Department of Transportation Office of the Chief Information Officer

SUPPORTING STATEMENT MEDICAL QUALIFICATION REQUIREMENTS

Introduction: The purpose of this Supporting Statement is for the Federal Motor Carrier Safety Administration (FMCSA) to request the Office of Management and Budget's (OMB) approval to revise an information collection (IC) entitled, "Medical Qualification Requirements," covered by OMB Control Number 2126-0006, which is currently due to expire on May 31, 2010. This revision is due to the Agency's development of a notice of proposed rulemaking (NPRM) entitled, "National Registry of Certified Medical Examiners (NRCME)," (73 FR 73129), December 1, 2008 that would require medical examiners who conduct medical examinations for interstate commercial motor vehicle (CMV) drivers to be certified by FMCSA. This certification would require medical examiners to: (1) be familiar with FMCSA's physical qualification standards; (2) pass a certification test; and (3) maintain competence through periodic retraining and retesting. Medical examiners would be required to submit demographic and eligibility data in order to apply to take the certification test. The NPRM also requires medical examiners to provide: (1) FMCSA with certain information about completed Medical Examination Reports of CMV drivers; and (2) authorized representatives of FMCSA or authorized federal, State or local enforcement agency representatives with copies of Medical Examination Reports and medical examiner's certificates.

Part A. Justification.

1. Circumstances that make the collection of information necessary:

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 also takes a physically and mentally fit driver to do so. Information on driver medical fitness must be collected in order for our highways to be safe. The FMCSA is the Federal government agency that is authorized to require the collection of this information, and the authorizing regulations are located at 49 CFR §§ 390-399 (See Attachment A).

Section 391.41 of title 49, CFR, sets forth the medical standards that almost all CMV drivers in interstate commerce must meet, with the exception of drivers of migrant workers (who must meet the medical standards in 49 CFR § 398.3). The regulations on keeping records for driver medical qualifications are found at 49 CFR § 391.43, which specify that a physical examination be performed on CMV drivers who operate in interstate commerce. The results of the examination shall be recorded in accordance with the requirements in the section.

If two medical examiners disagree about the medical certification of a driver, the requirements at 49 CFR § 391.47 mandate a third medical examiner's opinion. The third medical examiner is an impartial medical expert whose participation to give a medical opinion is mutually agreed upon by the driver and motor carrier. If there is disagreement on the opinion by either party, 49 CFR § 391.47 provides a procedure for submitting an application to the FMCSA for resolution of the medical conflict.

The provisions of 49 CFR §§ 391.51 and 398.3 require that a motor carrier retain the medical qualification certificate in the driver's qualification file for 3 years. The certificate affirms that the driver is medically qualified to drive a CMV in interstate commerce.

Persons who are not medically qualified to drive under section 391.41 due to a limb impairment must file an application for, and be issued, a skill performance evaluation (SPE) certificate (formerly a limb waiver) to be qualified. This is specified in 49 CFR § 391.49. The application must be submitted to the appropriate FMCSA service center in which the driver has legal residence. If the application is submitted jointly by the person (driver applicant) who seeks the SPE certificate and by the motor carrier who will employ the driver applicant, the application must be submitted to the FMCSA service center where the motor carrier sprincipal place of business is located. If the SPE certificate is granted by the FMCSA, the motor carrier must retain a copy of it in the driver's qualification file for 3 years. The SPE certificate is valid for 2 years (unless otherwise specified) and may be renewed.

Title 49 CFR § 381.300 establishes the procedures persons must follow to request exemptions from the regulations. Without an exemption, individuals who do not meet the vision or diabetes requirements at 49 CFR § 391.41 would not be qualified to operate a CMV in interstate commerce.

On September 3, 2003, the FMCSA announced in a Final Notice of Disposition (68 FR 52441, See Attachment B) that it will issue exemptions to CMV drivers with insulin-treated diabetes mellitus (ITDM) from the Federal diabetes standard in 49 CFR § 391.41(b)(3). Exemptions will be granted only to those applicants who meet specific conditions and comply with all the requirements of the exemption. Exemptions will be issued for a period of 2 years; after 2 years, those holding exemptions may reapply for another 2-year exemption.

On November 8, 2005, the FMCSA announced in a Notice of Revised Final Disposition titled, "Eligibility Criteria and Applications; Diabetes, (70 FR 67777, See Attachment C) its decision to revise the terms and conditions of its previous decision to issue exemptions to CMV drivers with ITDM from the Federal diabetes standard in the Federal Motor Carrier Safety Regulations (FMCSRs). This action was taken in response to section 4129 of the Safe, Accountable, Flexible and Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU) (Public Law 109-59119 Stat. 1144; Aug. 10, 2005) (at Attachment D) which required the FMCSA, within 90 days of enactment, to modify its exemption program to allow individuals who use insulin to treat diabetes mellitus to operate CMVs in interstate commerce. These individuals would be able to obtain an exemption from the physical qualification standards without having to demonstrate

safe driving experience operating a CMV while using insulin. Nonetheless, individuals who use insulin to treat ITDM were required to have a minimum period of insulin use to demonstrate stable control of diabetes before operating a CMV in interstate commerce.

Title 49 U.S.C. § 31149, enacted by section 4116(a) of the SAFETEA-LU (See Attachment E), requires the Secretary of Transportation (Secretary) to establish and maintain a current national registry of medical examiners who are qualified to perform examinations and issue medical certificates and verify whether a CMV driver's health meets FMCSA standards. The FMCSA is developing the NRCME program to produce trained, certified medical examiners who are qualified to determine if a CMV driver's health meets FMCSA standards. In addition, section 4116(b) of SAFETEA-LU requires that the medical examinations of CMV operators are performed by medical examiners who have received training in physical and medical examination standards and, after the registry is established, are listed on the registry (See Attachment F). SAFETEA-LU also requires medical examiners to transmit electronically the name of the applicant and FMCSA numerical identifier for any completed Medical Examination Report required under 49 CFR § 391.43 to the FMCSA Chief Medical Examiner on a monthly basis. Close tracking and monitoring of certification activities and medical outcomes are crucial, and the NRCME NPRM addresses the information collection aspects of the NRCME rule's implementation.

This information collection 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 complicated, modern CMVs can safely perform the increased physical and mental demands of their duties. The FMCSA medical standards provide this assurance by requiring drivers to be physically examined and medically qualified to drive a CMV in interstate commerce.

Third-party requirements of this information collection are being considered since State laws are generally in substantial conformity with the Federal regulations for medical qualifications of commercial drivers. Consequently, the estimate of the number of CMV drivers (respondents) covered by this information collection 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 mirror the Federal requirements in their compatible regulations; therefore, we assume the inclusion of intrastate drivers, which is consistent with other FMCSA information collections, accurately reflects the burden of this information collection.

Motor carriers are permitted to employ only drivers who are medically qualified to drive a CMV. Applicants with certain medical conditions are not qualified to drive CMVs. Individuals with limb impairments are permitted to operate a CMV only when they are otherwise qualified and are granted a SPE certificate by the FMCSA. The FMCSA must collect this type of medical information about drivers so that public safety is not compromised.

The medical conflict application provision (49 CFR 391.47) provides a mechanism for drivers and motor carriers to have the FMCSA make a final decision to resolve conflicting medical evaluations when either party does not accept the decision of a medical specialist. Without the last provision and its incumbent information-collecting requirements, an unqualified person may be permitted to drive and qualified persons may be prevented from driving.

Medical examiners must provide specific FMCSA-prescribed information about every driver they examine. If this information were not required, the threat to public safety would be immense and unacceptable.

The FMCSA may grant an exemption that relieves a person from the compliance with a regulation if the agency determines that the exemption is in the public interest and would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved by complying with the regulation. Information collected under 49 CFR § 381.310 is necessary to the FMCSA in making its determination to grant an exemption from compliance with a regulation.

NRCME:

Information collection requirements for implementation of the NRCME program require medical examiners to submit three types of data:

Medical Examiner Application and Test Results Data: To be listed on the NRCME, medical examiners must first pass a certification test to ensure that they demonstrate an established level of competency. Private-sector testing organizations would collect data from medical examiners as the medical professionals apply to take this certification test. Data elements required of medical examiners at the time of application would include (but not be limited to) professional contact and identifying information such as job title, address, and training and State licenses obtained. These data would be collected each time the medical examiner applied to sit for the certification test and information would be updated with the FMCSA as needed. Test results data would include total test score and responses for each test item. Private-sector testing organizations would regularly transmit the medical examiner application and test results data electronically to the FMCSA for inclusion in a centralized, confidential database.

These data would allow for the matching of documentation with verification

of identity and testing eligibility (for example, proof of State licensure, registration or certification that allows performance of medical examinations and completion of training by an accredited training provider). This information would also be utilized to track participant test taking trends, as well as provide respondents with test results and follow-up information.

It is important to note that there is currently no mechanism for identifying medical examiners conducting CMV driver medical examinations. The size of this population, as well as characteristics related to their training and location, for example, is not known. This database would therefore serve as the only resource containing this information for all certified medical examiners in the United States.

Ultimately, the data would therefore be used to provide CMV drivers with contact information for those medical professionals who passed the certification test; that is, this information would provide the content for the actual NRCME listing. In some cases, this medical examiner information would be needed to address removals from the NRCME.

CMV Driver Examination Data: Once every calendar month, each medical examiner listed on the NRCME would be required to transmit to the FMCSA (via the Chief Medical Examiner) the following information about each CMV driver examined during the previous month: name, FMCSA numerical identifier, date of examination, an indication of the examination outcome (for example, medically qualified or medically not qualified) and date of expiration of the driver's medical certification, if applicable. Data would be submitted electronically via a secure FMCSA-designated Web site, email address, or facsimile number. In order to be listed on and to continue participation in the NRCME, medical examiners would need to comply with this requirement on a monthly basis.

CMV driver examination data are intended to serve a monitoring function. First, these would be the only centralized, consistent national data that would enable the FMCSA to link medical examiners to the examinations they have conducted. In addition, this would be the first national database that would, after several years of implementation, house CMV driver medical examination certification outcomes.

Medical Examination Reports and Medical Examiner's Certificates:

The NRCME NPRM would require medical examiners to provide copies of Medical Examination Reports and medical examiner's certificates to authorized representatives of the FMCSA or authorized Federal, State or local enforcement agency representatives. These documents contain the driver's social security number, date of birth, driver license number, and

health and medical information.

Medical Examination Reports and medical examiner's certificates must be made available to an authorized representative of the FMCSA or an authorized federal, State or local enforcement agency representative to determine whether a medical examiner has issued a medical certificate to a driver who fails to meet the applicable FMCSA medical Standards. Failure to properly apply FMCSA medical standards may result in removal from the NRCME. Medical examiner's certificates provide additional documentation to determine proper application of FMCSA medical standards by linking the medical examiner to both the medical examination and the driver medical certification decision, and to ensure the certification decision matches the information in the medical examination and the certificate is completed correctly.

3. Extent of automated information collection:

The nature of the medical certificate and recordkeeping requirements in the driver's qualification files precludes automated collection by the motor carriers for this information at this time. A hard copy of the certificate must be signed by the medical examiner and retained on file by the motor carrier. There is nothing to preclude an electronic record of the medical examination. The FMCSA is constantly evaluating new information technology in an attempt to decrease the burden on motor carriers and medical examiners. Our evaluation is always done in the context of retaining highway safety as our highest priority. Any new or improved information technology in the medical or scientific field would be subject to rulemaking if it affected the medical qualifications of drivers.

Consistent with the OMB's commitment to the minimization of respondent burden and the increased use of secure electronic modes of communication, it is estimated that approximately 75 percent of the aforementioned NRCME data will be transmitted electronically. As indicated, medical examiner application and test results data as well as CMV driver examination data will be transmitted electronically, via secure Web site, email address, or facsimile number. The method of electronic collection of Medical Examination Reports and medical examiner's certificates when requested by enforcement personnel will be dependent upon individual medical examiner electronic capability, so it is likely that FMCSA will receive these data by various electronic means, including email and facsimile.

4. Efforts to identify duplication:

The FMCSA is the only Federal agency with the authority to regulate the qualifications of drivers operating CMVs in interstate commerce. Rulemaking under the Administrative Procedure Act provides the necessary medium for uncovering duplication if it existed. Comments to the docket on various FMCSA rulemaking notices have revealed no duplication.

5. Efforts to minimize the burden on small businesses:

For NRCME information collection, submission of medical examiner application data to private-sector testing organizations affects individuals not establishments. Collection and transmission of medical examiner application and test results data does affect private-sector testing organizations which could include small businesses. However, since collection and transmission of such data is part of their daily course of business, it is anticipated that this would not have a significant impact or require a significant time burden. The agency anticipates that collection of CMV driver examination data would affect medical clinics and practices, so there would be some impact on small businesses; however, since only five data elements are being collected, it is anticipated this would not have a significant impact or require a significant time burden. It is also anticipated that implementing a provision to require Medical Examination Reports and medical examiner's certificates to be given to an authorized representative of FMCSA or an authorized State or local enforcement agency representative would not have a significant impact or require a significant time burden on respondents subject to this collection.

6. Impact of less frequent collection of information:

If the medical examination of commercial drivers was conducted less frequently, it is likely that drivers whose medical condition has worsened would not be detected in time to prevent their being involved in an accident. A driver's physical or mental condition may worsen at any time. Federal vision and diabetes exemptions must be reviewed every 2 years to ensure that the granting of the exemption does not diminish safety under Section 381.310. In the interest of highway safety, the medical examination and exemption renewal should not be performed less frequently.

NRCME:

- 1) *Medical Examiner Application and Test Results Data*: As these data are collected each time a potential examiner sits for the certification test, less frequent collection of information would imply fewer test administrations. Less frequent test administrations would likely result in fewer qualified medical examiners being available to the CMV driver and motor carrier population. Once the NRCME program is implemented, the FMCSA would accept medical examinations performed only by certified medical examiners listed on the NRCME, as required by law. To meet the annual CMV driver medical examination requirements, the FMCSA estimates that at least 40,000 certified medical examiners are needed. Availability of fewer medical examiners could place a burden on drivers and motor carriers to find a qualified medical examiner to perform the medical examination.
- 2) <u>CMV Driver Examination Data, Medical Examination Reports, and Medical Examiner's Certificates</u>: SAFETEA-LU requires medical examiners to transmit to the FMCSA Chief Medical Examiner, electronically and on a monthly basis, the name of the applicant and FMCSA numerical identifier for any completed Medical Examination Report required under 49 CFR

§ 391.43; therefore, less frequent collection of driver examination data is not an option. In addition, less frequent collection of driver data, Medical Examination Reports and medical examiner's certificates would compromise the FMCSA's ability to determine medical examiner compliance with the FMCSA medical standards and guidelines in performing CMV driver medical examinations, which could result in having medical examiners listed on the NRCME who should be removed. Less frequent data collection would result in decreased validity of the data (i.e., less frequent data submission may increase the error rate due to unintentional omission of examination information).

7. Special circumstances:

There are no special circumstances associated with this information collection.

8. Compliance with 5 CFR § 1320.8:

On September 3, 2003, the FMCSA announced in a Final Notice of Disposition that it will issue exemptions to certain diabetic drivers of CMVs from the diabetes mellitus prohibitions contained in 49 CFR § 391.41(b)(3). Exemptions are granted only to those applicants who meet specific conditions and comply with all the requirements of the exemption. Exemptions will be issued for a period of 2 years; after 2 years, those holding exemptions may reapply for another 2-year exemption period.

On November 8, 2005, the FMSCA announced its decision to revise the terms and conditions of its previous decision to issue exemptions to CMV drivers with ITDM from the Federal diabetes standard in the FMCSRs. This action is in response to section 4129 of the SAFETEA-LU. As a result of the implementation of section 4129 of SAFTEA-LU, individuals with ITDM who are applying for an exemption from the physical qualifications requirements are no longer required to submit proof of their driving experience operating a CMV while using insulin. Proof of driving experience would typically include letters of reference from the current and previous employers that the person was employed as a CMV driver, and an estimate of the number of hours the individual spent driving each week over a 3-year period. Therefore, the elimination of the 3-year driving experience requirement has resulted in a significant reduction in the information burden associated with applying for a diabetes exemption.

NRCME:

FMCSA held three public meetings to discuss the NRCME program in 2005 and 2006 as follows: on June 22, 2005, in Arlington, Virginia, June 22, 2006, in San Diego, California, and July 26, 2006, in St. Louis, Missouri. During these meetings, a number of medical providers and CMV industry representatives expressed concern about the idea of a NRCME and about the current quality of CMV driver medical examinations. Representatives provided anecdotal evidence about drivers qualified by health care providers who were clearly unaware of FMCSA medical standards, guidelines, and other information needed to determine whether a driver can safely operate a CMV.

The FMCSA published an NPRM entitled, "National Registry of Certified Medical Examiners," (73 FR 73129), December 1, 2008 concerning the NRCME program. The NPRM contained information about the medical examiner training and certification testing process including the information collection requirements. The NPRM also defined the requirements for reporting CMV driver examination data and submitting Medical Examination Reports and medical examiner's certificates. The FMCSA believes numerous comments will be submitted to the Agency in response to this NPRM. Those comments will be addressed in a Final Rule to

implement the NRCME program.

9. Payments or gifts to respondents:

Respondents to this information collection do not receive any payments or gifts.

10. Assurance of confidentiality:

All medical records are kept confidential. The information is retained by the FMCSA in accordance with the requirements of the Privacy Act of 1974, 5 U.S.C. § 552a. The information on the physical examination form is retained on file in the office of the medical examiner and is subject to applicable State and Federal laws regarding the confidentiality of medical records. The FMCSA, in accordance with sections 391.51 and 398.3, requires only the medical certificate of physical qualification to be kept in the driver qualification file maintained by the employer.

NRCME:

The FMCSA would develop secure processes involving the transmission of information, records control and repository, and the ability to retrieve and search records. The FMCSA could create a secure information system using a Web interface for which each medical examiner on the NRCME would receive a unique login ID and password upon their acceptance into the NRCME. Only the active medical examiners and designated enforcement personnel would be able to access this information system. Designated personnel would be able to view and query data, as well as generate reports based on the information that a medical examiner transmitted. There is no anticipated change in how the Medical Examination Reports are prepared. Medical examiners would enter their NRCME Identification Number on the medical examiner's certificates.

Within the Web site, medical examiners could update or correct their information, hide or display part or all of their information, and securely upload the monthly driver examination information. If the FMCSA decides to remove a medical examiner from the NRCME, except at the request of the medical examiner, the certification credential issued by the FMCSA would no longer be valid. The removed person's information remains publicly available for 3 years, with an indication that the person is no longer listed on the NRCME as of the date of removal. Maintaining this information would allow enforcement personnel to verify whether a medical certificate was issued by a person on the NRCME at the time of issuance.

Access to medical examiner's certificates is required by regulations that generally require that document to be in the possession of the CMV driver, and to be furnished to the employer. Access to Medical Examination Reports would be limited to designated enforcement personnel. If provided electronically, these documents would be encrypted. Additionally, information could be purged on a frequent basis.

11. Justification for collection of sensitive information:

The medical examination process requires the medical examiner to inquire about aspects of driver physical and mental health, including history of frequent alcohol use, illicit drug use or habit-forming medication use.

NRCME:

- 1) <u>Medical Examiner Application and Test Results Data</u>: The medical examiner application data would allow the matching of documentation with verification of identity and testing eligibility (for example, proof of State licensure, registration or certification that allows performance of medical examinations and completion of training by an accredited training provider). This information would also be utilized to track participant test taking trends as well as provide respondents with test results and follow-up information.
- 2) CMV Driver Examination Data, Medical Examination Reports, and Medical Examiner's Certificates: Medical examiners would be required to submit CMV driver certification examination outcomes (e.g., medically qualified, medically unqualified, temporarily disqualified) in conjunction with driver names. Submission of this general medical examination information is necessary to tie a specific medical examiner to a specific driver examination in order to monitor the performance of certified medical examiners, as well as track CMV driver examinations and outcomes, preventing abuse and errors in both areas.

12. Estimate of burden hours for information requested:

IC-1: Current Medical Qualification Requirements

The NRMCE will have no impact on the burden for IC-1. The currently approved burden is discussed below.

Medical Examination Form and Medical Certificate

The Agency currently estimates that approximately 4,585,000 examinations are conducted annually for the 7,000,000 drivers subject to FMCSA physical qualification standards. A medical certificate usually is valid for two years after the date of examination. Biennial examinations of the 7,000,000 drivers result in 3,500,000 medical examinations on average per year. However, drivers with certain medical conditions must be certified more frequently than every two years. In addition, some employers require a newly-hired driver to obtain a new medical certification even if the driver's current certificate is still valid. As a result of these exceptions to the biennial medical certification schedule, the Agency estimates that the actual number of medical certifications conducted annually is 31 percent greater than would be the case if all drivers were only examined biennially, that is, an additional 1,085,000 (0.31 × 3,500,000) exams are conducted outside the biennial cycle.

Estimated Total Annual Responses: 4,585,000 (3,500,000 regular medical examinations + 1,085,000 out-of-cycle medical examinations).

It takes a medical examiner approximately 20 minutes to complete, document, and file the medical examination report and 1 minute to complete the medical examiner's certificate and furnish one copy to the person who was examined and one copy to the motor carrier who employs him or her. It takes a motor carrier approximately 1 minute to file the medical certificate. Therefore, the annual time burden to respondents for the medical examination and certificate is estimated at **1,681,167 hours** (4,585,000 certificates × 22 minutes/60 minutes per hour).

Although most drivers of migrant workers are now covered under different requirements, the Agency estimates that 300 of these drivers are still subject to the medical certification requirements under the definition in part 398. Under part 398, a driver of migrant workers is required to have a medical examination every 36 months. They are not subject to the reexamination requirements found in § 391.45(c). Therefore, about 1/3 of the 300 drivers, or 100, are examined each year. It takes about 1 minute for a physician to complete the medical certificate (a medical examination form is not required to be completed). The driver presents the certificate to the motor carrier, who makes a copy for its driver qualification file. A carrier needs about 1 minute to copy and file a certificate. The annual time burden to respondents for the migrant worker regulations is approximately **4 hours** (100 certificates × 2 minutes/60 minutes per hour, rounded up to the next whole hour).

Estimated Total Annual Burden of Medical Examination and Medical Certificate: 1,681,171 hours (1,681,167 hours for regular drivers + 4 hours for drivers of migrant workers).

The average hourly wage of a medical examiner (not limited to doctors of medicine, but may include doctors of osteopathy, physician assistants, advance practice nurses, and doctors of chiropractic) is currently estimated to be \$54.03, or 90 cents per minute. The current annual salary cost for medical examiners to complete the medical examination process is approximately **\$86,656,500** (4,585,000 examinations × \$18.90 (.90 × 21 minutes)).

The average hourly wage (including benefits) of motor carriers' administrative personnel is currently estimated to be \$11.09, or 19 cents per minute. The annual salary cost to motor carriers to file the certificate is about \$871,150 (4,585,000 certificates \times .19 (.19 \times 1 minute) = \$871,150).

Labor costs for drivers of migrant workers are estimated to be \$23 per hour of burden associated with these requirements. This includes the labor of both the medical examiners and motor carriers. The total annual salary cost associated with drivers of migrant workers is $$92 ($23 \times 4 \text{ hours})$.

The total annual salary cost to respondents for the medical examination form and certificate is

about **\$87,527,742** (\$86,656,500 salary costs for medical examinations + \$871,150 salary costs for administrative support + \$92 for drivers of migrant workers).

Resolution of Medical Conflict

The safety director of a motor carrier would generally submit the application to FMCSA for a resolution of medical conflict, and would attend a hearing if FMCSA deems it necessary to hold a hearing. A safety director would need approximately 1 hour to prepare paperwork for each case and an additional 8 hours to attend any hearing. There are approximately three cases per year submitted to FMCSA for resolution of conflicting medical opinions. One of every three cases is sent to a hearing before an Administrative Law Judge. The annual time burden to respondents for the resolution of medical conflicts is about **11 hours** (3 cases × 1 hour each to prepare + 8 hours for one hearing per year).

The average hourly wage (including benefits) of safety directors is currently estimated to be \$22.00. The motor carrier's cost would be about \$198 if the case went to a hearing (9 hours \times \$22 per hour) and approximately \$22 if the case did not go to a hearing. The annual salary cost to respondents for the resolution of medical conflicts is approximately **\$242** (\$198 for one case that goes to a hearing + ($\$22 \times 2$ cases that do not go to a hearing)).

Skill Performance Evaluation Certification Program (formerly the Limb Waiver Program)

There are approximately 3,400 active drivers with skill performance evaluation (SPE) certificates for limb impairments. An SPE certificate is valid for 2 years; therefore, FMCSA estimates that on average 1,700 SPE certificates are due for renewal each year. The Agency estimates that there are 400 new SPE certificates processed each year, making a total of 2,100 new and renewed annual SPE certificates. It takes an estimated 15 minutes for a driver to complete an application for a new SPE certificate, approximately 2 minutes for a driver to complete an application for an SPE certificate renewal, and approximately 1 minute for the motor carrier to make a copy of the SPE certificate and file it in the Driver Qualification (DQ) File. Motor carriers' annual time burden for the SPE certification program is about 35 hours (2,100 certificates × 1 minute/60 minutes per hour). Drivers who voluntarily participate in the SPE spend approximately 157 annual hours [57 hours (1,700 renewals × 2 minutes/60 minutes per hour) + 100 hours (400 new × 15 minutes/60 minutes per hour] to complete the SPE application and renewal processes.

The current annual hour burden for respondents (motor carriers and drivers) to complete the SPE certificate application and renewal (waiver) processes and retain a copy of the certificate in the driver's DQ file is **192 hours** [35 hours (carrier) + 157 hours (57 hours for driver renewals + 100 hours for new drivers))].

The average hourly wage (including benefits) of motor carriers' administrative personnel who would file the certificate, is estimated to be \$13.73. The average hourly earnings (including benefits) for drivers of general freight trucks is \$16.11, with the middle 50 percent earning

between \$12.67 and \$20.09 per hour. For the purposes of this analysis FMCSA will use \$20.09 per hour as an average. The total annual salary cost to respondents (carriers and drivers) to participate in the SPE certification program is **\$3,635** [\$480.55 for motor carriers (35 hours × \$13.73 per hour for administrative personnel) + \$3,154.13 for drivers (157 hours × \$20.09 per hour)].

<u>Vision Exemptions</u>

There are approximately 1,241 new applications for vision exemptions annually and 1,572 total applicants (new and renewals). Approximately 268 new vision exemptions or (22 percent) are granted annually. An exemption is valid for two years, but may be renewed. Currently, there are 1,004 active drivers with vision exemptions. It is estimated that 27 percent or 424 vision exemptions would be up for renewal annually (1,572 total applicants \times 0.27). It takes 1 hour for a driver to complete an application for a vision exemption. The annual time burden for applying for new vision exemptions and renewing existing vision exemptions is estimated at 692 hours ((268 new vision exemptions + 424 vision exemption renewals) \times 1 hour).

The total estimated annual burden hours for respondents (carriers and drivers) to complete the vision exemption application and renewal processes and retain a copy in the driver's DQ file is **727 hours** [692 hours (driver) + 35 hours (carrier)]. The total annual salary cost to respondents (drivers) to apply for or renew a vision exemption is estimated at \$13,902 (692 hours × \$20.09 per hour). The total annual salary cost to respondents (carriers and drivers) to participate in the vision exemption program is **\$14,383** (\$481 for motor carriers (35 hours × \$13.73 per hour for administrative personnel to file a copy of the exemption) + \$13,902 for drivers (692 hours × \$20.09 per hour)).

Diabetes Exemptions

FMCSA estimates that approximately 600 applications for the diabetes exemption could be filed annually, and that it would take an average of 1 hour to complete an application. The information collected from the diabetes exemption application will consist of an application letter with supporting documentation specified in the Notice of Revised Final Disposition (Attachment C) (e.g., vital statistics, medical, copy of driver's license). FMCSA would carefully evaluate each application for regulatory relief from the diabetes standard to assess the potential safety performance of each applicant. The diabetes exemption program creates an annual burden of **600 hours** (600×1 hour).

The total annual salary cost to respondents (CMV drivers) to complete the diabetes exemption application and renewal processes is estimated at \$12,054 (600 hours \times \$20.09 per hour). The total annual salary for motor carriers' administrative personnel would be \$137 (\$13.73 \times 10 hours (600 diabetes exemptions \times 1 minute per exemption/60 minutes per hour)). The total annual salary cost to respondents (drivers and carriers) to participate in the diabetes exemption program is estimated at **\$12,191** (\$12,054 (driver cost) + \$137 (carrier cost)).

IC-1: TOTALS FOR MEDICAL QUALIFICATION REQUIREMENTS

The total estimated annual time burden to respondents for all medical requirement components is **1,682,701 hours** (1,681,171 hours for medical examination form and certificate + 11 hours for resolution of medical conflict + 192 hours for skill performance evaluation + 727 hours for vision exemptions + 600 hours for diabetes exemptions). The total annual salary cost for respondents associated with these hours is approximately **\$87,558,193** (87,527,742 costs for physical examinations + \$242 resolution of medical conflict + 3,635 SPE certification program + \$14,383 vision exemptions + \$12,191 diabetes exemptions).

IC-2: NRCME

Medical Examiner Application and Test Results:

FMCSA estimates each of the respondents would provide medical examiner test application data every 6 years and updated information to the Agency as needed. It is estimated that 13,333 medical examiners will apply to take the certification test annually for the first 3 years of NRCME implementation. FMCSA estimates that the total annual burden hours for the collection of the medical examiner application data is **1,111 hours** (13,333 applicants × 5 minutes/60 minutes per hour). This annual burden includes medical examiner time for submitting the application data to the private-sector testing organizations.

It is estimated that one or more national private-sector testing organizations will deliver the FMCSA medical examiner certification test to 13,333 medical examiners annually for the first 3 years following implementation of the NRCME program. It is also estimated that it will take private-sector testing organization personnel 5 minutes to collect and upload to the FMCSA application data and test results per medical examiner. FMCSA estimates that the total annual burden for private-sector testing organizations to collect medical examiner application data and send medical examiner application and test results data to FMCSA is **1,111 hours** (13,333 applicants × 5 minutes/60 minutes per hour).

The total annual burden for provision of medical examiner application and test results data is **2,222 hours** (1,111 hours for medical examiners + 1,111 hours for testing organizations)

As stated above, the average hourly wage (including benefits) of a medical examiner (advanced practice nurses, doctors of chiropractic, doctors of osteopathy, medical doctors, and physician assistants) is estimated to be \$54.03. The annual salary cost for medical examiners to provide test application data to private-sector testing organizations is approximately \$60,027 (1,111 hours \times \$54.03). The average hourly wage (including benefits) of data entry personnel at private-sector testing organizations is approximately \$19.00. The annual salary cost for private-sector testing organizations to send medical examiner application and test results data to the FMCSA is approximately \$21,109 (1,111 hours \times \$19.00). The total annual salary cost for

medical examiner application and test results data is **\$81,136** (\$60,027 for medical examiners + \$21,109 for testing organizations).

CMV Driver Examination

FMCSA estimates that 40,000 certified medical examiners will be needed to perform the 4,585,000 CMV driver medical examinations required annually. The Agency estimates that each medical examiner will transmit CMV driver examination data 12 times per year, and that this task will take 1 minute per transmission, for a total of 8,000 hours of burden per year (40,000 examiners \times 12 transmissions per year \times 1 minute per transmission \div 60 minutes per hour). The Agency also estimates that entering the required data for each of the 4,585,00 medical certificates issued will take 30 seconds, for a total of 38,208 hours of burden per year (4,585,000 certificates \times 0.5 minutes per certificate \div 60 minutes per hour). The total annual burden of transmitting CMV driver medical certificate data is estimated to be 46,208 hours (8,000 hours for transmitting data + 38,208 hours for entering data). It is estimated that it would take medical examiner administrative personnel 30 seconds to file the medical examiner's certificate. This would require approximately 38,208 hours of administrative personnel time per year (4,585,000 examinations \times 0.5 minutes per certificate \div 60 minutes per hour).

The annual burden to medical examiner administrative personnel for transmitting CMV driver examination data to FMCSA and filing medical examiner certificates is approximately **84,416 hours** (46,208 hours to enter and transmit driver examination data elements + 38,208 hours to file the medical examiner's certificate).

The average hourly wage (including benefits) of administrative personnel in a medical examiner's office is estimated to be \$18.00. The annual salary cost for medical examiners to provide CMV driver medical examination data to FMCSA and file medical examiner certificates is estimated to be **\$1,519,488** (84,416 hours × \$18.00).

Medical Examination Reports and Medical Examiner's Certificates:

FMCSA estimates that authorized FMCSA representatives or authorized Federal, State or local enforcement agency representatives would request medical examiners to provide copies of the Medical Report Form and the medical examiner's certificate 2,100 times a year.

It is estimated that it will take medical examiner administrative personnel 5 minutes to provide both the Medical Examination Report and the medical examiner's certificate to FMCSA or an authorized Federal, State or local enforcement agency representative, so this would require approximately **175 hours** of administrative personnel time on a yearly basis (2,100 requests × 5 minutes ÷ 60 minutes per hours). The annual salary cost for medical examiner administrative personnel to provide both the Medical Examination Report and the medical examiner's certificate is approximately **\$3,150** (175 hours × \$18.00 hourly wage for administrative personnel).

IC-2: TOTALS FOR NRCME

The total estimated annual time burden to respondents for the NRCME components is approximately **86,813 hours** (2,222 hours for provision of medical examiner application and test results data + 84,416 hours for transmission of CMV driver examination data + 175 hours for provision of Medical Examination Reports and medical examiner's certificates). The total annual salary cost for respondents associated with these hours is approximately **\$1,603,774** (\$81,136 for provision of medical examiner application and test results data + \$1,519,488 for transmission of CMV driver examination data + \$3,150 for provision of Medical Examination Reports and medical examiner's certificates).

Estimated Number of Annual Responses: 55,433 (13,333 medical examiner application data + 40,000 medical examiners performing CMV driver medical examinations + 2,100 copies of medical examination reports and certificates).

TOTALS FOR ALL MEDICAL PROGRAM COMPONENTS:

The total estimated annual time burden to respondents for all medical requirement components is **1,769,514 hours** (1,682,701 currently approved hours + 86,613 new hours due to the NRMCE rule). The total annual salary cost to respondents associated with these hours is approximately **\$89,161,967**, (\$87,558,193 current costs + \$1,603,774 new costs due to the NRMCE rule).

Summary of Proposed Annual Burden			
	Current	Additional	New Total
	Hours	Hours	Hours
Medical Examination Form and Medical			
Certificate	1,681,171	0	1,681,171
Resolution of Medical Conflict	11	0	11
SPE	192	0	192
Vision Exemption	727	0	727
Diabetes Exemption	600	0	600
Medical Examiner Application and Testing	0	2,222	2,222
Transmission of CMV Drive Examination			
Data	0	84,416	84,416
Requests for Medical Reports and Examiner			
Certificates	0	175	175
Total	1,682,701	86,813	1,769,514

13. Estimate of total annual costs to respondents:

There are no additional costs to respondents beyond those associated with the hourly burden presented above.

14. Estimate of cost to the Federal government:

The cost to the Federal government due to the medical examination process requirements is minimal because the FMCSA does not receive or process the documents. The cost to the Federal government for the resolution of medical conflict is minimal; there are only about three cases per year submitted to the FMCSA for resolution of conflicting medical opinions.

The SPE program requires approximately 1.5 hours to analyze the letter of application and the accompanying materials. It takes approximately 8 hours to process the SPE certification forms and evaluate the applicant's driving abilities. An additional 30 minutes is needed to analyze paperwork prepared by the evaluating employee and issue the certificate to the applicant, making a total of 10 hours of staff work per SPE certificate. The average hourly wage (including benefits) of FMCSA field staff personnel is \$24.03. Therefore, the salary costs to the Federal government per SPE certificate is approximately \$204.30. The annual cost to the Federal government for the SPE certification program is approximately **\$429,030** (2,100 SPE certificates × \$204.30 per SPE certificate).

The cost to the Federal government to conduct the vision exemption process is approximately **\$578,000** annually. This is estimated using an average monthly amount of \$48,000 contract costs to conduct the vision exemption program.

The cost to the Federal government to conduct the diabetes exemption process is approximately **\$892,000** annually. This is estimated using an average monthly amount of \$75,000 contract costs to conduct the diabetes exemption program.

IC-1: TOTALS FOR MEDICAL QUALIFICATION REQUIREMENTS:

The total annual cost to the Federal government for all medical requirement components is approximately **\$1,899,030** (\$429,030 SPE Process + \$578,000 vision exemption process + \$892,000 diabetes exemption process).

IC-2: NRCME

1) Medical Examiner Application and Test Results:

The one-time cost to the Federal government to develop a centralized, secure Web application database that allows private-sector testing organizations to upload medical examiner application and test results data would be approximately \$275,000. The annual maintenance costs for the database would be \$96,000 (\$8,000 a month x 12 = \$96,000). Therefore, the cost for the first year of program implementation would be \$371,000 [\$275,000 + \$96,000 = \$371,000] and \$96,000 annually thereafter. The maintenance costs include hosting of the database, data input, database security and continuity of operations. For purposes of this Supporting Statement, spreading the development costs over the first 3 years of implementation and adding annual

maintenance costs yields an annual cost of **\$187,667** [\$275,000/3 years = \$91,667 + \$96,000 = \$187,667].

2) CMV Driver Examination Data, Medical Examination Reports:

It is estimated that 13,333 medical examiners will apply to take the certification test annually for the first 3 years of NRCME implementation. The FMCSA estimates it will cost \$350.00 per medical examiner for the first year a medical examiner submits CMV driver examination data and \$35.00 per medical examiner per year thereafter. The cost to the Federal government to develop and maintain a centralized, secure database that allows medical examiners to submit over the Internet at any time the CMV driver examination data defined in the NPRM is approximately \$5,000,000 a year. This breaks down as follows: \$4,700,000 for the first year of implementation, \$5,100,000 for the second year and \$5,600,000 for the third year as the number of certified medical examiners increases [Year 1: $13,333 \times $350.00 = $4,666,550 + Year 2$: $13,333 \times 350.00 + 13,333 \times 350.00 = 55,133,205 +$ **Year 3**: $13,333 \times 350.00 + 26,666 \times 100.00 = 100$ \$35.00 = \$5,599,860]. This is a total of \$15,399,615 for the first three years of NRCME implementation. This would be approximately \$5,000,000 annually. The cost includes provision of medical examiner account access, customer support for users, hosting of the database, database security, and continuity of operations. The FMCSA can also use this database in the future for medical examiners to upload CMV driver Medical Examination Reports for monitoring medical examiner performance as required by SAFETEA-LU.

IC-2: TOTALS FOR NRCME

The total annual costs for all NRCME components is approximately **\$5,187,667** [\$187,667 for the medical examiner application and test results database + \$5,000,000 for the CMV driver examination database = \$5,187,667].

TOTAL FOR ALL MEDICAL PROGRAM COMPONENTS:

The total annual cost to the Federal government for all medical requirement components is approximately **\$7,086,697** (\$1,899,030 for current costs + \$5,187,667 for NRCME program).

15. Explanation of program changes or adjustments:

The program change of 86,813 additional annual burden hours and an additional cost to the federal government of \$5,187,667 are due to addition of the NRCME program information collection requirements defined in the NPRM

16. Publication of results of data collection:

This information would not be published with the following exception.

NRCME:

<u>Medical Examiner Test Application Data</u>: As indicated, these data would ultimately be used to provide CMV drivers with contact information for those medical professionals who have satisfactorily completed the certification test and are listed on the NRCME. Medical examiners listed on the NRCME would elect to have their contact and professional information listed in a public, online database.

17. Approval for not displaying the expiration date for OMB approval:

The FMCSA is not seeking this approval.

18. Exceptions to certification statement:

There are no exceptions to the certification statement.

Part B. Collections of Information Employing Statistical Methods.

This information does not employ statistical methods.

Attachments

- A. Title 49 CFR §§ 390-399.
- B. Notice of Final Disposition (68 FR 52441) entitled, "Qualification of Drivers; Exemption Applications; Diabetes," dated September 3, 2003.
- C Notice of Revised Final Disposition (70 FR 67777) entitled, "Qualification of Drivers, Eligibility Criteria and Applications; Diabetes Exemption," dated November 8, 2005.
- D. Section 4129 of the Safe, Accountable, Flexible and Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU), Public Law 109-59, 119 Stat. 1144; August 10, 2005.
- E. Title 49 U.S.C. § 31149.
- F. Section 4116 of the Safe, Accountable, Flexible and Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU), Public Law 109-59, 119 Stat. 1144; August 10, 2005.