 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 in order 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) and 31502(b)]. The regulations discussing this collection are outlined in the Federal Motor Carrier Safety Regulations (FMCSRs) at 49 CFR 390-399. 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 commercial driver's license/commercial learner's permit (CDL/CLP) drivers 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 shall be recorded in accordance with the requirements set forth in that section.

49 CFR § 391.41(12) states that a person is physically qualified to drive a CMV if that person does not use any drug or substance identified in 21 CFR 1308.11 Schedule I, an amphetamine, a narcotic, or other habit-forming drug and does not use any non-Schedule I drug or substance that is identified in the other Schedules in 21 part 1308 except when the use is prescribed by a licensed medical practitioner, as defined in §382.107, who is familiar with the driver's medical history and has advised the driver that the substance will not adversely affect the driver's ability to safely operate a CMV.

In 2006, FMCSA's Medical Review Board (MRB) deliberated on the topic of the use of Schedule II medications. The MRB considered information provided in a 2006 FMCSA sponsored Evidence Report and a subsequent Medical Expert Panel (MEP) to examine the relationship between the licit use of a Schedule II drug and the risk for a motor vehicle crash. In 2013, FMCSA tasked the MRB with updating the opinions and recommendations of the 2006 Evidence Report and MEP.

On September 10, 2013, the MRB and Motor Carrier Safety Advisory Committee (MCSAC) met jointly to hear presentations on the licit use of Schedule II medications and their regulation, and on U.S. Department of Transportation drug and alcohol testing protocols. Subsequently, the committees engaged in a discussion on the issue as it applies to CMV drivers. On September 11, 2013, the MRB discussed the issue in greater detail as its task to present a letter report to the Agency relating to CMV drivers and Schedule II medication use and to develop a form for MEs on the National Registry of Certified Medical Examiners (National Registry) to send to treating clinicians of CMV drivers to expound on the use of these medications by driver applicants. On October 22, 2013, the MRB submitted their recommendations to FMCSA. A MEP convened to provide an updated opinion on *Schedule II Opioids and Stimulants & CMV Crash Risk and Driver Performance*. The FMCSA revised the task of the MRB instructing them to review an updated evidence report and the MEP opinion that was furnished subsequent to its deliberations on *Schedule II Opioids and Stimulants & CMV Crash Risk and Driver Performance: Evidence Report and Systematic Review*. FMCSA directed the MRB to consider this report's findings and confer with the MCSAC on this topic during a joint meeting in October 2014. The MRB met in public meetings on July 29-30, 2014, and

developed Schedule II medication recommendations. The MRB presented these recommendations to the MCSAC in a joint public meeting on October 27, 2014, where they were deliberated by both committees. As a result, FMCSA's MRB and MCSAC provided joint recommendations related to the use of Schedule II medications by CMV drivers. Because there is moderate evidence to support the contention that the licit use of opioids increases the risk of motor vehicle crashes and impacts indirect measures of driver performance negatively, included was the recommendation that FMCSA develop a standardized medication questionnaire to assist the certified ME when reviewing prescription medications that have been disclosed during the history and physical examination for CMV driver certification. The two advisory groups recommended to FMCSA that the standardized CMV driver medication questionnaire be voluntary and include the following information and questions:

1. Questionnaire should be titled *391.41 CMV Driver Medication Questionnaire*.
2. Questionnaire should request the following information:
    a. Identifying name and date of birth of the CMV driver.
    b. Introductory paragraph stating purpose of the CMV Driver Medication Report.
    c. Statements of 391.41(b)(12) (Physical Qualifications of Drivers relating to driver use of scheduled substances) and The Driver's Role, as found in the Medical Examination Report form found at the end of *49 CFR 391.43 (Medical Examination; Certificate of Physical Examination).*
    d. Name, state of licensure, signature, address and contact information of the prescribing healthcare provider, as well as the date the form was

completed.

e. Name, signature, date, address and contact information of the certified ME.

3. Report should include the following information:

a. 1 – List all medications and dosages that you have prescribed to the above named individual.

b. 2 – List any other medications and dosages that you are aware have been prescribed to the above named individual by another treating healthcare provider.

c. 3 – What medical conditions are being treated with these medications?

d. 4 – It is my medical opinion that, considering the mental and physical requirements of operating a CMV and with awareness of a CMV driver's role (consistent with *The Driver's Role* statement on page 2 of the form), I believe my patient: (a) has no medication side effects from medication(s) that I prescribe that would adversely affect the ability to operate a CMV safely; and (2) has no medical condition(s) that I am treating with the above medication(s) that would adversely affect the ability to operate a CMV safely.

The public interest in, and 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.

The purpose for collecting this information is to assist the ME in determining if the driver is medically qualified under 49 CFR § 391.41 and to ensure that there are no disqualifying medical conditions that could adversely affect their safe driving ability or cause incapacitation constituting a risk to the public. 49 CFR § 391.41(12) states that a person is physically qualified to drive a CMV if that person does not use any drug or substance identified in 21 CFR 1308.11 Schedule I, an amphetamine, a narcotic, or other habit-forming drug and does not use any non-Schedule I drug or substance that is identified in the other Schedules in 21 part 1308 except when the use is prescribed by a licensed medical practitioner, as defined in §382.107, who is familiar with the driver's medical history and has advised the driver that the substance will not adversely affect the driver's ability to safely operate a CMV.

The use of this ICR is at the discretion of the ME to facilitate communication with treating healthcare professionals who are responsible for prescribing certain medications so that the ME fully understands the reasons the medications have been prescribed. This information will assist the ME in determining whether the underlying medical condition and the prescribed medication will impact the driver's safe operation of a CMV. Therefore, there is no required collection frequency.

The *391.41 CMV Driver Medication Form* will be available as a fillable pdf or may be downloaded from the FMCSA website. Prescribing healthcare providers will also be able to fax or scan and email the report to the certified ME. Consistent with the 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 50 percent of the *391.41 CMV Driver Medication Forms* will be transmitted electronically.

The information collected from the *391.41 CMV Driver Medication Form*, will be used by the certified ME that requested the completion of the form and will become part of the CMV driver's record maintained 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 who operate in interstate commerce. The results of the examination shall be recorded in accordance with the requirements set forth in that section. MEs are required to maintain records of the CMV driver medical examinations they conduct.

**Title: 391.41 CMV Driver Medication Form**.

**OMB Control Number:** 2126-00XX.

**Type of Request:** New collection.

**Respondents:** Prescribing healthcare professionals

**Estimated Number of Respondents:** 1,082,200 (total number of prescribing healthcare providers in the U.S.)

**Estimated Time per Response:** 8 minutes

**Expiration Date:** N/A. This is a new ICR.

**Frequency of Response:** Voluntary

**Estimated Total Annual Burden:** 144,293 hours [1,082,200 responses x 8 minutes to complete response/60 minutes = 144,293].

**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: Nov 6, 2015

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

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