Department of Transportation
Office of the Chief Information Officer

Supporting Statement
391.41 CMV Driver Medication Form

INTRODUCTION

This is to request the Office of Management and Budget's (OMB) approval of a new information collection request (ICR) entitled, *391.41 CMV Driver Medication Form*. This information collection request (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 to communicate with treating healthcare professionals who are responsible for prescribing certain medications, to fully understand the reasons the medications have been prescribed. The information obtained by utilizing the IC will assist the ME in determining whether the underlying medical condition and the prescribed medication will impact the safe operation of a CMV.

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 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.

CMVs are by their nature a threat to highway safety if not operated properly by qualified individuals. 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 and mentally fit 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 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(b)(12) provides that a person is medically qualified to operate 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 CFR 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) considered 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 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 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 considered 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. However, FMCSA revised the task of the MRB instructing them to review an updated evidence report and the Medical Expert Panel 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 relating 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[1], included was the recommendation that FMCSA develop a standardized medication report to assist the certified ME when reviewing prescription medications that have been

1 Schedule II Opioids and Stimulants & CMV Crash Risk and Driver Performance Evidence Report and Systematic Review, October 18, 2014

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:
    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)*.
    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.

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 medical 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 driver medical fitness must be collected in order for our highways to be safe. The purpose for the voluntary collection of this information is to enable

the ME to determine 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. Therefore, this new collection will ensure that certified MEs responsible for issuing MECs to CMV drivers communicate with healthcare professionals responsible for prescribing the use of certain medications to fully understand the reasons the medications have been prescribed and determine whether the use of the medications and the underlying condition being treated preclude the issuance of a 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 will assist certified MEs in determining whether a CMV driver is physically qualified to drive a CMV.

Prescribing Healthcare Provider Population[2]

Third-party requirements of this ICR are being considered. The baseline number of healthcare professionals, 1,082,200[3] covered by this ICR includes those healthcare providers responsible for prescribing the use of certain medications to 5.6 M CMV drivers[4], 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 Federal compatible State regulations, the Agency anticipates that it is likely that these drivers will use certified MEs on the National Registry for their medical qualification examinations which may result in certified MEs requesting prescribing healthcare providers to complete the Form MCSA-5895, "*391.41 CMV Driver Medication Form*," on the FMCSA website The Agency recognizes that using the 1,082,200 baseline number of prescribing healthcare providers may be a high estimation but is using the information obtained from the Bureau of Labor Statistics.

3. EXTENT OF AUTOMATED INFORMATION COLLECTION

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 form 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.

2 http://www.deadiversion.usdoj.gov/pubs/manuals/pract/section5.htm
3 http://www.bls.gov/news.release/pdf/ocwage.pdf
4 FMCSA 2014 Pocket Guide to Large Truck and Bus Statistics

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. FMCSA does not require MEs to maintain these records electronically. However, there is nothing to preclude a 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 motor carriers and 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 Administrative Procedures Act allows for public comment which would provide a means of identifying any duplication that exists.

5. EFFORTS TO MINIMIZE THE BURDEN ON SMALL BUSINESSES

This ICR does impact CMV drivers, MEs, and the firms that employ them, many of them considered small entities. The *391.41 CMV Driver Medication Form* is voluntary and was created by FMCSA's MRB who streamlined the process to only capture data that was absolutely necessary in determining the medical qualification of CMV drivers. In addition, this is information that the certified ME should already be collecting from the driver through the health history section of the MER.

6. IMPACT OF LESS FREQUENT COLLECTION OF INFORMATION

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 to fully understand 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. 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's MRB and MCSAC provided recommendations to FMCSA based on presentations on the licit use of Schedule II medications, the *Schedule II Opioids and Stimulants & CMV Crash Risk and Driver Performance: Evidence Report and Systematic Review*, and MEP opinions. FMCSA partnered with Acclaro Research Solutions, Inc. to conduct a systematic review of the literature and to identify relevant studies addressing how the licit use of prescribed schedule II opioids and stimulants may impact the risk of CMV crashes or indirect measures of CMV driver performance. Acclaro convened a MEP to discuss and review the findings.

On November 25, 2015 (80 FR 73871), FMCSA published a notice in the Federal Register with a 60-day public comment period to announce this proposed information collection request. A summary of the 14 comments received in response to this notice and the Agency's responsive considerations are also provided in the 30-day comment request Federal Register notice issued on July 8, 2016 (81 FR 44675), for this ICR and is as follows:

Overview of Comments

In response to the Federal Register notice published on November 25, 2015, requesting public comment concerning the necessity of the proposed IC, the accuracy of the estimated burden, how the quality of collected information could be enhanced, and ways in which the burden could be minimized without reducing the quality of the collected information (80 FR 73871), FMCSA received 14 comments. The commenters included certified MEs, CMV drivers, training organizations, the American Trucking Association (ATA), the Owner-Operator Independent Drivers Association (OOIDA), and the American College of Occupational and Environmental Medicine (ACOEM).

The first area of comments involved the effectiveness of the 391.41 CMV Driver Medication Form. The second area of comments discussed the burden hours and costs. The final area of comments were issues that were considered outside the scope of this ICR and the optional use of the 391.41 CMV Driver Medication Form. These comments will be briefly summarized with an explanation as to why the issues raised are not within the scope of this notice.

Five commenters expressed support for the ICR and two commenters explicitly opposed the ICR. The remaining seven neither supported nor opposed the ICR, but raised concerns or provided suggestions for changes to the optional form.

The following sections provide details regarding specific issues raised by the commenters.

Effectiveness of the *391.41 CMV Driver Medication Form*

ACOEM acknowledged that the current process used by MEs is clearly inadequate but also feels that the form falls far short of being able to adequately assess whether a driver will be impaired by medications or an underlying medical condition. They also stated that many healthcare providers do not fully understand the safety risks and responsibilities of the CMV driver and

would rely on the patient's statement that the medication does not impair the driver's ability to safely operate a CMV. Therefore, they believe that the prescribing healthcare provider statements would not be reliable. ACOEM also believes that the form does not go far enough to address the use of opioids by drivers and the rapid increase in adverse effects of opioid use and suggests that FMCSA strive for a form that becomes the standard of practice that requires the treating provider and the ME to be aware of medications and conditions, including opioid use.

Others commented that some physicians have no problem stating that their patient is safe to drive a CMV while taking these medications leaving the ME that disagrees and is not willing to issue the driver a MEC with a driver that is angry based on the differing opinions. OOIDA stated that the form would be a direct challenge to the treating physician according to 391.41(b)(12)(ii) that states "A person is physically qualified to drive a commercial motor vehicle if that person 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 392.107, 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 commercial vehicle." They believe that this form challenges the opinion of the driver's treating physician and puts it in the hands of a stranger with no knowledge of the driver's background and who is unfamiliar with the driver's medical history.

FMCSA response

FMCSA is providing the 391.43 CMV Driver Medication Form at the request of MEs to be used at their discretion, and as a resource for assisting MEs in making medical certification determinations of interstate CMV drivers. Use of the form is voluntary and MEs may do so in an effort to communicate with treating healthcare providers who are responsible for prescribing certain medications, so that the ME fully understands the reasons the medications have been prescribed. Information about the driver's role was specifically added to the form to assist those healthcare providers that do not fully understand the safety risks and responsibilities of the CMV driver and in an effort to obtain reliable data. The form was specifically designed to address any medications that a driver is taking that may impair his/her ability to safety operate a CMV and was not intended to address only opioids.

The information obtained by the ME when utilizing the optional 391.41 CMV Driver Medication Form 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 the driver's safe driving ability or cause incapacitation constituting a risk to the public. The decision to certify a driver is a discretionary decision that rests with the certifying ME. MEs may disqualify a driver who takes any medications or combination of medications and substances that may impair or interfere with safe driving practices.

Burden Hours and Costs

Several commenters expressed concern that prescribing healthcare providers would not respond in a timely manner or at all, and that delays would be costly to drivers and motor carriers. ATA stated that FMCSA should consider the impact of potential delays to driver recertification, because the form does not advise prescribing healthcare providers to complete and return the form to the requesting ME within a specific timeframe, nor does it require MEs to certify a driver who is medically qualified even in the absence of the completed form. They expressed concern that the lack of such language could result in unnecessary and costly delays that would penalize qualified drivers due to circumstances that are out of their control. ATA recommended that if a prescribing healthcare provider is unable to return the form to a ME in a timely manner, FMCSA should advise MEs to continue to use their own judgement and certify drivers in these circumstances if they find them to be medically qualified.

Others commented that MEs will find the proposed form to be too restrictive and excessive explaining that although a full list of medications seems to be a good idea, it could significantly increase the effort required by the prescribing healthcare providers which is counterproductive to obtaining their assistance. Suggestions were made to ask the prescribing healthcare provider a single question such as is the driver taking any other medications that may be a risk to safe driving, to list only those medications that would negatively affect the ability of the driver to safely operate a CMV, or to only ask about medications that are of concern that the patient reported. Dr. Michael Megehee recommended including a statement that FMCSA guidelines require the ME to ask the prescribing healthcare provider for assistance in determining whether the driver is safe to operate a CMV and they meet the FMCSRs and that although the ME considers the opinions of treating physicians, the ME is responsible for making the final medical qualification determination.

ATA stated that while this IC may be a useful tool to many MEs in determining whether a driver is medically qualified, in certain cases, it will not always be necessary. They believe that in most situations, the ME should be able to verify the accuracy of the information provided by the driver and the need for the medication based upon their training and experience in performing medical examinations and a robust conversation with the driver. They suggested that to avoid any unnecessary and costly delays to drivers and carriers alike, FMCSA should emphasize to MEs that the form is strictly voluntary and not a de facto standard when performing medical examinations. They also suggested that the form be consistent with the newly revised MER Form, MCSA-5875 by limiting its inquiry into medications that the driver is currently prescribed and that the prescribing healthcare provider should only report those medications that they can confirm have been prescribed. They stated that asking for all prescribed medications imposes a burden on healthcare providers without any significant positive impact on safety and suggested asking healthcare providers to list those medications that a driver is currently prescribed and would negatively affect their ability to safely operate a CMV will dramatically limit the collection burden without diminishing the quality of the information being collected.

OOIDA stated that there will be an increase in the number of inconsistencies in the medical certification process as MEs with no personal relationship with the driver attempt to evaluate a great deal of long-term medication usage. They stated that the proposed use of the 391.41 CMV

Driver Medication Form invites second guessing of a primary physician by MEs who are empowered by an unreliable medical form and that it invites the ME to question every medication and dosage which has been previously prescribed. They feel that this IC will only increase problems drivers have already experienced with MDs, which have resulted in higher costs and lengthier delays for drivers. Ultimately, they stated that the IC will lead to higher costs and longer wait times for drivers as they complete the examination with a ME and that it is already a common occurrence for the ME to conduct excessive testing beyond what is required under the current medical examination form. OOIDA points out that the IC is not limited to Schedule II drugs and could include items with no perceptible link to the safe operation of a CMV and believes that requesting an unlimited amount of information is not helpful to determining a driver's fitness to operate a CMV and that there is no need to require a listing of any prescribed drugs beyond those regulated by 382.213: Controlled substance use.

FMCSA response

FMCSA does not believe that the form will add any time to the certification decision nor is it necessary to advise the ME to make a certification decision at any specified time after sending the 391.41 CMV Driver Medication Form to the prescribing healthcare provider. In addition, the Medical Examiner's Certification Integration final rule provides a determination pending category that allows the driver to continue to operate a CMV as long as the driver has an unexpired MEC, for a maximum of 45 days, if the ME needs additional information to make a certification decision making additional delays unlikely.

As previously stated, the form was specifically designed to address any prescription medications that a driver is taking that may impair his/her ability to safely operate a CMV. Therefore, the Agency does not believe that the form is too restrictive or excessive nor will it significantly increase the effort required by the prescribing healthcare providers. Instead, the Agency believes that the form will be a useful resource for MEs in making a medical certification decision of drivers that are taking prescribed medications.

Because the prescribing healthcare provider is not trained regarding the FMCSRs and may not be a certified ME, FMCSA does not believe that asking the prescribing healthcare provider a single question such as is the driver taking any other medications that may be a risk to safe driving, to list only those medications that would negatively affect the ability of the driver to safely operate a CMV, or to only ask about medications that are of concern that the patient reported would provide reliable information to assist the ME in making a medical certification decision. FMCSA is not requiring MEs to use the 391.41 CMV Driver Medication Form, use of the form is completely voluntary. Therefore, it would not be appropriate to add a statement that FMCSA is requiring MEs to ask the prescribing healthcare provider for assistance in determining whether the driver is safe to operate a CMV and that they meet the FMCSRs. The fact that the ME is responsible for making the final medical certification determination is stated on the form.

FMCSA continues to emphasize that the 391.41 CMV Driver Medication Form is optional and may be used at the discretion of the ME as a resource for the ME to communicate with

prescribing healthcare providers, enabling the ME to make a more informed medical certification determination. When used, this form will supplement the MER Form, MCSA-5875 by asking for all medications that the prescribing healthcare provider has prescribed and any other medications that they are aware have been prescribed by another treating healthcare provider, and was designed to address any prescription medications that a driver is taking that may impair his/her ability to safety operate a CMV. The Agency does not feel that asking for all medications prescribed on this optional form imposes a burden on healthcare providers without any significant positive impact on safety and that limiting the collection to only medications that a driver is currently prescribed that the prescribing healthcare provider feels would negatively affect their ability to safely operate a CMV would diminish the quality of the information being collected.

Interstate CMV drivers are required to use a certified ME listed on the National Registry for their medical examination and certification. Therefore, in many cases the driver is going to a ME that they do not have a personal relationship with. The use of the optional 391.41 CMV Driver Medication Form does not change this fact nor does it have a negative impact. The 391.41 CMV Driver Medication Form is a tool to collect information that the MEs already collect at their discretion when performing driver examinations. This optional form will serve as a resource for the ME to use in communicating with prescribing healthcare providers, enabling the ME to make a more informed medical certification determination. The decision to certify a driver is a discretionary decision that continues to rest with the certifying ME. As previously stated, MEs may disqualify a driver who takes any medications or combination of medications and substances that may impair or interfere with safe driving practices.

Issues Outside the Scope of this Notice

A number of respondents submitted comments on topics that were outside the scope of what was proposed in this notice. This notice specifically requested comments related to the proposed IC and optional form to be used as an IC tool.

Schedule II Medication Use

OOIDA disputed the fact that there is moderate evidence of increased risk due to Schedule II drug use and stated that the paucity of data shows that few CMV drivers have had problems with licit Schedule II drug use, or even prescription medications. They also stated that studies do not show that a significant number of CMV operators are crashing due to prescription medication use and that because insufficient data exists regarding the use of Schedule II drugs by CMV drivers should be an indication to the MRB and FMCSA that there are very few CMV drivers who have had problems with licit Schedule II drug usage.

Dr. Kurt T. Hegmann stated that this form should not be adopted for opioids/Schedule II medications, because this form is not evidence-based, not validated, there is no objective test to figure out who is unsafe and will crash if using opioids/Schedule II medications, and the form will cause a false sense of security that both endorses narcotics-using truck drivers and a method

to sign the form to approve them to drive under the influence, and is likely to inadvertently further increase fatalities. He also stated that the form appears to evade the FDA-supported advice on opioid prescription labels that uniformly warn against vehicle operation and suggested we adopt the 2006 MEP recommendation to eliminate the potential exception that a prescriber who thought someone could driver, would be allowed to driver on opioids. Dr. Hegamann believes that this form will not help the Agency meet its primary mission. Instead he states that individuals using opioids should not drive trucks and instead should be tapered and/or de-toxed and then resume driving off those medications.

On the other hand, ACOEM, stated that the form does not go far enough to address the use of opioids by drivers and the rapid increase in adverse effects of opioid use. They pointed out that the original proposed version of this form goes back to the 2006 Schedule II Medication Panel and had significantly more content, which would have given the treating provider and the ME a clearer understanding of the impairment risks of the medications. They suggested any form incorporate some of the recommendations from the MRB and MCSAC joint Task 14-3: Schedule II Controlled Substances and CMV Drivers including the recommendation that a driver should not be medically qualified to operate a CMV while he/she is under treatment with narcotics or any narcotic derivative without exception. They go on to explain that because the current exception remains in the FMCSRs (40 CFR 391.41(b)(12)(ii), they recommend guidelines be provided to MEs regarding the use of narcotics.

FMCSA Response

Although optional use of the 391.41 CMV Driver Medication Form was introduced as a result of the MRB and MCSAC recommendations related to the use of Schedule II medications by CMV drivers, the recommendation was for FMCSA to develop a standardized form to assist the certified ME when reviewing prescription medications that have been disclosed during the history and physical examination for CMV driver certification. Therefore, the form was not designed to specifically address Schedule II medications. The form was designed to address any prescription medications that a driver is taking that may impair his/her ability to safety operate a CMV. FMCSA is not considering a change in the regulations or guidance that would prohibit or advise the ME regarding Schedule II medications at this time. Therefore, these comments are outside of the scope of this notice.

Qualifications of the ME

Several commenters stated that a ME might not be qualified to make a medical qualification decision if the driver uses Schedule II medications, because of a lack of training in pharmacology.

OOIDA stated that the personal physician is best equipped to review a driver's medical history and suggested that a personal physician be the one to review the driver's medical history and make the decision whether a medication will adversely affect the driver's ability to safely operate a CMV.

Dr. Hegmann advocated for implementation of the MRB's recommendation that ME eligibility be limited to those medically trained (i.e., MD, DO, PA and NPs). He stated that the concept that these medically untrained examiners can make an informed judgment about driver impairment from narcotics, assess how opioids may interact with other medications, provide guidance to truck drivers, and judge fitness to drive is factually false. Dr. Hegmann feels that FMCSA does not rely on recommendations of the MRB and will selectively use whichever source of guidance is least restrictive which is directly contrary to the central, stated purpose of the Agency.

FMCSA Response

FMCSA responded to the question of who is qualified to be a ME in the National Registry of Certified Medical Examiners final rule (77 FR 24106, April 20, 2012), and is not considering a change to the regulation in 49 CFR 390.103, Eligibility requirements for medical examiner certification in this notice. Therefore, these comments are outside the scope of this notice.

9. PAYMENTS OR GIFTS TO RESPONDENTS

Respondents to this ICR do not receive any payments or gifts.

10. ASSURANCE OF CONFIDENTIALITY

All information that will be collected as part of this ICR is information that will be retained by the ME conducting the CMV driver medical examination.

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.

All medical records are kept confidential. The information is retained by FMCSA in accordance with the requirements of the Privacy Act of 1974. FMCSA, in accordance with 49 CFR § 391.51 and 398.3, requires the MEC that contains limited information (i.e.. driver identification, whether or not medically qualified, and variance information) or a copy of the MVR obtained from the SDLA and a note regarding verification of the national registry number on the MEC to be kept in the driver's qualification file maintained by the motor carrier.

11. JUSTIFICATION FOR COLLECTION OF SENSITIVE INFORMATION

The medical examination process requires the 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 (MER) Form prior to the examination.

12. ESTIMATE OF BURDEN HOURS FOR INFORMATION REQUESTED

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 medical examination of the CMV driver and supporting physical qualification records.

There are an estimated 1,082,200[5] healthcare providers prescribing certain medications that may be affected by this IC. This includes those healthcare providers responsible for prescribing the use of certain medications to 5.6 M CMV drivers, 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 Federal compatible State regulations, the Agency anticipates that it is likely that these drivers will use certified MEs on the National Registry for their medical qualification examinations which may result in certified MEs requesting prescribing healthcare providers to complete the MCSA-5895, "*391.41 CMV Driver Medication Form*." The Agency recognizes that using the 1,082,200 baseline number of prescribing healthcare providers may be a high estimation but is using the information obtained from the Bureau of Labor Statistics.

Population of Prescribing Healthcare Providers

Baseline – Total Prescribing Healthcare Providers in U.S.
1,082,200

Prescribing Healthcare Provider Task

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

FMCSA estimates that it will take the prescribing healthcare provider 8 minutes to complete and provide the MCSA-5895, "*391.41 CMV Driver Medication Form,*" to the certified ME. In

5 http://www.bls.gov/news.release/pdf/ocwage.pdf

addition, as a standard medical practice, the prescribing healthcare provider will need to obtain the CMV driver's signature to be able to release the requested medical information.

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

Hourly wage of prescribing healthcare provider	Number of prescribing healthcare providers in the U.S.	Time for prescribing healthcare provider to complete and provide form to Certified ME	Total annual burden hours for prescribing healthcare provider to complete and provide form to Certified ME	Total annual salary costs for prescribing healthcare provider to complete and provide form to Certified ME
$104.84[6]	1,082,200	8 minutes	144,293	$15,127,678

Annual Burden Hours: 144,293 hours (1,082,200 prescribing healthcare providers x 8 minutes/60 minutes = 144,293)
Annual Number of Respondents: **1,082,200** (1,082,200 prescribing healthcare providers)
Annual Number of Responses: 1,082,200 (1,082,200 forms completed)

13. ESTIMATE OF TOTAL ANNUAL COSTS TO RESPONDENTS

There are no additional annual costs to respondents other than the respondents' salary costs associated with the burden hours discussed above.

14. ESTIMATE OF COST TO THE FEDERAL GOVERNMENT

The cost to the Federal government is minimal because FMCSA does not receive or process the form and information collected.

15. EXPLANATION OF PROGRAM CHANGES OR ADJUSTMENTS

This program change increase of an estimated 144,293 annual burden hours is due to a new ICR that will be used by medical examiners (MEs) to communicate with health care professionals who are responsible for prescribing certain medicines, so that the ME fully understands the reasons why the medications have been prescribed.

16. PUBLICATION OF RESULTS OF DATA COLLECTION

This information would not be published.

6 http://www.bls.gov/news.release/pdf/ocwage.pdf

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.