Information Collection Clearance

The Supporting Statement

Survey of Medical Examiners Who Certify the Physical Qualifications of Commercial Motor Vehicle Drivers

INTRODUCTION

The Federal Motor Carrier Safety Administration (FMCSA) requests approval from the Office of Management and Budget (OMB) for a new survey (see Attachment A) to compare the performance of medical examiners who conduct physical examinations of commercial motor vehicle (CMV) drivers. Comparisons would be made to a performance standard determined by a panel of medical examiners who represent physicians (doctors of medicine and osteopathy), advanced practice nurses, physician assistants, and chiropractors. These four groups dominate the medical examiner population.

This is a resubmission of a previously withdrawn proposed information collection request (ICR). Whenever possible, we have modified our approach to address the following OMB concerns:

- 1) Use of results to impact FMCSA policy. The main foci of the study have changed. As the rulemaking and National Registry of Certified Medical Examiners (NRCME) formation processes have progressed, data that will best inform these efforts have shifted in focus. Results of this research are not intended to impact policy directly, but will be utilized instead to complement these existing endeavors.
- 2) Use of a convenience sample. Given that the population of medical examiners is largely hidden and study resources are limited, it is most appropriate to conduct this study with a sample that is readily available. Please note that the NRCME listserv, which will comprise a segment of our sample, was a result of several months of exhaustive efforts to locate previously unidentified medical examiners conducting CMV driver physical examinations. The preferred sampling approach, that of pure random sampling, will be achieved when the NRCME is in place.
- 3) Ability to recruit 4,000 medical examiners and reach an 80% response rate. The use of modified recruitment approaches, including contacting a group of known medical examiners with an established interest in research participation, as well as contacting members of four supplemental listservs of occupational medicine professionals likely to perform CMV driver examinations, should enable us to achieve the expected response rate. In addition, the survey will be delivered electronically in an effort to make

completion as burden-free as is possible; a link to the survey URL will only be sent to those individuals who have expressed interest in completing the survey. Should the projected sample size not be reached initially, repeat email reminders will be sent to our participant pool in an effort to increase the response rate. In addition, subject matter experts working on the study may be asked to stress the importance of the project to those in the sample from their respective medical professions.

Additional changes have been made to the following approach, including:

- Merger of participant groups. Given the similarities in training and licensure, medical doctors and doctors of osteopathy have been combined into one group for this study. As NRCME Role Delineation Study recruitment illustrated that there are fewer doctors of osteopathy in comparison to the other medical groups, combining these two groups should help to prevent widely discrepant subsample group sizes.
- 2. Change in number of observations. The number of on-site observations of medical professionals conducting CMV driver physical examinations has changed. In order to conduct the research in a timely manner that will inform efforts already underway, it was necessary to reduce the number of proposed observations from 150 to 28. Limitations to the generalizability of these data are noted; they will be used solely for descriptive purposes.

Part A. Justification

1. Circumstances that make collection of information necessary.

The United States Congress, National Transportation Safety Board, and many other prominent organizations have expressed significant interest in improving the quality of the interstate CMV driver physical qualification examination. To date, there has been no research that examines directly the performance of medical examiners who determine the physical qualifications of CMV drivers in the United States. FMCSA's proposed research will therefore fill a need by providing the following:

- An analysis of medical examiner methods and clinical outcomes by four groups of professionals (doctors of medicine and osteopathy, advanced practice nurses, physician assistants, and chiropractors) who perform FMCSA physical examinations of CMV drivers;
- A snapshot of medical examiner performance and the CMV driver physical examination process as they exist in the field in 2008; and
- Background information to inform the development of the NRCME.

An estimated six million drivers are examined each year for certification to operate a CMV. In some cases, examiners certify drivers who are not medically

qualified to drive. Given the negative effect this could have on the FMCSA mission of reducing crash rates, injuries, and fatalities involving large trucks and buses, this is an area of public safety warranting systematic investigation. However, no significant research has been conducted in the area of medical examiner performance to date.

We theorize that highly performing medical examiners should be able to recognize:

- Disqualification conditions as described in Federal Motor Carrier Safety Regulations (FMCSRs).
- When more diagnostic information is needed before a medical qualification decision can be made.
- When a driver's diagnosis does not affect his or her ability to drive a CMV safely.

A series of cases has been developed by an expert panel of medical examiners to simulate these kinds of scenarios. Survey responses should permit inferences about performance challenges for medical examiners.

This study will also examine whether current practices and methodologies employed in certification examinations are optimal. Due to a lack of data in this area, a planned research method includes the use of both a survey and direct observation of several examination procedures as they are conducted in the field. Results should permit data-supported recommendations – specifically incorporating medical examiner feedback – to improve the current process, where possible.

The medical standards that almost all CMV drivers in interstate commerce must meet are in 49 CFR 391.41, with the exception of drivers of migrant workers (who must meet the medical standards in 49 CFR 398.3).

This information collection supports the DOT Strategic Goal of Safety (i.e., reducing the highway fatality rate). The quality of the medical certification for CMV drivers has been an issue for some time. Too often drivers have been certified by medical examiners who documented that these drivers were qualified when basic physical qualifications required by FMCSA regulations were not met. FMCSA wants to ensure that each driver carries a valid medical certificate and each certificate accurately reflects that the driver has met all FMCSA medical standards at the time of certification. FMCSA currently has insufficient confidence that all CMV drivers have been medically certified based on consistent application of FMCSA medical standards and guidelines. FMCSA's responsibility is to ensure that physically unqualified drivers are not on the roadway with the motoring public, in order that the goal of reducing crashes, injuries, and fatalities involving large trucks and buses is reached.

2. How, by whom, and for what purpose the information will be used.

How the information will be collected:

Data will be collected via a survey developed by FMCSA, a national Working Integrated Project Team (WIPT) comprised of two professionals from each of the five medical professions currently conducting CMV driver physical examinations (both MDs and DOs had two representatives each), and research representatives from both Axiom Resource Management, Inc. (FMCSA's contractor for the Medical Examiner Performance Study) and Applied Measurement Professionals, Inc. (AMP) (See Attachment A). Consistent with OMB's commitment to compliance with the Government Paperwork Elimination Act (GPEA), the Medical Examiner Performance Study survey will be delivered electronically via the World Wide Web. Individuals will respond to surveys using the survey software WebSurveyor (www.websurveyor.com) and responses will be housed on WebSurveyor's secure server.

Who will collect the information?

Axiom Resource Management, Inc. and AMP will collect these data.

For what purpose will the information be used?

The first survey section contains hypothetical cases developed by the WIPT. Each case describes a driver and his or her medical history along with some findings from the physical examination. A standard series of questions follows each case, including one that asks whether the driver should be certified. For each case, a consensus opinion was developed by WIPT members regarding the optimal certification outcome (e.g., gather more clinical information, certify, disqualify), which becomes the performance standard against which responses will be compared.

The second survey section will solicit open-ended responses regarding circumstances in which medical examiners have felt uncertain about a driver certification decision. Medical examiners can also suggest improvements to the driver certification process. Responses from this section hold the potential to identify critical issues on which training should concentrate or driver qualification standards that should be clarified so examiners receive guidance in self-identified areas of need.

The third survey section presents a selected set of tasks that must be done to complete a medical examination. Some medical examiners may delegate some of these tasks to other people who work in assistive roles. Responses in this

section will identify which tasks are often done by support staff and permit comparisons among groups of medical examiners regarding tasks they delegate.

The final survey section will stimulate responses that will permit summarization of demographic characteristics for this sample. Some of these responses will be used to group examiners for analyses of other survey items. However, we want to emphasize that these results will face some generalizability challenges since sample members will volunteer their responses.

A second, independent survey will be made available to initial nonresponders; this survey will contain only questions pertaining to medical examiners' demographic characteristics. Data gathered from this survey will be used in nonresponse bias analyses. However, even if little evidence of bias is observed between survey responders and nonresponders, this study may leave a substantial portion of the population hidden, so generalizability challenges will have to be considered when using study results.

Direct observations of driver examinations are planned and survey items in the final section of the first, full survey will permit respondents to opt in for those observations. Demographic responses will facilitate stratification of this opt-in sample followed by random selection as needed to produce 28 medical examiners from each of four medical examiner groups (doctors of medicine and osteopathy, advanced practice nurses, physician assistants, and chiropractors) distributed across each region of the United States.

All of the above will provide FMCSA with unprecedented data toward improving the CMV driver physical examination process as well as developing training and educational materials.

The Physical Qualifications Division of FMCSA, through its contractors, will retain control over the information and safeguard it from improper access, modification, and destruction, consistent with FMCSA standards for confidentiality, privacy, and electronic information. See response #10 of this Supporting Statement for more information on confidentiality and privacy. The information collection is designed to yield data that meet all applicable information quality guidelines. Prior to dissemination, the information will be subjected to quality control measures and pre-dissemination review pursuant to guidelines for the Data Quality Act, section 515 of Public Law 106-554 (see Attachment B).

3. Extent of automated information collection.

One hundred percent of the recruitment effort will be conducted via email and 100% of survey responses will be submitted to the Agency electronically.

4. Efforts to identify duplication.

No duplication of data was discovered in preparatory work for this project. No research exists detailing the performance of medical examiners conducting CMV driver examinations. Existing related data are primarily the result of the collection of CMV crash data. These crash investigation data reflect whether a driver medical problem or condition was identified during the crash investigation. These data sets do not contain information about the performance of the medical examiner related to these driver outcomes.

5. Efforts to minimize the burden on small businesses.

It is anticipated that this survey will not affect small businesses since these data are being collected from individuals, not establishments.

6. Impact of less frequent collection of information.

If the Medical Examiner Performance Study survey is not conducted, then there will be no systematic examination of the performance of medical examiners responsible for the physical certification of CMV drivers. Without this research, strengths and deficiencies in performance will remain unknown beyond anecdotal evidence, preventing this information from informing efforts such as training associated with FMCSA's NRCME program as well as the Federal rulemaking process, currently already in progress. FMCSA is also aware that medical examiner delegates are performing many of the tasks associated with the CMV driver physical examination, but the extent to which this is occurring, as well as which specific tasks are being delegated, has not been explored. In addition, this is the first large-scale forum in which medical examiners can provide FMCSA with feedback as to how the CMV driver physical examination process might be improved.

7. Special circumstances.

There are no special circumstances related to this information collection.

8. Compliance with 5 CFR § 1320.8.

On June 19, 2006, FMCSA published a notice in the Federal Register (71 FR 35324) advising the public of its intent to seek OMB approval to collect this information (see Attachment C) by conducting a survey of medical examiners and on-site observations of CMV driver physical examinations. Comments and FMCSA responses are found in Attachments D through G. Four comments were received concerning issues related to the physical certification of CMV drivers. Two supported the concept of a national registry of qualified medical examiners; two others were outside the scope of the current data collection effort. FMCSA

published another notice in the Federal Register with a 30-day comment period on April 2, 2007 (72 FR 15753) to announce that this package was initially sent to OMB for review and approval (see Attachment H).

9. Payments or gifts to respondents.

No payments or gifts will be offered to the respondents. Survey responses will be provided by volunteers who practice within the four medical profession groups authorized to perform FMCSA CMV driver physical examinations and consent forms will be completed on site by volunteer medical examiners and CMV drivers.

10. Assurance of confidentiality.

Respondents will be given information regarding the specific uses of these data, as well as the extent to which the privacy of their responses can be ensured. Crucial elements will be outlined for prospective participants, including information regarding the 1) expectations of respondents, 2) voluntary nature of responding, 3) importance and usefulness of their responses to the FMCSA mission, and 4) aggregate, rather than individual, reporting of data. Considerations specific to electronic data collection (e.g., Medical Examiner Performance Study survey data will be housed on a secure server) will also be addressed. The expert panel of medical examiners (WIPT) will review informed consent materials to ensure their understanding and readability for persons who will be observed.

FMCSA, through its contracted services, will ensure that storage and access to these data, both paper and electronic, is restricted only to those persons authorized by FMCSA. Raw data will not be available to the public. After data analysis is completed, links between direct identifiers, including zip code, will be removed from these data and destroyed so that anonymity is preserved.

11. Justification for collection of sensitive information.

Typical background information questions include items intended to prompt responses about geographic region, practice setting, age, gender, ethnicity, and race. If respondents provide this information, it will help FMCSA to begin to understand characteristics of medical examiners who perform FMCSA CMV driver physical examinations. This is particularly important given that medical examiners who conduct CMV driver certification examinations are considered a hidden population, one without a well-established sampling frame. FMCSA does not expect to define medical examiner demographics with this study. Rather, the purpose of this study is to compare performances of medical examiners from various backgrounds in applying driver certification regulations.

12. Estimate of burden hours for information requested.

FMCSA estimates that the total burden hours for the collection of the survey data is 1,689.5 hours [3,379 returned surveys x 30 minutes per response = 1,689.5 hours]. These numbers were calculated using the following considerations:

For the NRCME listserv: FMCSA and Axiom Resource Management, Inc. will send the registration link to the approximately 4,000 medical examiners who are members of this listserv. The rate of returned recruitment correspondence due to inaccurate contact information for the NRCME Role Delineation Study, sent to a similar sample, was 4.4%. If applied to this study, that would result in a total of 3,824 emails reaching their intended recipients. We will attempt, using all reasonable follow-up approaches, to achieve an 80 percent response rate. We therefore estimate that 3,059 individuals from the current NRCME listserv will complete the survey.

For the OCC-ENV-MED, MCOH/EH, SAFETY, and MRO listservs: FMCSA and Axiom Resource Management, Inc. will send the survey link to approximately 8,000 total contact emails available through these four listservs. We anticipate that there will be considerable overlap in membership between multiple listservs. Because listserv administrators cannot allow us access to the names of members, we cannot estimate the amount of overlap. Therefore, we will apply the conservative estimate of 5%; that is, we estimate that 5% of the total sample will 1) be medical examiners from the four medical profession groups, 2) currently conduct CMV driver physical examinations, 3) not be duplicated on the NRCME listserv directory, and 4) be reached by the recruitment correspondence at an active email address. Using the 80 percent survey response rate, we estimate that 320 additional individuals from these listservs will complete the survey.

FMCSA estimates that it will also take 4.67 hours to complete the observation consent forms for the survey [(28 medical examiners + 28 drivers) x 5 minutes/60 minutes = 4.67 hours].

Estimated Number of Respondents: 3,435 respondents [3,379 medical examiners for survey + 56 additional respondents (28 medical examiners + 28 drivers for on-site observations) = 3,435 respondents].

Estimated Annual Burden to Respondents: 1,694.17 hours (1,689.5 to complete the surveys + 4.67 hours to complete the observation consent forms = 1,694.17 hours).

FMCSA estimates that 3,379 medical examiners who currently perform FMCSA CMV driver physical examinations will provide responses to the survey. We further estimate that the cost for the medical examiner respondents for the medical examiner survey is \$91,233 (3,379 respondents x 30 minutes per

response/60 minutes = $1,689.5 \times 54.00 per hour = \$91,233). The amount of \$54.00 per hour is the weighted hourly average wage for the medical examiner professions authorized to perform FMCSA CMV driver physical examinations.

CMV drivers' salary costs associated with the burden for completion of the observation consent forms are estimated as follows. The average hourly earnings (including benefits) for drivers of general freight trucks is \$20.00. Therefore, we estimate that the cost for CMV drivers to complete observation consent forms is \$46.67 (28 CMV drivers x 5 minutes/60 minutes x \$20.00 per hour = \$46.67). Using the weighted hourly average for medical examiners (please see above) we estimate that the cost for medical examiners to complete observation consent forms is \$126.00 (28 medical examiners x 5 minutes/60 minutes x \$54.00 per hour = \$126.00). Therefore, the total salary cost for all respondents to complete observation consent forms is \$172.67 (\$46.67 + \$126.00 = \$172.67).

There is no additional record keeping, information gathering or contracted services that the respondents must incur to respond to the survey.

Estimated Annual Total Cost to Respondents: A one-time cost of \$91,405.67; (\$91,233 + \$172.67 = \$91,405.67). This is not a longitudinal design, and there are no plans to conduct the Medical Examiner Performance Study Survey on a recurring basis.

13. Estimate of total annual costs to respondents.

None except those reported in Item 12 above for the respondents' time to complete the survey and consent forms.

14. Estimate of cost to the Federal government.

FMCSA estimates that the total cost for collecting and analyzing the medical examiner survey data is \$160,000. These costs will be absorbed in a current contract agreement between FMCSA and Axiom Resource Management, Inc.

As the Medical Examiner Performance Study Survey is a single event research effort, there will be no cost to the Federal government beyond those expenses absorbed in the contract agreement detailed above.

Estimated Total Annual Cost to Federal Government: \$160,000.

15. Explanation of program changes or adjustments.

The program change of 1,694.17 estimated total annual burden hours is due to a new information collection.

16. Publication of results of data collection.

The current estimated schedule for conducting the survey and site visits and release of results is as follows:

<u>Month</u>	<u>Task</u>
1, 2, 3	Email recruitment correspondence to potential respondents; email correspondence to registered respondents providing a URL address and user-specific identifier;
1, 2, 3	Collect survey responses; email follow-up correspondence to those who have not yet registered as well as registered respondents who have not yet completed the survey;
4	Begin preliminary analysis of survey responses; deliver initial survey analysis to FMCSA;
4, 5,	Conduct medical examiner site visits, ongoing WIPT review of site visit outcomes;
5	Draft Medical Examiner Performance Report, incorporating site visit findings, and submit for review; and
6	Submit final Medical Examiner Performance Report.

A comprehensive final Medical Examiner Performance Report will be delivered to FMCSA in month 6 of the current project schedule. An Executive Summary of results of the Medical Examiner Performance Study, including survey results, will be posted on the FMCSA Web site (http://www.fmcsa.dot.gov/). Publication of the data is optional, and would likely be limited to the transportation and health literature, as well as presentations at appropriate conferences and meetings.

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.

ATTACHMENTS

- A. Survey Instrument
- B. Section 515 of Public Law 106-554
- C. FMCSA's 60-day notice requesting comments (Federal Register notice, dated June 19, 2006 (71 FR 35324)
- D. Comment from the 60-day notice and FMCSA response thereto
- E. Comment from the 60-day notice and FMCSA response thereto
- F. Comment from the 60-day notice and FMCSA response thereto
- G. Comment from the 60-day notice and FMCSA response thereto
- H. FMCSA's 30-day notice requesting comments
- I. Recruitment Email 1
- J. Recruitment Email 2
- K. Recruitment Email 3
- L. Recruitment Email 4
- 49 CFR 391.41, Physical qualifications and examinations
- 49 CFR 398.3, Qualifications of drivers or operators