



4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2019-0101]

Agency Information Collection Activities; Information Collection Renewal: 391.41

CMV Driver Medication Form, OMB Control Number: 2126-0064

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 renewal Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for its review and approval and invites public comment. This Information Collection (IC) is voluntary and may be utilized by certified Medical Examiners (ME) responsible for issuing Medical Examiner's Certificates (MEC) to commercial motor vehicle (CMV) drivers. Certified MEs who choose to use this IC do so in an effort to communicate with treating healthcare professionals, who are responsible for prescribing certain medications, so that the certified MEs fully understand the reasons the medications have been prescribed. The information obtained by this IC assists the certified MEs in determining if drivers are physically qualified and if there are medical conditions or being treated with certain prescribed medications that would adversely affect the drivers' ability to safely operate CMVs. FMCSA requests approval to renew an ICR titled, "391.41 CMV Driver Medication Form." In response to the **Federal Register** notice published on July 3, 2019, requesting public comment, FMCSA received two comments.

DATES: Please send your comments to OMB by **[insert date 30 days after the date of publication of this notice in the Federal Register]**. OMB must receive your comments by this date in order to act quickly on the ICR.

ADDRESSES: All comments should reference Federal Docket Management System (FDMS) Docket Number FMCSA-2019-0101. Interested persons are invited to submit written comments on the proposed IC to the Office of Information and Regulatory Affairs at OMB. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/Federal Motor Carrier Safety Administration, and sent via electronic mail to oir_submission@omb.eop.gov or faxed to (202) 395-6974. An alternative, though slower, method is by U.S mail to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Mr. 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. Office hours are from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

SUPPLEMENTARY INFORMATION:

Title: 391.41 CMV Driver Medication Form

OMB Control Number: 2126-0064.

Type of Request: Renewal of a currently approved collection.

Respondents: Prescribing healthcare professionals.

Estimated Number of Respondents: Up to 1,223,470 (total number of prescribing healthcare professionals in the U.S.).

Estimated Number of Responses: Up to 1,967,006 (total number of CMV drivers who may be asked by a certified ME to have the 391.41 CMV Driver Medication Form, MCSA-5895, completed by a prescribing healthcare professional).

Estimated Time per Response: 8 minutes.

Expiration Date: January 31, 2020.

Frequency of Response: Voluntary.

Estimated Total Annual Burden: 262,267 hours

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 responsibility under 49 U.S.C. 31136 and 31502 to prescribe regulations that ensure 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 perform their work safely.

Information used to determine and certify that a driver meets the physical qualification standards 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. 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 IC are outlined in the Federal Motor Carrier Safety Regulations (FMCSRs) at 49 CFR parts 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 commercial driver's license/commercial learner's permit holders 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.

The physical qualification standard regarding the use of drugs and substances in 49 CFR 391.41(b)(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; or does not use any non-Schedule I drug or substance that is identified in the other Schedules in 21 CFR part 1308 except when the use is prescribed by a licensed medical practitioner, as defined in 49 CFR 382.107,¹ 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 by a subsequent Medical Expert Panel (MEP) to examine the relationship between the licit use of a Schedule II drug and the risk of a motor vehicle crash. In 2013, FMCSA tasked the MRB with updating the opinions and recommendations of the 2006 Evidence Report and MEP.

¹ A licensed medical practitioner means a person who is licensed, certified, or registered, in accordance with applicable Federal, State, local, or foreign laws and regulations, to prescribe controlled substances and other drugs (49 CFR 382.107).

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 in light of 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 certified MEs on the National Registry of Certified Medical Examiners (National Registry) to send to treating healthcare professionals of CMV drivers to expound on the use of these medications by driver applicants. On October 22, 2013, the MRB submitted its recommendations to FMCSA.

Thereafter, an MEP convened to provide an updated opinion on its prior report titled, “Schedule II Opioids and Stimulants & CMV Crash Risk and Driver Performance.” FMCSA revised the task of the MRB and instructed it to review the updated evidence report and MEP opinions in the report titled “Schedule II Opioids and Stimulants & CMV Crash Risk and Driver Performance: Evidence Report and Systematic Review” that was furnished subsequent to the MRB’s deliberations. 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 negatively impacts indirect measures of driver performance,² 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 committees 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 at the end of 49 CFR 391.43 (Medical Examination; Certificate of Physical Examination).³

2 Schedule II Opioids and Stimulants & CMV Crash Risk and Driver Performance: Evidence Report and Systematic Review, October 18, 2014, available at <https://rosap.ntl.bts.gov/view/dot/199>.

3 After the recommendations, FMCSA began using a new version of the examination form titled Medical Examination Report Form, MCSA-5875. This version does not include The Driver’s Role statement. Therefore, The Driver’s Role statement no longer appears in 49 CFR 391.43, but still appears on the 391.41 CMV Driver Medication Form, MCSA-5895.

- 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 questions:
- a. Question 1—List all medications and dosages that you have prescribed to the above named individual.
 - b. Question 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. Question 3—What medical conditions are being treated with these medications?
 - d. Question 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 physical qualification standards provide this assurance by requiring drivers to be examined and medically certified as physically qualified to drive.

Accordingly, FMCSA developed the 391.41 CMV Driver Medication Form, MCSA-5895.

The purpose of this voluntary collection of information is to assist the certified ME in determining if the driver is physically qualified under 49 CFR 391.41 and if there are disqualifying medical conditions or certain prescribed medications that would adversely affect the driver's ability to drive safely. Section 391.41(b)(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; or does not use any non-Schedule I drug or substance that is identified in the other Schedules in 21 CFR part 1308 except when the use is prescribed by a licensed medical practitioner, as defined in 49 CFR 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 the 391.41 CMV Driver Medication Form, MCSA-5895, is at the discretion of the certified ME and facilitates communication with treating healthcare professionals, who are responsible for prescribing certain medications, so that the certified ME fully understands the reasons the medications have been prescribed. Because the use of the form is voluntary, there is no required collection frequency.

The 391.41 CMV Driver Medication Form, MCSA-5895, may be downloaded from the FMCSA website. Prescribing healthcare professionals can fax or scan and email the report 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 believes that approximately 50 percent

of the 391.41 CMV Driver Medication Forms, MCSA-5895, are transmitted electronically.

The information collected from the 391.41 CMV Driver Medication Form, MCSA-5895, is used by the certified ME who requested the completion of the form and is attached to the Medical Examination Report Form, MCSA-5875, which becomes part of the CMV driver's record maintained by the certified ME. Therefore, the information is not 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 must 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.

Discussion of Comments Received:

In response to the **Federal Register** notice published on July 3, 2019 (84 FR 31980), requesting public comment concerning: 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 burden could be minimized without reducing the quality of the collection information, FMCSA received two comments. One was from the Owner-Operator Independent Drivers Association (OOIDA), and the other one was from an individual. These comments are outlined below, along with FMCSA's responses.

Is the collection necessary for the performance of FMCSA's functions?

OOIDA Comment

OOIDA stated that if this ICR is renewed the number of inconsistencies will continue to grow as certified MEs with no personal relationship with the driver attempt to evaluate years of long-term medication usage. It also stated that the ICR invites second guessing of a primary physician by certified MEs who are empowered by an unreliable medical form and that studies do not show a significant number of CMV operators are crashing due to prescription medication use. OOIDA continued that this ICR will only increase problems its members have already experienced with certified MEs, which have resulted in higher costs and lengthy delays for drivers.

FMCSA Response

Section 391.41(b)(12)(ii) provides that a certified ME may only certify a driver who uses controlled drugs or substances listed on Schedules II through V in 21 CFR part 1308 if the prescribing healthcare professional provides certain information to the certified ME. Interstate CMV drivers are required to use a certified ME listed on the National Registry for their physical qualification examination and certification. Therefore, in many cases the driver is going to a certified ME from whom he or she does not routinely receive healthcare and who is not a healthcare professional prescribing medications for the driver. The 391.41 CMV Driver Medication Form, MCSA-5895, is an optional tool a certified ME can use to communicate with the prescribing healthcare professional who has a relationship with the driver and understands the driver's medical history. The form provides a standardized and efficient way for the certified ME to obtain the information needed to make a more informed medical certification determination. The decision to certify a driver is discretionary and continues to rest with the certifying ME.

FMCSA believes that use of the form should streamline the certification process and minimize the amount of time needed to obtain the necessary information from the prescribing healthcare professional. In addition, 49 CFR 391.43(g)(4) provides a “determination pending category” that allows up to 45 days to complete the certification examination if the certified ME determines additional information is needed. The driver may continue to operate a CMV during this period, as long as the driver has an unexpired MEC.

Individual Comment

This individual stated that the 391.41 CMV Driver Medication Form, MCSA-5895, would not be necessary for every examination because not every driver is taking a medication that would require the certified ME to collect this information. The individual noted that when a driver is using a Schedule II drug or any other drug that may have negative side effects, the information collected aids the certified ME in determining whether or not the driver’s prescribing physician has taken the driver’s role into consideration and standardizes the process.

FMCSA Response

The individual is correct that the form would not be necessary for every examination. The comment supports that the form is useful in the certification process.

Ways for FMCSA to enhance the quality, usefulness, and clarity of the collected information.

Individual Comment

This individual provided the following suggestions for enhancing the quality, usefulness, and clarity of the collected information.

- Add the commercial driver’s license number as an identifier near the driver’s date of birth on the form since this is becoming the primary identifier for CMV drivers across Commercial Driver Medical Exams (CDMEs) and drug screening for FMCSA.
- Consider making this form mandatory during the CDME process for drivers currently taking a Schedule II drug.
- Facilitate use by the prescribing provider by putting the CDME information, date it was initiated, and contact information on page 1, just under the introduction (before the 49 CFR 391.41 excerpt).
- Change wording for precision in question 2 to “...prescribed to the above named individual by any other treating health care provider.”, instead of “... by another treating....”
- Add a comments section for the prescribing provider to use if having difficulty answering “yes” or “no” to question 4, or if has qualification or clarification, etc.
- Consider adding wording to “The Driver’s Role” that indicates:
 - Duties may also include overhead activity such as reaching, or forcefully pushing or pulling (adjusting rear-view mirror, tightening/loosening load straps), and squatting (inspection, on the road maintenance).
 - FMCSA does not allow drivers to be cleared medically for specific jobs or duties; a medically qualified driver must be able to do all aspects of “The Driver’s Role.”

FMCSA Response

Because there is moderate evidence to support the contention that the licit use of opioids increases the risk of motor vehicle crashes and negatively impacts indirect measures of driver performance, FMCSA's MRB and MCSAC recommended 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. As part of their recommendations, they suggested what should be included on the form to assist the certified ME in making a physical qualification determination. FMCSA considered their recommendations and included the necessary information on the form.

FMCSA has considered the suggestions, but does not believe they would enhance the usefulness of the form or serve the purpose for which the form was intended to be used. Adding the driver's license number to the form would provide unnecessary personally identifiable information to the prescribing healthcare professional. The certified ME's contact information is already clearly set forth on page 2 of the form. The use of "by any other," rather than "another," is not likely to create confusion. FMCSA declines to add a comments section to question 4 because unqualified medical opinions are sought. The Driver's Role statement adequately covers the activities suggested. Question 4 states that the medical opinions are to be consistent with The Driver's Role statement, which is sufficient to indicate the entire statement is to be considered.

The Agency also declines to make the use of the form mandatory for Schedule II drugs, which would require a regulatory change to implement. The form was not intended to address only opioids. Moreover, 49 CFR 391.41(b)(12) provides that a certified ME may only certify a driver who uses controlled drugs or substances listed on Schedules II

through V in 21 CFR part 1308 if the prescribing healthcare professional provides certain information to the certified ME. FMCSA has provided the 391.41 CMV Driver Medication Form, MCSA-5895, to be used by certified MEs at their discretion and as a resource in making medical certification determinations of interstate CMV drivers. The use of the form is voluntary. The form is just one way that certified MEs may communicate with prescribing healthcare professionals so that the certified MEs fully understand the reasons the medications have been prescribed. FMCSA encourages certified MEs to use the form as often as they find necessary.

Public Comments Invited: You are asked to comment on any aspect of this IC, including: (1) whether the proposed collection is necessary for the FMCSA to perform its functions; (2) the accuracy of the estimated burden; (3) ways for the 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.

Issued under the authority delegated in 49 CFR 1.87 on: October 31, 2019

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

[FR Doc. 2019-24231 Filed: 11/5/2019 8:45 am; Publication Date: 11/6/2019]