

**Department of Transportation
Federal Motor Carrier Safety Administration**

**Supporting Statement
391.41 CMV Driver Medication Form**

SUMMARY

This supporting statement estimates the burden hours and costs for prescribing healthcare professionals to complete the voluntary *391.41 CMV Driver Medication Form, MCSA-5895*, if requested by a certified Medical Examiner (ME) for commercial motor vehicle (CMV) drivers.

- There have not been any changes to the *391.41 CMV Driver Medication Form, MCSA-5895*.
- The commercial motor vehicle driver population in section 12 has been updated with current numbers from FMCSA's 2021 Pocket Guide to Large Truck and Bus Statistics.
- The prescribing healthcare professional population and wage data in section 12 have been updated with current numbers from the Bureau of Labor Statistics.
- The burden hours and costs in sections 12 and 15 have been updated resulting in an increase of 17,198 in annual burden hours from 262,267 to 279,465 hours and an increase of \$13,285,309 in annual costs from \$27,396,411 to \$49,681,720.

INTRODUCTION

This is to request the Office of Management and Budget's (OMB) renewed three-year approved clearance for the information collection request (ICR) titled, *391.41 CMV Driver Medication Form* (OMB Control No. 2126-0064), which is currently due to expire on April 30, 2023.

Part A. Justification

1. CIRCUMSTANCES THAT MAKE THE COLLECTION OF INFORMATION NECESSARY

The primary mission of the Federal Motor Carrier Safety Administration (FMCSA) is to reduce CMV 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 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.

CMVs (trucks and buses) are longer, heavier, and more difficult to maneuver than automobiles. Not only does it take a skilled driver to operate them safely, it takes a physically qualified driver to do so as well. 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.

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 physical qualification regulations relating to this information collection are found 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 (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 specifies that a medical examination must 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)(12) of title 49 of the CFR provides that a person is medically qualified to operate a CMV if that person “[d]oes 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.

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 negatively², FMCSA’s Medical Review Board (MRB) and Motor Carrier Safety Advisory Committee (MCSAC) recommended that FMCSA develop a standardized medication report to assist the certified ME when reviewing prescription medications that have been disclosed during the history and physical examination for CMV driver certification. They recommended 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:

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].

² *Schedule II Opioids and Stimulants & CMV Crash Risk and Driver Performance: Evidence Report and Systematic Review, October 18, 2014.*

- a. Identifying name and date of birth (DOB) of the CMV driver.
 - b. Introductory paragraph stating purpose of the CMV Driver Medication form.
 - 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*).³
 - d. Name, state of licensure, signature, address, and contact information of the prescribing health care provider, as well as the date the form was completed.
 - e. Name, signature, date, address, and contact information of the certified ME.
3. Questionnaire 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 health care 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.

FMCSA considered the recommendations and developed the *391.41 CMV Driver Medication Form, MCSA-5895*.

This ICR supports the U.S. Department of Transportation (DOT) Strategic Goal of Safety by ensuring that CMV drivers are medically qualified to operate trucks and buses on our nation's highways.

2. HOW, BY WHOM, AND FOR WHAT PURPOSE IS THE INFORMATION USED

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 and mentally qualified to drive.

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. The purpose of the voluntary collection of this information is to enable the certified ME to determine if the driver is physically qualified

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.

under 49 CFR 391.41 and if there are disqualifying medical conditions 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. This voluntary collection allows certified MEs responsible for issuing Medical Examiner's Certificates (MECs) to CMV drivers to communicate with healthcare professionals responsible for prescribing the use of certain medications. The information obtained allows certified MEs to fully understand the reasons the medications have been prescribed and to determine whether the use of the medications and the underlying condition being treated preclude the issuance of an MEC. Because there is moderate evidence to support the contention that the licit use of opioids increases the risk of a motor vehicle crashes and impacts indirect measures of driver performance negatively, the collection of this information assists certified MEs in determining whether a CMV driver is physically qualified to drive a CMV.

Prescribing Healthcare Professional Population

Third-party requirements of this ICR are being considered. Certified MEs will be asking the prescribing healthcare professionals to complete the *391.41 CMV Driver Medication Form, MCSA-5895*, for CMV drivers.

CMV Driver Population

In addition to the population of prescribing healthcare professionals, the population of CMV drivers who certified MEs may ask to have the *391.41 CMV Driver Medication Form, MCSA-5895*, completed by a prescribing healthcare professional, has been calculated. This ICR reflects both interstate drivers subject to the FMCSRs and intrastate drivers subject to compatible State regulations. Although Federal regulations do not require States to comply with the medical requirements in the FMCSRs, most States do mirror the Federal requirements. If intrastate CMV drivers are subject to compatible State regulations, the Agency anticipates that it is likely that these drivers use certified MEs on the National Registry of Certified Medical Examiners (National Registry) for their physical qualification examinations, which may result in certified MEs requesting prescribing healthcare professionals to complete the *391.41 CMV Driver Medication Form, MCSA-5895*.

3. EXTENT OF AUTOMATED INFORMATION COLLECTION

The voluntary *391.41 CMV Driver Medication Form, MCSA-5895*, is available for download from the FMCSA website. Prescribing healthcare professionals can 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 believes that approximately 50 percent of the *391.41 CMV Driver Medication Forms, MCSA-5895*, are transmitted electronically, whereas the other 50 percent of the forms are hand carried by the driver to the ME.

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. Certified MEs are required to maintain records of the CMV driver medical examinations they conduct. FMCSA does not require certified MEs to maintain these records electronically. However, there is nothing to preclude a certified ME from maintaining electronic records of the medical examinations he/she conducts. FMCSA is continuously evaluating new information technology in an attempt to decrease the burden on respondents, drivers, and certified MEs.

4. EFFORTS TO IDENTIFY DUPLICATION

FMCSA is the only Federal agency with the authority to regulate the qualifications of CMV drivers operating in interstate commerce. Therefore, there is no Federal agency duplication. The Paperwork Reduction Act allows for public comment that would provide a means of identifying any duplication that exists.

5. EFFORTS TO MINIMIZE THE BURDEN ON SMALL BUSINESSES

Requiring the treating healthcare professional of the driver to provide the *391.41 CMV Driver Medication Form, MCSA-5895*, to the certified ME does affect medical clinics and practices. As such, there will be some impact on small businesses. However, because this is the driver's treating healthcare professional, it is expected the healthcare professional routinely collects this information. Therefore, it is anticipated that this IC will not have a significant impact on small businesses or require a significant time burden. In addition, the *391.41 CMV Driver Medication Form, MCSA-5895*, is voluntary and has been created to streamline the process and to only capture the data that is absolutely necessary in determining the physical qualification of CMV drivers.

6. IMPACT OF LESS FREQUENT COLLECTION OF INFORMATION

The use of this ICR is at the discretion of the certified ME to facilitate communication with treating healthcare professionals, who are responsible for prescribing certain medications, to fully understand the reasons the medications have been prescribed. This information assists the certified ME in determining whether the underlying medical condition and the prescribed medication will adversely affect the driver's safe operation of a CMV. Therefore, there is no required collection frequency. 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, the MRB and MCSAC recommended that FMCSA develop a voluntary and 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.

7. SPECIAL CIRCUMSTANCES

There are no special circumstances related to this ICR.

8. COMPLIANCE WITH 5 CFR § 1320.8

FMCSA published the notice announcing its intention to submit this Information Collection renewal request to OMB on September 8, 2022 (87 FR 55077). A summary of the one comment received in response to the 60-day notice and the Agency's response follows. FMCSA published a 30-day comment request Federal Register notice for this ICR on February 3, 2023, (88 FR 7514).

Discussion of comment received

The NTSB supports the renewal of the IC, but suggested FMCSA revise the IC to make it a significantly more effective evaluation tool. It specifically recommended the following:

- Revise the 391.41 CMV Driver Medication Form, MCSA-5895, to include all medications (prescriptions, non-prescriptions, supplements) that the provider is aware the driver uses and all medical conditions that the provider is aware the driver has, regardless of whether those conditions are treated with medications.
- Do not limit the IC to cases with known potentially impairing medications by removing the sentence on the form that states, "During the medical evaluation, it was determined this individual is taking medication(s) that may impair his/her ability to safely operate a CMV."
- Clarify what is being asked of responding providers by removing all reference to regulations from the instructions and clarifying that the responding provider is expected only to list medications/medical conditions and to give a medical opinion on safety, not to apply medical certification standards, which is the responsibility solely of the ME.
- Enable responding providers to give complete medical opinions by revising item 4 to ask the responding provider's medical opinion about whether any of the driver's known medications or medical conditions pose a risk to safe CMV operation, to provide the item with a third response option ("yes/no/unsure"), and to include a field for any clarifying comments.

FMCSA Response

FMCSA considered the NTSB's comments but does not believe its recommendations would enhance the quality, usefulness, and clarity of the form based on the purpose for which the form was intended to be used. The 391.41 CMV Driver Medication Form, MCSA-5895, was developed and intended to be used as a tool to supplement the information obtained from the Medical Examination Report Form, MCSA-5875, the driver during the ME's review of the driver's health history, and from the physical examination conducted by the ME. The Medical Examination Report Form, MCSA-5875, already provides the ME with a complete health history of the driver including all current medications (prescriptions, non-prescriptions, supplements) and medical conditions as reported by the driver.

The 391.41 CMV Driver Medication Form, MCSA-5895, specifically addresses medication(s) that may impair the driver's ability to safely operate a CMV so that the ME fully understands the reasons the medications have been prescribed and can consider the impact the medication(s) and medical conditions for which the medication(s) has been prescribed may have on the driver. This information combined with the information obtained from the Medical Examination Report Form, MCSA-5875, the driver during the ME's review of the driver's health history, and the physical examination conducted by the ME, is used by the ME when making a physical qualification determination.

The 391.41 CMV Driver Medication Form, MCSA-5895, contains information regarding the driver's role and regulation in 49 CFR 391.41(b)(12) as a reference for healthcare professionals and does not indicate that the healthcare professional must interpret the regulation. The 391.41 CMV Driver Medication Form, MCSA-5895, clearly states what is and is not expected of from the healthcare professional completing the form by requesting the healthcare professional review the regulation provided, complete the form, and return it to the ME. The form explains that the final determination as to whether the individual listed on the form is physically qualified to drive a CMV will be made by the certified ME. Question 4 was specifically intended to obtain the medical opinion of the healthcare professional completing the form regarding the specific medication(s) they have prescribed to the driver for a particular medical condition(s). It is the responsibility of the ME to use the information provided by the healthcare professional completing the 391.41 CMV Driver Medication Form, MCSA-5895, as a tool to assist them in making a physical qualification determination.

9. PAYMENTS OR GIFTS TO RESPONDENTS

With the possible exception of payments for professional services by healthcare professionals, respondents to this ICR do not receive any payments or gifts.

10. ASSURANCE OF CONFIDENTIALITY

All information collected as part of this ICR is information that is retained by the certified ME conducting the CMV driver physical qualification examination. All medical records are kept confidential by certified MEs listed on the National Registry. Certified MEs are required to maintain and disclose medical information and personally identifiable information in accordance with applicable Federal and State privacy laws.

FMCSA does not routinely request or maintain the *391.41 CMV Driver Medication Form, MCSA-5895*. If FMCSA requests a *391.41 CMV Driver Medication Form, MCSA-5895*, from a certified ME, the form would be retained by FMCSA in accordance with the requirements of the Privacy Act of 1974. All information collected is protected by reasonable security safeguards against loss or unauthorized access, destruction, usage, modification, or disclosure. These safeguards incorporate standards and practices required for Federal information systems under the Federal Information System Management Act and are detailed in Federal Information Processing Standards Publication 200, Minimum Security Requirements for Federal Information

and Information Systems, NIST Special Publication 800-53, Rev. 4, Security and Privacy Controls for Federal Information Systems and Organizations, dated April 30, 2013. FMCSA has a comprehensive information security and privacy program that contains management, operational, and technical safeguards that are appropriate for the protection of the information collected.

11. JUSTIFICATION FOR COLLECTION OF SENSITIVE INFORMATION

The medical examination process requires the certified ME to inquire about aspects of driver physical and mental health, including history of frequent alcohol use, and illicit and licit drug use or habit-forming medication use. CMV drivers give consent to the collection of this information by signing the *Medical Examination Report Form, MCSA-5875*, prior to the examination.

12. ESTIMATE OF BURDEN HOURS FOR INFORMATION REQUESTED

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 of 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, resulting in a required collection of information about the physical qualification of CMV drivers. The information is collected through the physical qualification examination of the CMV driver and supporting physical qualification records. Use of the *391.41 CMV Driver Medication Form, MCSA-5895*, is voluntary and at the discretion of the certified ME.

Population of Prescribing Healthcare Professionals

There are an estimated 1,163,160⁴ healthcare professionals who are allowed to prescribe certain medications that may be affected by this IC. This includes those healthcare professionals responsible for prescribing the use of certain medications to up to 6.5 million CMV drivers. The Agency recognizes that using the 1,163,160 as the baseline number of prescribing healthcare professionals may be a high estimation but is using information obtained from the Bureau of Labor Statistics.

Population of CMV Drivers

In addition to the population of prescribing healthcare professionals, the population of CMV drivers who certified MEs may ask to have the *391.41 CMV Driver Medication Form, MCSA-5895*, completed by a prescribing healthcare professional, has been calculated to determine the estimate of burden hours and costs for this IC. This number includes interstate drivers subject to the FMCSRs and intrastate drivers subject to compatible State regulations. Although Federal regulations do not require States to comply with the medical requirements in the FMCSRs, most States do mirror the Federal requirements. If intrastate CMV drivers are subject to compatible State regulations, the Agency anticipates that it is likely that these drivers will use certified MEs

⁴[https://www.bls.gov/oes/current/oes_nat.htm#\(5\)](https://www.bls.gov/oes/current/oes_nat.htm#(5)).

on the National Registry for their physical qualification examinations, which may result in certified MEs requesting prescribing healthcare complete the *391.41 CMV Driver Medication Form, MCSA-5895*, for these drivers.

There are approximately 6.5 million CMV drivers⁵ subject to FMCSA’s physical qualification standards. Periodic evaluation and certification is required to assess driver physical qualification, due to the potential for onset of new conditions or changes in existing conditions that may adversely affect a driver’s ability to drive safely and/or cause incapacitation that could be a risk to public safety. An MEC can be issued for up to 2 years. However, drivers with certain medical conditions must be certified more frequently than every 2 years and certified MEs have discretion to certify for shorter time periods. Halving the number of drivers underestimates the total number of examinations that are conducted annually as various other reasons may mean that drivers need to be examined more frequently. As a result of these exceptions to the biennial medical certification schedule, the Agency estimates that the actual number of physical qualification examinations conducted annually is 40.20 percent greater than would be the case if all drivers were only examined biennially. Therefore, the Agency estimates that approximately 4,556,500 examinations are conducted annually (6.5 million/2 x 40.20%).

According to the 2015 National Survey on Drug Use and Health (NSDUH), an estimated 46 percent of Americans 18 or older used psychotherapeutics of any kind, consisting of prescription pain relievers (38 percent), tranquilizers (16 percent), sedatives (7 percent), or stimulants (6 percent) in the last year.⁶ These drugs are controlled substances listed on Schedules II, III, and IV (see 21 CFR 1308.11-1308.14). Therefore, the Agency utilized this data by multiplying the number of CMV driver examinations conducted annually, 4,556,500, by 46 percent, resulting in 2,095,990 drivers that certified MEs may ask to have a *391.41 CMV Driver Medication Form, MCSA-5895*, completed on an annual basis. The Agency recognizes that using the estimated 46 percent for the number of Americans 18 or older who used controlled substances in the past year is an overestimate because it would include one-time users.

Population of CMV Drivers

Baseline – Total CMV Drivers to have Form Completed
2,095,990 ⁷

⁵FMCSA. 2021. Pocket Guide to Large Truck and Bus Statistics. Available at <https://www.fmcsa.dot.gov/sites/fmcsa.dot.gov/files/2022-01/FMCSA%20Pocket%20Guide%202021.pdf>.

⁶Table B-2 Source: Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, 2015, available at <https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR2-2015/NSDUH-FFR2-2015.htm>.

⁷ 4,556,500 annual CMV driver examinations x 46 percent.

Population of Prescribing Healthcare Professionals

Baseline – Total Prescribing Healthcare Professionals Completing Forms
1,163,160

Prescribing Healthcare Professionals Task

Task	Time to Complete Task
Complete and provide form to certified ME	8 minutes

FMCSA estimates that it takes the prescribing healthcare professional 8 minutes to complete and provide the *391.41 CMV Driver Medication Form, MCSA-5895*, to the certified ME.

Prescribing Healthcare Professional Annual Burden Hours and Salary Costs to Complete and Provide Form to the Certified ME

Hourly wage of prescribing healthcare provider	Number of CMV drivers who may need to have form completed	Time for prescribing healthcare professional to complete and provide form to certified ME	Total annual burden hours for prescribing healthcare professional to complete and provide form to certified ME	Total annual salary costs for prescribing healthcare professional to complete and provide form to certified ME
\$145.57 ⁸	2,095,990	8 minutes	279,465	\$40,681,720

Annual Burden Hours: 279,465 hours (2,095,990 CMV drivers that may need form completed by prescribing healthcare professionals x 8 minutes/60 minutes = 279,465 rounded to the nearest whole hour)

Annual Number of Respondents: 1,163,160 (1,163,160 prescribing healthcare professionals)

Annual Number of Responses: 2,095,990 (2,095,990 forms completed)

13. ESTIMATE OF TOTAL ANNUAL COSTS TO RESPONDENTS

There are no additional annual costs or non-related wage costs to the respondents.

14. ESTIMATE OF COST TO THE FEDERAL GOVERNMENT

There is no cost to the Federal government. FMCSA does not routinely request or process the form and information collected. There are no IT costs, or Federal or contractor staff costs, to collect, review, and maintain the information being collected.

15. EXPLANATION OF PROGRAM CHANGES OR ADJUSTMENTS

⁸ [https://www.bls.gov/oes/current/oes_nat.htm#\(5\)](https://www.bls.gov/oes/current/oes_nat.htm#(5)).

Program adjustment – due to updated population and wage data.

As a result of the above updates, the annual burden hours have increased by 17,198 hours (262,267 to 279,465) and the annual costs have increased by \$13,285,309 (\$27,396,411 to \$40,681,720).

Current Approved Annual Burden Hours for the IC	262,267
Proposed Annual Burden Hours	279,465
Total Increase in Annual Burden Hours from Current Approved Annual Burden Hours	17,198

16. PUBLICATION OF RESULTS OF DATA COLLECTION

This information is not published.

17. APPROVAL FOR NOT DISPLAYING THE EXPIRATION DATE OF OMB APPROVAL

No such approval is requested.

18. EXCEPTIONS TO CERTIFICATION STATEMENT

There are no exceptions to the certification statement.