DEPARTMENT OF TRANSPORTATION

[4910-EX-P]

Federal Motor Carrier Safety Administration
49 CFR Parts 350, 383, 390, and 391
[Docket No. FMCSA-2008-0363]
RIN 2126-AA97
National Registry of Certified Medical Examiners
AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.
ACTION: Final rule.

SUMMARY: FMCSA establishes a National Registry of Certified Medical Examiners (National Registry) with requirements that all medical examiners who conduct physical examinations for interstate commercial motor vehicle (CMV) drivers meet the following criteria: complete certain training concerning FMCSA's physical qualification standards, pass a test to verify an understanding of those standards, and maintain and demonstrate competence through periodic training and testing. Following establishment of the National Registry and a transition period, FMCSA will require that motor carriers and drivers use only those medical examiners on the Agency's National Registry and will only accept as valid medical examiner's certificates issued by medical examiners listed on the National Registry. FMCSA is developing the National Registry program to improve highway safety and driver health by requiring that medical examiners be trained and certified so they can determine effectively whether a CMV driver's medical fitness for duty meets FMCSA's standards.

DATES: Effective on May 21, 2012. Compliance required beginning on May 21, 2014.

FOR FURTHER INFORMATION CONTACT: Elaine Papp, Office of Carrier, Driver and Vehicle Safety Standards (MC-PSP), Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590-0001. Telephone (202) 366-4001. E-mail: FMCSAMedical@dot.gov.

ADDRESSES: Availability of Rulemaking Documents: For access to docket FMCSA-2008-0363 to read background documents and comments received, go to http://www.regulations.gov at any time, or to U.S. Department of Transportation, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m. e.t., Monday through Friday, except Federal holidays.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement, published in the <u>Federal</u> <u>Register</u> on April 11, 2000 (65 FR 19476), or you may visit http://DocketInfo.dot.gov.

SUPPLEMENTARY INFORMATION: This document is organized as follows:

I. Table of Acronyms and Abbreviations

II. Legal Basis for the Rulemaking

III. Background

IV. Discussion of Comments Received on the Proposed Rule

V. Section-by-Section Explanation of Changes from the NPRM

Acronym or Abbreviation	Term
	American Academy of Numa Drastition and
AANP	American Academy of Nurse Practitioners
AAOHN	American Association of Occupational Health Nurses

VI. Regulatory Analyses and Notices **Table of Acronyms and Abbreviations**

AAPA	American Academy of Physician Assistants
ABA	American Bus Association
ACOEM	American College of Occupational and Environmental
	Medicine
ADA	American Diabetes Association
Advocates	Advocates for Highway and Auto Safety
AME	Aviation Medical Examiner
APN	Advanced Practice Nurse
ATA	American Trucking Associations, Inc.
BISC	Bus Industry Safety Council
CAA	Clean Air Act
CDL	Commercial Driver's License
CDLIS	Commercial Driver's License Information System
CME	Continuing Medical Education
CMV	Commercial Motor Vehicle
DC	Doctor of Chiropractic
DEP	Diabetes Expert Panel
DO	Doctor of Osteopathy
DOT	U.S. Department of Transportation
EA	Environmental Assessment
FHWA	Federal Highway Administration
FMCSA	Federal Motor Carrier Safety Administration
FMCSRs	Federal Motor Carrier Safety Regulations
HIPAA	Health Insurance Portability and Accountability Act
ISAREC	Indiana Statewide Association of Rural Electric Cooperatives
LTCCS	Large Truck Crash Causation Study
LFC	Licencia Federal de Conductor
MCMIS	Motor Carrier Management Information System
MCSAP	Motor Carrier Safety Assistance Program
MD	Doctor of Medicine
ME	Medical Examiner
MEP	Medical Expert Panel
Med. Cert./CDL	Medical Certification Requirements as Part of the CDL
MOU	Memorandum of Understanding
MRB	(FMCSA's) Medical Review Board
MRO	Medical Review Officer
NADME	National Academy of DOT Medical Examiners
NAFTA	North American Free Trade Agreement
NCCA	National Commission of Certifying Agencies
NPRM	Notice of Proposed Rulemaking
National Registry	National Registry of Certified Medical Examiners
NSTA	National School Transportation Association
NTSB	National Transportation Safety Board
OOIDA	Owner-Operator Independent Drivers Association

PA	Physician Assistant
PHI	Protected Health Information
PIA	Privacy Impact Assessment
PII	Personally Identifiable Information
PRA	Paperwork Reduction Act
RDS	Role Delineation Study
RIA	Regulatory Impact Analysis
SAFETEA-LU	Safe, Accountable, Flexible, Efficient Transportation Equity
	Act: A Legacy for Users
SBA	Small Business Administration
SDLAs	State Driver Licensing Agencies
Wynne	Wynne Transport Services, Inc.

I. Summary of the Final Rule

This rule establishes a training, testing, and registration program to certify medical professionals as qualified to conduct medical certification examinations of commercial drivers. Current regulations require all interstate commercial drivers (with certain limited exceptions) to be medically examined by a licensed health care provider to determine whether these drivers meet the FMCSA physical qualification requirements. All drivers must carry a medical examiner's certificate as proof that they have passed this physical qualification examination. The MEs who conduct said physical examinations must retain copies of the Medical Examination Reports of all drivers they examine and certify. The Medical Examination Report lists the specific results of the various medical tests used to determine whether a driver meets the physical qualification standards set forth in subpart E of part 391 of the FMCSRs.

Before the adoption of this rule, there was no required training program for the medical professionals who conduct driver physical examinations, although the FMCSRs required MEs to be knowledgeable about the regulations (49 CFR 391.43(c)(1)). The former rules required that any medical professional licensed by his or her State to conduct

physical examinations could conduct driver medical certification exams. No specific knowledge of the Agency's physical qualification standards was required or verified by testing. As a result, some of the medical professionals who conduct these examinations may be unfamiliar with FMCSA physical qualification standards and how to apply them. These professionals may also be unaware of the mental and physical rigors that accompany the occupation of CMV driver, and how various medical conditions (and the therapies used to treat them) can affect the ability of drivers to safely operate CMVs.

This rule establishes the National Registry to ensure that all MEs who conduct driver medical certifications have been trained in FMCSA physical qualifications standards and guidelines. In order to be listed on the National Registry, MEs are required to attend an accredited training program and pass a certification test to assess their knowledge of the Agency's physical qualifications standards and guidelines and how to apply them to drivers. Upon passing this certification test, and meeting the other administrative requirements associated with the Program, MEs will be listed on the National Registry. Once this rule is fully implemented, only medical certificates issued to drivers by MEs on the National Registry will be considered valid by the Agency as proof of medical certification.

II. Legal Basis for the Rulemaking

The primary legal basis for the National Registry of Certified Medical Examiners program comes from 49 U.S.C. 31149, enacted by section 4116(a) of Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users, Pub. L. 109-59, 119 Stat. 1726 (Aug. 10, 2005) (SAFETEA-LU). Subsection (d) of section 31149 provides that:

The Secretary, acting through the Federal Motor Carrier Safety Administration--

- shall establish and maintain a current national registry of medical examiners who are qualified to perform examinations and issue medical certificates;
- shall remove from the registry the name of any medical examiner that fails to meet or maintain the qualifications established by the Secretary for being listed in the registry or otherwise does not meet the requirements of this section or regulation issued under this section;
- shall accept as valid only medical certificates issued by persons on the national registry of medical examiners; and
- may make participation of medical examiners in the national registry voluntary if such a change will enhance the safety of operators of commercial motor vehicles.

In addition to implementing the provisions in subsection (d), which specifically directs the establishment of a national registry of qualified medical examiners, FMCSA implements through this rulemaking certain other provisions from section 31149 related to a national registry. First, subsection (c) requires FMCSA, with the advice of the Agency's Medical Review Board and Chief Medical Examiner (established by subsections (a) and (b), respectively), to develop, as appropriate, specific courses and materials for training required for medical examiners to be listed on a national registry. Medical examiners will be required to undergo initial and periodic training and testing in order to be listed on the national registry (section 31149(c)(1)(A)(ii) and (c)(1)(D)). Second, FMCSA also implements requirements for medical examiners to transmit electronically, on a monthly basis, certain information about completed Medical Examination Reports of CMV drivers (section 31149(c)(1)(E)). Third, the rule requires medical examiners to provide copies of Medical Examination Reports and medical examiner's certificates to FMCSA within 48 hours of a request from enforcement personnel. This level of responsiveness is required to enable FMCSA to investigate patterns of errors or improper certification by medical examiners, in accordance with 49 U.S.C. 31149(c)(2). Finally, the rule establishes the procedures and grounds for removal of medical examiners from the National Registry, as authorized by section 31149(c)(2)and (d)(2).

SAFETEA-LU also revised the statutory minimum standards for the regulation of CMV safety to ensure that medical examinations of CMV drivers are "performed by medical examiners who have received training in physical and medical examination standards and, after the national registry maintained by the Department of Transportation ... is established, are listed on such registry" (49 U.S.C. 31136(a)(3), as amended by section 4116(b) of SAFETEA-LU). The statute requires FMCSA, in developing its regulations, to consider both the effect of driver health on the safety of CMV operations and the effect of such operations on driver health (49 U.S.C. 31136(a)).

In addition to the general rulemaking authority in 49 U.S.C. 31136(a), the Secretary of Transportation is specifically authorized by section 31149(e) to "issue such regulations as may be necessary to carry out this section." Authority to establish and

implement the National Registry program has been delegated to the Administrator of FMCSA (49 CFR 1.73(g)).

III. Background

On December 1, 2008, FMCSA published a notice of proposed rulemaking (NPRM) to establish the National Registry (73 FR 73129). The public comment period for the NPRM closed on January 30, 2009. The FMCSA also proposed to require that all medical examiners who conduct physical examinations for interstate CMV drivers complete certain training concerning FMCSA physical qualification standards, pass a test to verify an understanding of those standards, and maintain and demonstrate competence through periodic training and testing. Following establishment of the National Registry and a transition period, only medical examiner's certificates issued by medical examiners listed on the National Registry would be accepted as valid.

IV. Discussion of Comments Received on the Proposed Rule

A. Overview of Comments

In response to the December 2008 NPRM, FMCSA received approximately 80 comments. Most of the commenters were individuals, many of whom identified themselves as health care professionals. Among other commenters were the following: nine health care provider professional associations, among them the American College of Occupational and Environmental Medicine (ACOEM) and the American Chiropractic Association; the American Diabetes Association; five trucking and other trade associations, including the American Trucking Associations, Inc. (ATA), Owner-Operator Independent Drivers Association (OOIDA), and jointly from American Bus Association (ABA) and Bus Industry Safety Council (BISC); six motor carriers; six other private businesses, including driver training and testing organizations; nine State agencies (from Arizona, California, Delaware, Florida, Illinois, Indiana, Iowa, Missouri, and Virginia); Advocates for Highway and Auto Safety (Advocates); and the National Transportation Safety Board (NTSB). Comments were also received from FMCSA's Medical Review Board (MRB), an advisory group of physicians appointed by FMCSA to make evidence-based recommendations for the development of physical qualification standards for drivers, driver examination requirements, and materials for training Medical Examiners (MEs). The MRB is convened by FMCSA to provide information, advice, and recommendations to the Secretary of Transportation and the FMCSA Administrator on the development and implementation of science-based physical qualification standards applicable to interstate CMV drivers. The MRB does not hold regulatory development responsibilities, manage programs, or make decisions affecting such programs.

Fourteen commenters expressed support for the proposed rule. However, nearly all of those supporting the proposed rule added recommendations or voiced concern about various parts of the proposed requirements, including increased costs and training requirements for MEs, the implementation period, and the lack of a developed training curriculum. Seven commenters explicitly opposed the proposed rule. Other commenters expressed serious concerns over specific requirements that they believed would cause the proposed rule to fail, including increased costs, lack of access to MEs, and driver privacy rights if State Driver Licensing Agencies (SDLAs) are permitted to obtain the commercial driver's Medical Examination Reports. The following sections provide details regarding specific issues raised by the commenters.

B. Scope of National Registry Program

1. Eligibility to Be a Medical Examiner

<u>Who should be eligible?</u> Under 49 CFR 390.103, FMCSA proposed a requirement, based on the existing regulation at 49 CFR 390.5, that medical examiners must be licensed, certified, or registered in accordance with applicable State laws and regulations to perform physical examinations. The list of major health care professionals who may apply for ME certification included: Advanced Practice Nurses (APNs), Doctors of Chiropractic (DCs), Doctors of Medicine (MDs), Doctors of Osteopathy (DOs), Physician Assistants (PAs), or other health care professionals authorized by their States to perform physical examinations. Commenters asserted that only physicians (MDs and DOs), or only physicians, APNs, and PAs, or only health care providers who are permitted by their States to prescribe medications, should be eligible to be certified and be on the National Registry. Others argued that other health care professionals who are licensed by their States to perform physical examinations are qualified to perform the driver examinations and should be eligible.

Several commenters thought that the proposed requirements would lead to a decrease in the quality of MEs. Arizona stated that with fewer doctors serving as MEs due to the time needed for training and testing, there would be an increase in the number of allied health and non-physician medical professionals completing examinations. On the other hand, Schneider National suggested that the National Registry requirements will deter only those medical professionals who today may be performing commercial driver medical examinations with little or no knowledge of the driver physical requirements of FMCSA.

FMCSA Response: The final rule makes no change in the regulatory text. In a 1992 rule, the Federal Highway Administration (FHWA) (which was responsible for administering Federal motor carrier safety requirements until 1999) amended the FMCSRs to expand the definition of "medical examiner" to allow other health care professionals such as PAs, APNs, and DCs, in addition to MDs and DOs authorized previously, to perform examinations of CMV drivers (57 FR 33276; July 28, 1992). All medical examiners were required to be licensed, registered, or certified by their States to perform physical examinations, and to be proficient in the use of, and to use, medical protocols necessary to perform the examination in accordance with the FMCSRs. The 1992 rule acknowledged that should an ME discover a medical condition outside his or her scope of practice, best practice would be to refer the driver to an MD, DO, or specialist. The FHWA indicated this was consistent with what other medical practitioners do in "this age of specialization." States determine who is legally qualified to perform physical examinations within their jurisdictions by setting scope of practice requirements, and FMCSA will continue to rely on State determinations.

<u>Qualification by Other Criteria.</u> FMCSA proposed that medical examiner candidates be required to complete training that meets the core curriculum specifications established by FMCSA for medical examiner training and pass an FMCSA-provided certification test. Both the core curriculum specifications and the FMCSA-provided certification test will be based on FMCSA regulations and guidelines.

Several commenters proposed the substitution of other types of training for the training requirements proposed in the NPRM. Two MDs, and the States of Arizona and Delaware, suggested that Federal Aviation Administration (FAA) aviation medical

examiners (AMEs) could be certified, without further training or testing as FMCSA MEs. One physician recommended that we accept MD and DO board certification. The American Association of Occupational Health Nurses (AAOHN) suggested similarly that we should reduce required training for APNs and physicians who are experienced and professionally trained in occupational health.

National Registry Training Systems, an independent entity not affiliated with FMCSA, and a clinician suggested that we should certify health care professionals who participated as subject matter experts in the development of the National Registry program training and testing components. Similarly, a MD suggested that we permit health care professionals to by-pass training if they have a working knowledge of the DOT requirements and guidance.

FMCSA Response: The FMCSA acknowledges the specialized knowledge and expertise that some health care professionals bring to the driver qualification process. Physicians can and do serve as both MEs for CMV drivers and designated AMEs for pilots. However, the National Registry program has been developed with strategic differences from the FAA AME designee program, as detailed in the regulatory evaluation for this rulemaking, to be suitable for the oversight of large numbers of MEs performing examinations for large numbers of drivers, using medical standards and guidelines developed specifically for CMV drivers. The final rule will require all ME candidates to undergo the initial training and the certification testing that objectively measures candidate qualification and ensures that all MEs have the same level of working knowledge of the FMCSA regulations and guidelines. Due to the specialized nature of CMV driving, FMCSA retains the requirement that MEs must take training and pass its

certification test to give driver exams. Only the specified training will provide pertinent knowledge of the FMCSA regulations and guidelines.

Limitations on Performance of Driver Examinations. FMCSA did not propose any change in the regulations and guidelines for performance of the driver qualification physicals.

The MRB's members submitted comments that reiterated the Board's recommendation that only physicians should perform examinations on drivers who have more severe or multiple medical conditions. ADA commented specifically on drivers with diabetes. Claiming that not all MEs would have the requisite clinical knowledge to complete the examination, ADA urged FMCSA to include physicians who treat individuals with diabetes, including endocrinologists, in the process of certifying drivers with diabetes. The commenter said that a physician or endocrinologist should examine drivers with that condition before such drivers are rejected. ADA also referenced the recommendations of FMCSA's Medical Expert Panel (MEP) on Diabetes, Expert Panel Commentary and Recommendations, Diabetes and Commercial Motor Vehicle Driver Safety, September 8, 2006, available at http://www.fmcsa.dot.gov/rules-regulations/topics/mep/mep-reports.htm and recommended that no denial of certification could be made for any reason related to diabetes without the review and approval of an endocrinologist.

OOIDA, the American Academy of Nurse Practitioners (AANP), and the American Academy of Physician Assistants (AAPA) claimed that we should reject the recommendation to only allow physicians as MEs for drivers who have multiple active medical problems, claiming that this requirement would require most drivers to be

examined by MEs who are physicians and would contribute to a shortage of qualified MEs. Both OOIDA and AAPA stated that this requirement would negatively affect a significant portion of the CMV driver population. OOIDA said that a large percentage of drivers would have to travel greater distances for medical exams. AAPA noted the results of a survey of 1,167 drivers across the United States, which found 32 percent of drivers with hypertension and 14 percent with diabetes. AAPA said that the proposed requirement could mean a driver who discovers an additional condition during an exam with an ME, who is not a physician, would have to stop that examination and reschedule with a physician.

AANP and AAPA argued that practitioners in their respective professions are well-qualified to perform examinations on drivers with multiple active medical problems. AANP noted that its members have been performing driver examinations since 1992 without incident. AAPA similarly claimed that PAs have regularly been performing examinations on this class of drivers for 17 years and have specifically received authorization to do so in the FMCSRs. This commenter also noted that State laws and regulations do not preclude PAs from treating patients with diabetes or multiple medical conditions.

AAPA stated that SAFETEA-LU and the Agency charge the MRB with making science and evidence-based recommendations, but the commenter claimed that no evidence, studies, or data were presented in support of restricting PAs from performing examinations on drivers with multiple active medical problems. AAPA argued that it would be unfair to eliminate PAs from performing these types of examinations since the commenter and many individual PAs aided FMCSA's development of the National

Registry program by participating as subject matter experts in the development of several components of the program.

Finally, because of the potential for a conflict of interest in completing an objective examination, comments from the MRB and Schneider National recommended against allowing primary care or personal health care professionals to perform the examinations. The MRB advised FMCSA to allow for an exception to this prohibition if no other medical provider was located within a 200-mile radius from the driver's residence or location of employment. In its comments, OOIDA recommended that the final rule expressly prohibit motor carriers from restricting the driver's rights to be examined by the ME of his or her choice, noting that once the final rule is implemented, all MEs listed on the National Registry will be equally qualified to perform a driver examination. Therefore, there should be no ME quality concern on the part of the motor carrier.

FMCSA Response: We do not believe we should impose an additional burden on drivers by requiring them to be examined by MEs who do not provide primary care to them. FMCSA anticipates that requirements for medical examiners to be trained and tested in FMCSA standards and guidelines will result in more consistency in certification decisions among MEs. FMCSA anticipates that MEs will be deterred from making driver qualification decisions that violate FMCSA standards by the provisions in the rule that would allow FMCSA to remove an ME from the National Registry.

In addition, we believe that employers should continue to have the option to require their drivers to be examined by a ME selected and/or compensated by the employer, because they have an obligation to require drivers to comply with the

regulations that apply to the driver (49 U.S.C. 31135(a) and 49 CFR 390.11). This option is permitted by 49 CFR 390.3(d), which states that nothing in the FMCSRs "shall be construed to prohibit an employer from requiring and enforcing more stringent requirements relating to safety of operation and employee safety and health."

Comments that recommended restricting some MEs from performing examinations for certain drivers or to include specialists in the driver certification decision relate to medical standards and guidelines for determining the physical qualifications of drivers and are therefore beyond the scope of this rulemaking. Moreover, the MRB does not have authority to undertake regulatory development responsibilities, manage programs, or make decisions affecting such programs.

2. Employer and Carrier Responsibilities

FMCSA proposed that all driver examinations would be performed by a medical examiner on the National Registry three years after the final rule implementation date, and all examinations for drivers who worked for an employer who employed 50 or more drivers would be required to be performed by a medical examiner on the National Registry two years after the final rule implementation date. FMCSA also proposed that medical examiners on the National Registry would be required to provide copies of the Medical Examination Reports and medical examiner's certificates to FMCSA or to authorized Federal, State and local enforcement agency personnel within 48 hours of the request.

Daecher Consulting Group and Comcar Industries expressed concern that motor carriers would be responsible for determining whether a driver's physical qualification information was accurate. Asserting that the proposed rule was an attempt to make

carriers responsible for ensuring that physical examination data are correct, Comcar Industries said that a carrier could not provide such assurances because it is not present for the physical examination and has no access to medical information from any previous employer.

Dart Transit Company suggested that the ME should be required to notify the motor carrier if a driver fails the medical examination. ATA recommended that motor carriers should have access to an electronic database to obtain their drivers' Medical Examination Reports. OOIDA opposed disclosure of sensitive medical information to motor carriers because misconceptions or prejudices about the driver's medical condition could lead to termination of an employee from a job, even though the condition would not prevent the driver from doing his or her job in a safe and professional manner.

Daecher Consulting Group stated that there was no method proposed in the NPRM for notifying a carrier that it employs a driver certified by an examiner who was removed from the National Registry. The commenter said that unless a notification system is devised and implemented (which would require registering Commercial Driver's License (CDL)-licensed drivers in a database, matching them with current carriers employing them, and having a method to track any change in carriers), significant liability may rest with carriers that use a driver certified by a once-certified ME who has since been involuntarily removed from the National Registry.

FMCSA Response: Although the rule provides for FMCSA and State and local law enforcement personnel to obtain copies of driver examination records, the purpose of this requirement is to monitor ME performance, not driver qualification. FMCSA is not requiring employers to monitor ME performance. In order to clarify this matter in light of

these comments, FMCSA is making one change in employer responsibility under this rule. FMCSA is adding a requirement that the employer verify that the driver was issued a medical certificate by an ME on the National Registry and place a note to that effect in the driver qualification file required by 49 CFR 391.51. This will also be consistent and enhance compliance with 49 U.S.C. 31149(d)(3). Beyond that, FMCSA recognizes that employers are not required by the current FMCSA regulations to obtain copies of Medical Examination Reports for their drivers, and does not hold employers responsible for knowing what medical conditions may be recorded therein.

FMCSA has the discretion to void any medical certificate issued to a driver by a medical examiner who has been removed from the National Registry (49 U.S.C. 31149(c)(2)). The NPRM did not need to propose and does not include any provisions to implement that authority, which can be exercised by FMCSA on a case-by-case basis when the facts and circumstances indicate that it would be appropriate.

Notification of employers of failed examinations is desirable, and in the future, FMCSA may use driver physical examination results data to notify employers. However, FMCSA modifies the final rule to require employers, upon hiring or upon expiration of a medical examiner's certificate on or after 24 months after the effective date of this final rule to verify the driver presenting a medical certificate was examined by a ME on the National Registry. The rule does not require employers to recheck the National Registry Web site to determine if the medical examiner has been involuntarily removed subsequent to conducting an examination and completing the certificate.

3. State Responsibilities

FMCSA proposed revising medical examiner's certificate to include the National

Registry number issued by FMCSA to identify the ME. California and Virginia expressed uncertainty about the State's role in determining whether the medical examination was completed by an ME on the National Registry and expressed concern about the cost of reprogramming the Commercial Driver's License Information System (CDLIS) to query the ME database, when processing driver medical certifications. Indiana asked whether MEs would be expected to include the National Registry number on any old medical examiner's certificate forms or would States have to look up the number.

Indiana questioned how involuntary removal of an ME from the National Registry will affect that ME's previously issued certificates. Similarly, Indiana also requested that we clarify how we will notify SDLAs that an ME has been removed from the National Registry.

FMCSA Response: States will not be required to cross-check National Registry numbers with the National Registry database when processing driver medical certifications. Indiana's concern about entering National Registry numbers on old certificates is moot, because the final rule will not allow the use of any old forms. This final rule does not require changes to State driver's license databases or CDLIS beyond those required by the already-published final rule in Medical Certification Requirements as Part of the CDL (73 FR 73096, December 1, 2008) (Med. Cert./CDL). However, FMCSA anticipates initiating a future rulemaking to expand medical certification information exchange with the States.

Certificates previously issued by a medical examiner who has been involuntarily removed are not automatically voided. FMCSA has the discretion to void any medical certificate issued to a driver by an ME who is removed from the National Registry (49

U.S.C. 31149(c)(2)). The NPRM did not need to propose and does not include any provisions to implement that authority, which can be exercised by FMCSA on a case-by-case basis when the facts and circumstances indicate that it would be appropriate.

State Investigation of Driver Certification. Advocates criticized the lack of any systematic procedure in the proposed rule that requires State law enforcement agencies to compare each Medical Examination Report with the related medical examiner certificate. The commenter noted that in the preamble to the proposal we do not explain why and how State enforcement agencies would have reason to investigate specific Medical Examination Reports and medical certificates. On the other hand, OOIDA argued that Federal preemption would prohibit State and local agencies from requesting an ME to give a driver's Medical Examination Report to them as we proposed. The commenter said that once we prescribe safety standards requiring MEs on the National Registry to examine and issue certificates to show a CMV driver's physical condition is adequate for safe vehicle operations, those regulations would have a preemptive effect under section 31136.

OOIDA cited <u>Freightliner Corp.</u> v. <u>Myrick</u>, 514 U.S. 280, 287 (1995), and <u>Gade</u> v. <u>National Solid Wastes Management Ass'n</u>, 505 U.S. 88, 98 (1992), in support of implied preemption "when a 'state law is in actual conflict with federal law…or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress'." OOIDA argued that allowing State and local authorities to access a driver's personal medical information might dissuade drivers from openly discussing their health issues with an ME. OOIDA said unqualified State government personnel might apply their own standards to driver medical information and

inconsistently judge them medically unfit for reasons that are erroneous or unjustifiably exceed the Federal medical standards being applied. OOIDA concluded that, at a minimum, we should require States to limit any Medical Examination Report (commonly called the "long-form") request to circumstances where the State has clearly articulated legitimate reasons for believing that the medical certificate was falsified or otherwise improperly issued.

FMCSA Response: OOIDA's comment does not recognize that State and local enforcement personnel have a role in enforcing the FMCSRs. The final rule retains the requirement for MEs to give State and local enforcement personnel access to Medical Examination Reports and ME certificates within 48 hours of a request for purposes of monitoring ME performance. States that receive Motor Carrier Safety Assistance Program (MCSAP) grant funds are required as a condition of receiving the grants to adopt regulations that are compatible with these final regulations (49 U.S.C. 31102(a) and 49 CFR 350.201(a)). States receiving MCSAP grants, therefore, will generally have to adopt regulations compatible with requirements that all drivers be examined by an ME on a registry of trained and certified MEs applicable to both interstate and intrastate transportation as soon as practicable, but not later than 3 years from effective date of this rule (49 CFR 350.331(d)).¹ State government personnel operating under MCSAP will have the same authority and responsibility to request that an ME produce a driver's Medical Examination Report that FMCSA personnel will have in accordance with this final rule. The States receiving MCSAP grants will be expected to adopt and implement

¹ As explained later, States that have in effect variances for physical qualification requirements for drivers operating CMVs in intrastate commerce will have the option of not establishing a separate registry of medical examiners trained and qualified to apply those standards.

compatible provisions and apply them consistently. There will be no inconsistency between State and Federal law that would require either express or implied preemption.

FMCSA believes that the establishment of the National Registry, with its training and testing requirements will improve the performance of the MEs. Verification of the certification and listing of the MEs on the National Registry will be enhanced. In addition, the availability of the examiner's records to enforcement personnel, when necessary to conduct an investigation into the validity of the medical certificate, is sufficient to deter improper medical certification of CMV drivers.

4. Intrastate-Only CMV Drivers

FMCSA proposed that MEs would include information on the monthly reports of driver examinations whether each driver operated only in intrastate commerce. OccuMedix and Missouri raised the issue that MEs would not be able to distinguish between interstate drivers and intrastate-only drivers required by their States to obtain a medical certification from an ME on the National Registry. The commenters suggested that the final rule should require all drivers – interstate and intrastate – to obtain medical examinations from examiners listed on the National Registry.

Missouri said we should consider that many States require CMV drivers operating in intrastate commerce to follow the FMCSRs and that there would be confusion if we require MEs to examine only CDL drivers operating in interstate commerce. Missouri argued that we can promote public safety further if all nonexempt CDL drivers are required to obtain medical examinations from examiners listed on the National Registry, even when the drivers operate CMVs exclusively in intrastate commerce.

FMCSA Response: States will continue to set requirements for intrastate drivers. States that receive MCSAP grant funds are required, as a condition of receiving the grants, to adopt regulations compatible with these final regulations (49 U.S.C. 31102(a) and 49 CFR 350.201(a)); however, the Agency is including in this final rule a revision to 49 CFR 350.341 to make it clear that States that have in effect variances for physical qualification requirements for drivers operating CMVs in intrastate commerce will have the option of not establishing a separate registry of medical examiners trained and qualified to apply those intrastate standards, although they have the discretion to do so if they wish. A State with variances in effect under 350.341(h)(1) and (2) that chooses to set up a separate registry of examiners qualified to apply those variances to intrastate drivers will not be allowed to use MCSAP funds for that purpose. Such use of MCSAP grant funds would not be consistent with the overall purpose of establishing a uniform standard for all CMV drivers nationwide. Intrastate-only CMV drivers in States that do not have such variances can utilize MEs on the National Registry because they will be trained and qualified in applying physical qualification standards that are identical for both interstate and intrastate drivers. All MCSAP States, either with or without variances, thus will have the option to establish their own registries, but FMCSA is not requiring them to do so as a condition of receiving MCSAP funds.

The rule does not restrict MEs who are certified to perform physical examinations for interstate drivers from performing physical examinations for intrastate only drivers. MEs should ask drivers whether they intend to operate in intrastate commerce only. FMCSA Form MCSA-5850, CMV Driver Medical Examination Results Form, requires

MEs to identify "Intrastate Only" drivers on the CMV Driver Examination Results so that FMCSA can distinguish data about intrastate-only driver examinations.

5. Canadian and Mexican Drivers

The NPRM noted that existing reciprocity agreements with Canada and Mexico will govern Canada-domiciled and Mexico-domiciled drivers, respectively, operating in the United States (73 FR 73131, n.3). As a result, Canadian and Mexican drivers do not need to be examined by an ME on the National Registry before operating a CMV in the United States. OOIDA said this language constituted an exemption from Federal regulations, and that we had no authority to grant such an exemption.

FMCSA Response: OOIDA's contention that 49 U.S.C. 31149 does not allow FMCSA to "exempt" Canadian and Mexican drivers operating in the United States from being examined by an ME is incorrect because two separate executive agreements² with Canada and Mexico remain in effect. A brief history of these two agreements is provided for clarification.

Prior to the amendments made by section 4116(b) of SAFETEA-LU, the provisions of 49 U.S.C. 31136(a)(3) stated:

The Secretary of Transportation shall prescribe regulations on commercial motor vehicle safety. The regulations shall prescribe minimum safety standards for commercial motor vehicles. At a minimum, the regulations shall ensure that —

• the physical condition of operators of commercial motor vehicles is adequate to enable them to operate the vehicles safely....

² Executive agreements have the same legal effect as treaties.

For this purpose, a "commercial motor vehicle" is defined in 49 U.S.C. 31132(1).

FMCSA regulations generally required all operators of CMVs in the United States to be examined by an ME (as defined in 49 CFR 390.5) and to obtain from the examiner a certificate that the operator is physically qualified. 49 CFR 391.11(b)(4) and 49 CFR part 391, subpart E. These requirements will continue to apply after establishment of the National Registry Program.

In 1991, the Secretary and his counterpart in Mexico entered into an agreement on the matter of driver license reciprocity. The agreement is contained in a memorandum of understanding (MOU) that was reproduced as Appendix A to a final rule issued in 1992 by FMCSA's predecessor agency, the FHWA. <u>Commercial Driver's License Reciprocity</u> <u>with Mexico</u>, 57 FR 31454 (July 16, 1992), affirmed, *Int'l Brotherhood of Teamsters v. Peña* 17 F.3rd 1478 (D.C. Cir. 1994). The primary purpose of the MOU was to establish reciprocal recognition of the CDL issued by the States to U.S. operators and the Licencia Federal de Conductor (LF) issued by the government of the United Mexican States (i.e., by the national government of Mexico, not by the individual Mexican states). In light of the agreement, the FHWA determined that an LF meets the standards contained in 49 CFR part 383 for a CDL. 49 CFR 383.23(b)(1) and note 1. The FHWA's final rule preamble also states, at 57 FR 31455:

It should be noted that Mexican drivers must be medically examined every 2 years to receive and retain the Licencia Federal de Conductor; no separate medical card [certificate] is required as in the United States for drivers in interstate commerce. As the Licencia Federal de Conductor cannot be issued to or kept by any driver who does not pass stringent physical exams, the Licencia Federal de Conductor itself is evidence that the driver has met medical standards as required by the United States. Therefore, Mexican drivers with a Licencia Federal de Conductor do not need to possess a medical card while driving a CMV in the United States.

Implicit in the determination that Mexican drivers with an LF do not need to possess a separate medical certificate is an underlying determination that the medical examination necessary to obtain the LF meets the standards for an examination by an ME in accordance with FMCSA regulations, and would therefore meet the requirements of 49 U.S.C. 31136(a)(3).

The MOU does not specifically address medical qualifications for Mexican drivers operating a CMV in the United States that does not require a CDL. In order to enter the United States at the border crossing points (all of which are accessed only by federal highways in Mexico) a Mexican driver must have a Licencia Federal. FMCSA enforcement policy accepts a Licencia Federal as proof of physical qualification for a driver to operate a CMV that does not require a CDL in the United States.

In 1998, a similar agreement was reached with Canada under the auspices of the Land Transportation Standards Subcommittee established by the North American Free Trade Agreement (NAFTA). This agreement supplements a 1988 agreement with Canada accepting the CDLs issued by Canadian provinces in accordance with the Canadian National Safety Code as valid for operation of a CMV in the United States. 49 CFR 383.23(b), note 1. The 1998 agreement, which became effective on March 30, 1999, provides, with some exceptions, that Canadian drivers holding such a CDL issued in Canada are physically qualified to operate a CMV in the United States and are not

required to possess a medical certificate issued by a ME. In Canada, drivers are required to have CDLs in order to operate a CMV that would not require a CDL to operate in the United States. Under the 1998 agreement, a Canadian CDL issued in conformity with the National Safety Code is accepted by FMCSA as proof of a driver's physical qualification to operate a CMV in the United States.

The substance of these two agreements is also reflected in a note in 49 CFR 391.41(a)(1), as recently amended. <u>Medical Certification Requirements as Part of the</u> <u>CDL</u>, 73 FR 73096, 73127 (December 1, 2008).

In 2005, 49 U.S.C. 31136(a)(3) was amended by SAFETEA-LU section 4116(b), which added the following at the end:

[T]he periodic physical examinations required of such operators are performed by medical examiners who have received training in physical and medical examination standards and, after the national registry maintained by the Department of Transportation under section 31149(d) is established, are listed on such registry.

As explained above, section 4116(a) of SAFETEA-LU added a new 49 U.S.C. 31149, which among other things, includes a provision that FMCSA "shall accept as valid only medical certificates issued by persons on the national registry of medical examiners." Section 31149(d)(3).

OOIDA contends that this statute supersedes the two agreements with Canada and Mexico and that drivers from these two countries operating CMVs will have to be examined and certified by MEs on the National Registry. According to the cases that are

cited in OOIDA's comments subsequently enacted statutes may abrogate an executive agreement or treaty. The case law states, however, that "neither a treaty nor an executive agreement will be considered abrogated or modified by a later statute unless such purpose on the part of Congress has been clearly expressed." <u>Roeder v. Islamic Republic of Iran</u>, 333 F.3d 228, 237(D.C. Cir. 2003), <u>cert. denied</u>, 542 U.S. 915 (2004) (internal quotations and citations omitted). There is no such clear expression of purpose in the relevant statutes. Neither the amended statutes nor their legislative histories contain any provision addressing these two executive agreements. The reciprocity agreements with Canada and Mexico, and the implementing provisions in the note in 49 CFR 391.41(a)(1), will continue to be in effect after issuance of this final rule. Accordingly, Canadian and Mexican drivers operating CMVs in the United States who hold the proper licenses will not be required to obtain a medical certificate from an ME on the National Registry.

In any case, FMCSA has reviewed the Canadian and Mexican physical qualification processes. Driver medical examinations in Canada are performed only by MDs. National standards direct the medical examiners when to obtain the opinion of a medical specialist. In addition, in most jurisdictions, doctors, including family doctors, have a legal obligation to report any medical condition that may affect driving functions.

The medical examinations in Mexico are conducted by Federal government doctors or Federal government-approved doctors. In addition, the medical certification for an LF is part of Mexico's licensing process for commercial drivers. This means the license is not issued or renewed unless there is proof the driver has satisfied the Mexican physical qualifications standards. FMCSA has compared each of its physical

qualifications standards with the corresponding requirements in Mexico and continues to believe acceptance of the Mexico government's medical certificate is appropriate.

C. Components of the National Registry Program

1. Training of Medical Examiners

Length of Training. In the NPRM, FMCSA projected it would take one day to cover the FMCSA core curriculum specifications. Two commenters claimed that the length of training was inadequate and we should consider increasing it. A chiropractor stated that training should last perhaps two long days followed with reading and study materials. NRCME Training Systems claimed that it would be very difficult in a lecture-based setting, with all of the class questions and discussions generated in a presentation of this nature, to complete quality training in one day. The commenter concluded that, at minimum for a 17-module National Registry training program to thoroughly provide quality training for examiner candidates, five to six, six-hour days of didactic lecture in an attended seminar format would be required.

FMCSA Response: The rule does not prescribe how long training must be. The core curriculum specifications are limited to FMCSA regulations and guidelines, and the mental and physical demands of CMV driving. One advantage of the Public-Private Partnership, is that training can be expanded to meet the needs of health care professionals from diverse educational and professional backgrounds.

<u>Training Intervals.</u> The NPRM proposed that the ME would be required to complete periodic retraining at least every three years and repeat the complete initial training program once every 12 years in lieu of periodic training. Some commenters asserted that repeating the initial training was not necessary, or suggested other

frequencies for training. AAPA and ACOEM recommended that FMCSA eliminate the proposed requirement to retake the initial training course every 12 years. AAPA stated that the requirement offers no benefit to MEs who are already required to participate in periodic training and recertification examinations. ACOEM supported requiring MEs to obtain 12 hours of advanced training every three years instead. Iowa recommended requiring MEs to attend a one-day course in person after the sixth year to renew certification.

FMCSA Response: FMCSA agrees with the commenters that the proposed requirement for MEs to repeat the initial training is not necessary for those MEs who do not allow their certifications to lapse and has modified the final rule to require only periodic training at five-year intervals for recertification. MEs will be required to pass the test for recertification every 10 years.

<u>Training Program Accreditation.</u> FMCSA proposed that medical examiner candidates be required to complete a training program accredited by a nationallyrecognized medical profession accrediting organization. NRCME Training Systems endorsed having post-graduate institutions review and approve National Registry training for MEs, reasoning that these institutions are already certified by a national accrediting agency and that FMCSA would retain control over the training programs through thirdparty post-graduate programs.

FMCSA Response: Only training programs that have been accredited by a nationally recognized medical profession accrediting organization to provide continuing education units will be eligible to provide the required training to MEs. As long as the training program is accredited, and is based on FMCSA's core curriculum specifications

and guidelines, the Agency does not seek to restrict the number or location of programs that provide ME training. Post-graduate divisions of colleges and universities would be eligible to provide training to MEs, as would other accredited training organizations such as professional association continuing medical education (CME) programs and provider network training organizations.

<u>Core Curriculum Specifications.</u> Several commenters expressed concern that we did not provide the content of the core curriculum in the proposed rule and questioned how it would be established and implemented.

One physician commenter was concerned that since the core curriculum specifications have not been developed or approved, it will likely be several years before there are a significant number of trained MEs to accommodate the proposed requirements. A certified Medical Review Officer (MRO) urged us to incorporate good scientific rationale into the development of the curriculum and commented that all sections of the driver examination need to be addressed.

ABA and BISC requested that we engage the private bus industry in developing ME curricula that are related to bus operations and driver wellness. ADA requested that the FMCSA-appointed Diabetes Expert Panel (DEP) be consulted with regard to curriculum elements pertaining to diabetes and suggested that these core curriculum elements be submitted to the DEP for final approval. The commenter also suggested that the DEP's 2006 suggested training module be incorporated in the curriculum.

FMCSA Response: The core curriculum specifications are being issued as guidance for organizations delivering training for MEs who apply for listing on the National Registry when it is implemented. FMCSA published a notice of availability of

draft guidance and request for comments on the core curriculum specifications in the Federal Register on May 17, 2011 (76 FR 28403). Additionally, FMCSA has posted these specifications on the National Registry Web site (<u>http://nrcme.fmcsa.dot.gov</u>) and in the docket for this rulemaking. The guidance for the core curriculum specifications is Appendix A to this Federal Register document.

The guidance for the core curriculum specifications are based on current FMCSA regulations on physical qualifications published in 49 CFR part 391, as well as guidance that is published in 49 CFR 391.43. The guidance for the core curriculum specifications are also based on the task list developed in the Role Delineation Study (RDS) completed in April 2007, as described in the NPRM. The RDS is a rigorous methodology regularly employed in the certification and medical fields when developing a valid, reliable, and fair certification test. An executive summary of the RDS Final Report and the full text of the Final Report are available through the National Registry Web site³ and the docket for this rulemaking.

The Agency does not envision separate medical criteria for bus drivers at this time. Any changes in the basic requirements for training specified in 49 CFR 390.105(b) will be subject to notice and comment proceedings. On the other hand, future changes in the guidance for the core curriculum specifications do not require a notice and comment rulemaking proceeding because they will reflect only regulations and guidelines for performing the driver physical examination. FMCSA has provided and continues to provide for stakeholder input into revising the standards and guidelines through MRB meetings, and public notice of MRB meetings, including specific instructions on where to send comments. FMCSA will revise the guidance for the core curriculum specifications

http://nrcme.fmcsa.dot.gov/training.aspx, retrieved July 13, 2011.

only after we have established new or revised existing, regulations and guidelines. The training provider could expand its course content to tailor training to the needs of its target audience but the course content must cover the FMCSA core curriculum specifications.

FMCSA considered the recommendations of the DEP for ME training in the development of the guidance for the core curriculum specifications. At this time, FMCSA is not adopting the ADA's request to implement the recommendation of the DEP on drivers with diabetes. In general, such MEPs are convened on an <u>ad hoc</u> basis to act in an advisory capacity to FMCSA in its work of reviewing and revising physical qualification standards and guidelines. In any event, FMCSA will consider recommendations from the MEP on standards and specifications for drivers with diabetes in future proceedings.

Comments on the Notice of Availability of the Core Curriculum Specifications.

FMCSA published a notice of availability and request for comments on the draft guidance for the core curriculum specifications in the Federal Register on May 17, 2011 (76 FR 28403). Additionally, FMCSA has posted this guidance on the National Registry Web site (<u>http://nrcme.fmcsa.dot.gov</u>) and in the docket for this rulemaking. FMCSA received five comments from interested parties during the public comment period. The Agency considered the public comments on the draft guidance and now publishes the guidance as Appendix A to this Federal Register document.

In response to the notice of availability, ATA suggested that FMCSA needs to educate MEs about the mental and physical demands of driving a CMV. Several commenters suggested that the curriculum convey to MEs an understanding of the

distinction between guidance and recommendations submitted by various FMCSA advisory committees and boards. NRCME Training Systems thought that FMCSA expected training programs to give continuing education credits. There was also a comment requesting notice and comment rulemaking for future changes in the core curriculum. There were several comments addressing other aspects of the rulemaking other than the core curriculum specifications, which are beyond the scope of the notice of availability.

FMCSA Response: In response to ATA's comment, MEs are, and will still be, required to be knowledgeable of the specific physical and mental demands associated with operating a CMV. 49 CFR 391.43(c)(1). Section 2 of the core curriculum specifications addresses the job of CMV driving, including physical and emotional demands. Section 7 includes consideration of driver ability to perform physical tasks associated with operating a CMV.

The guidance for the core curriculum specifications expands the description of the topics to be covered in training, and do not provide the details that should be included in the actual training. FMCSA commercial driver medical certification regulations, advisory criteria, MRB and MEP functions, and other resources on the website are outside the scope of this notice. Nonetheless, FMCSA continuously reviews and updates information on its websites for content and clarity, and will make sure the difference between regulations, guidance, and advisory recommendations are made clear.

FMCSA wants to clarify that it is not requiring that the training given to MEs qualify for continuing education credits, although the training organizations must be accredited to give continuing education credits.

The Agency is making no changes to the draft guidance for the core curriculum specifications, and issues them as an appendix A to this Federal Register document. Only future changes in medical certification standards will be subject to notice and comment rulemaking. FMCSA will then update the guidance for the core curriculum specifications as appropriate. Because the core curriculum specifications are guidance, consideration and issuance of updated specifications does not require notice and comment in a rulemaking proceeding.

2. Testing of Medical Examiners

<u>Certification Testing Intervals.</u> Some commenters suggested different intervals for such testing. FMCSA proposed a requirement that MEs pass the ME certification test every 6 years in order to remain listed on the National Registry.

FMCSA Response: FMCSA modifies the requirement for MEs already on the registry to pass the certification test again before 10 years instead of before 6 years to demonstrate knowledge of changes and retention of previous knowledge and application. This period was chosen as there are varying lengths of times utilized by medical and healthcare boards to issue board certifications. FMCSA chose 10 years because it is not as burdensome on the medical examiner, but, in FMCSA's judgment, it is a short-enough period to verify MEs are knowledgeable about any changes to our physical qualifications standards and guidance. MEs will also be kept knowledgeable by completing refresher training every 5 years, and receiving updates from FMCSA by email and website postings.

3. Accreditation of National Registry Program

FMCSA asked for comment on its consideration of obtaining accreditation of the components of the National Registry Program that test and certify MEs for listing on the National Registry, in order to demonstrate the robustness of its Program. This accreditation was not the same as the accreditation that was proposed to be required for training.

Several commenters commented regarding the process of obtaining National Commission of Certifying Agencies (NCCA) accreditation of the certification component of the National Registry Program. ATA expressed concern that the accreditation process might cause delay or increase program costs. Calling accreditation time-consuming, burdensome, and costly, ATA said it would oppose accreditation of the ME certification program if the process delayed implementation of the National Registry. Instead, ATA recommended that we either certify the program through a periodic program evaluation and audits conducted by a designated oversight authority, or certify the program using a third-party certifying body.

FMCSA Response: The Agency agrees that accreditation of the National Registry certification component could be expensive and delay implementation of the program. As stated in the NPRM, FMCSA proposed accrediting the testing and certification components of the National Registry Program using the accreditation standards of the NCCA, and is considering the costs and benefits of applying for accreditation for these components (which are administered by the Agency). A new certification program (one that has not previously received accreditation by the NCCA), may apply for accreditation either after 1 year of administration of the certification test or when at least 500 candidates have been assessed with that test instrument, whichever

comes first. FMCSA will conduct program evaluations which are subject to internal and external audits, as well as Congressional oversight.

4. Public Participation in Development of Components

Advocates said FMCSA failed to provide the key features of the preferred Public-Private Partnership approach for evaluation through notice and comment. Advocates contended that the Agency should publish a supplementary notice of proposed rulemaking (SNPRM) with details of the major features to allow for public review and comment. The features Advocates believes are not covered are the core curriculum provided for training companies to use, the criteria to qualify private organizations to conduct training and testing, and the reason for choosing the NCCA as the accreditation organization for the program. Advocates asserts further that another feature of the proposal that "must be exposed to public comment" is the specific content of the test that would be administered to MEs.

FMCSA Response: FMCSA has determined that it is unnecessary to accept Advocate's view that an SNPRM is either required or appropriate. However, the Agency has taken steps to make certain components of the National Registry program available for public comment before their implementation.

FMCSA has determined that the guidance for the core curriculum specifications and other similar documents implementing the National Registry program, such as information for testing providers, does not have to be a subject to a notice and comment rulemaking. The guidance for the core curriculum specifications will meet the minimum requirements of 49 CFR 390.105(b), but will not establish a "binding norm" for MEs for compliance with that provision. <u>American Hospital Ass'n v. Bowen</u>, 834 F.2d 1037, 1046

(D.C. Cir., 1987). Organizations that will provide the training must have the flexibility to develop a particular training curriculum suitable for the type of medical professionals who intend to be listed on the National Registry. This is especially important because, as explained above in Section IV.B.1, FMCSA's regulations will continue to allow several different types of medical professionals, with a wide range of different backgrounds, knowledge, and skills, to act as MEs. This approach is entirely consistent with the authority granted to FMCSA to "develop, <u>as appropriate</u>, specific courses and materials for medical examiners" 49 U.S.C. 31149(c)(1)(D) (emphasis added). In view of the nature of the training that needs to be provided to applicants for certification and listing on the National Registry, and the broad discretionary authority delegated to the Agency to implement the training component, FMCSA has determined that it is appropriate to issue guidance providing the core curriculum specifications for development of training by the various training providers.

Moreover, there are criteria for determining which organizations would be deemed acceptable for conducting the training. The requirements of 49 CFR 390.105 that the Agency proposed in the NPRM set out the criteria that candidates for certification and listing on the National Registry must use in selecting an organization to provide their training. Those criteria were thus available for public comment. FMCSA has responded to those comments (including substantive comments by Advocates) in Section IV.C.1 above.

Finally, MEs seeking to be listed on the National Registry will need to successfully complete a test administered in accordance with 49 CFR 390.103 and 390.107. Like the core curriculum specifications, the specific content of the test will be

based on current FMCSA regulations and guidelines on the Medical Examination Report applicable at the time the test is administered. As those underlying regulations and guidelines are updated, both the core curriculum specifications and the certification test will be modified accordingly.

The Agency has added a requirement to the final rule (49 CFR 390.107(d)) to make it clear that any testing organization administering the test must use only the test obtained from FMCSA. This requirement was stated in the preamble to the NPRM (73 FR at 73133).

5. Records and Record-keeping

Retention of Driver Examination Records. The NPRM proposed implementation of the SAFETEA-LU requirement that MEs electronically transmit to the FMCSA Chief Medical Examiner on a monthly basis the name of the CMV driver and a numerical identifier for any completed Medical Examination Report required under 49 CFR 391.43 (49 U.S.C. 31149(c)(1)(E)). Additionally, the proposed rule would require MEs to retain for 3 years the Medical Examination Report for each examination performed and the medical examiner's certificate, if the ME certified the driver as physically qualified. It would also require MEs to provide copies of specified Medical Examination Reports and medical examiner's certificates to FMCSA or to authorized Federal, State, and local enforcement agency personnel, within 48 hours of the request, in order to allow for investigation of errors and improper certification of CMV drivers (49 U.S.C. 31149(c)(2)).

ACOEM, AAOHN, and an occupational medicine consulting firm, OccuMedix, Inc., claimed that MEs should be required to retain driver examination records for longer

than 3 years to allow MEs to check their own records or the records of other MEs so that medical conditions would not be overlooked. The commenters noted that some drivers may use different MEs from year to year or may enter or leave the driver pool, so records should be maintained for 6 or 7 years and reviewed if questions arise.

FMCSA Response: FMCSA proposed a minimum time of 3 years for retention of driver examination records because a driver is certified for a period of 2 years or less, and an additional year will allow FMCSA time to request driver examination records from MEs to assess ME performance by determining whether the ME completed the medical examination report accurately and did not certify a driver in error. Also, MEs are still subject to any State laws requiring medical records to be retained for longer than 3 years. Therefore, FMCSA will retain the requirement for MEs to keep the Medical Examination Report and the medical examiner's certificate for 3 years and retains the words "at least" from the Med. Cert./CDL rule to clarify that this is a minimum.

<u>Privacy of Information</u>. Transportation Safety Services, a consulting firm, stated that Federal government databases established to monitor medical information cannot be adequately protected from unauthorized access. AAOHN, however, suggested that a standardized electronic database with appropriate safeguards is imperative for the confidentiality of personal health information and compliance with Health Insurance Portability and Accountability Act (HIPAA) regulations. Dart Transit Company encouraged us to address the question of possible conflicts with HIPAA that would be encountered in the industry's attempt to comply with the rule.

FMCSA Response: Pursuant to 49 CFR 391.43(g), as revised by this final rule, each month MEs will be required to transmit on Form MCS-5850 the results of every

physical examination performed on a CMV driver and the information from each medical examination certificate issued to a CMV driver. This form indicates whether or not the driver examined was issued a medical certificate. This information is necessary to satisfy the requirements of 49 U.S.C. 31149(c)(1)(E). The form does not contain any personal health information about the driver. It does include information identifying each driver examined such as driver's name and driver's license information.

If the Agency should find it appropriate in conducting any review of the performance of MEs on the National Registry, as provided by 49 U.S.C. 31149(c)(1)(C) and (F), to obtain copies of the Medical Examination Reports and any supporting medical records for CMV drivers examined, it will follow the applicable policies and procedures to ensure the security and privacy of the personal health information about the drivers contained therein. FMCSA will also follow similar procedures in conducting any investigation into whether or not a CMV driver is or should be physically qualified to operate a CMV. Therefore, we are requiring submission of medical records through a secure Web application for which each certified ME will have a password-protected account. FMCSA will implement policies and procedures to reasonably limit the uses and disclosures of Protected Health Information (PHI). The Privacy Impact Assessment (PIA) supporting the final rule gives a full and complete explanation of FMCSA practices for protecting Personally Identifiable Information (PHI) in general and specifically in relation to this rule. The PIA is available for review in the docket.

On the other hand, HIPAA privacy regulations do not apply to the transmission of PHI to FMCSA because the Agency does not provide services on behalf of the ME, and therefore does not qualify as a business associate. The definition of a business associate

requires more than receipt of PHI. As stated in 45 CFR 160.103, to qualify as a business associate the entity or person must perform a function or activity involving the use or disclosure of individually identifiable health information on behalf of such covered entity or of an organized health care arrangement. FMCSA is not providing services on behalf of a covered entity or in association with an organized health care arrangement. In this case, FMCSA is not performing services for the ME, but for the public by ensuring the safe performance of commercial vehicle drivers. FMCSA will monitor the performance of MEs in order to ensure they effectively determine whether CMV drivers are safe to drive in interstate commerce.

FMCSA disagrees that there are possible conflicts with HIPAA that would be encountered by employers (or the MEs for that matter) in complying with the final rule. The Agency did not propose and is not making any changes in the existing regulations governing the physical qualifications of drivers and the responsibilities of employers to ensure compliance with those requirements, with the exception of the requirement for employers to verify that the ME is listed on the National Registry. The employer may validate the National Registry Number from the medical examiner's certificate or State driver record, without the need to access any of the driver's personal health information.

<u>Public Web site.</u> We indicated in the preamble to the proposed rule that information about the National Registry Program would be available through a public Web site, so that drivers and employers could find the names and addresses of nearby MEs listed on the National Registry. Several commenters described other information pertaining to the ME that should be provided as well. A chiropractor and Dart Transit Company suggested that the Web site should also include information about parking,

hours, and directions. Schneider National, Inc. mentioned that the ME's State license number, National Registry Number, and certification expiration date should be posted. Schneider National, ACOEM, and OccuMedix expressed that the Web site and e-mail notifications to MEs could be used for informational purposes.

Wynne Transport Service, Inc. (Wynne), California, and AAOHN noted that the National Registry itself must be updated frequently so drivers and motor carriers always have access to the most current ME information. Wynne asked whether the ME's unique identifier will be recognizable as valid. OOIDA noted that although we envision a resource center with a toll-free telephone number, it is not clear what information will be available by telephone and whether the Resource Center would be staffed by knowledgeable people who can answer a variety of physical examination-related questions. California urged us to ensure that the toll-free telephone number is staffed during regular business hours in the Pacific Time Zone.

OOIDA also argued that reliance on the Internet posed an obstacle because longhaul drivers often spend extended periods of time away from home and not all own laptop computers that could be used to identify conveniently located MEs over the Internet.

FMCSA Response: FMCSA is considering these ideas in the design and implementation of the National Registry Web site. FMCSA anticipates the National Registry will include the unique National Registry Number and the certification date for each ME. Information for MEs who have been removed from the National Registry will be shown with the date of removal. We anticipate using the public Web site and email notifications to MEs for informational updates. Callers to the Resource Center will be

able to receive assistance in locating an ME on the National Registry and will be given access to knowledgeable personnel who can answer questions about the commercial driver physical examination.

<u>Access to Driver Examination Records.</u> ATA, Road Ready, Inc., and Florida argued for a Web-based electronic data entry and document-storage system for Medical Examination Reports. Road Ready, a company that electronically collects and stores drivers' DOT medical examination information for motor carriers, argued that developing and maintaining such a system would enhance our ability to effectively manage and audit driver files and obtain required medical information. Florida said an FMCSA repository of Medical Examination Reports would eliminate the need to require and enforce monthly entry of separate data.

AAOHN, Dart Transit Company, ATA, and an individual MD suggested that the ME should have access to previous driver physical examination records in order to more easily detect disqualifying illnesses not reported by the driver.

FMCSA Response: The Agency acknowledges the potential benefits of a comprehensive, searchable Web-based database of Medical Examination Reports. This type of system could incorporate automated checks that would prevent the erroneous certification of drivers who do not meet certification standards and would facilitate the collection of driver examination records for monitoring ME performance. However, this rule will not require MEs to enter all data into a prescribed on-line Medical Examination Report form, because of the administrative burden this would place on MEs.

<u>Medical Examiner's Certificates.</u> The NPRM proposed a change in the medical examiner's certificate form to require the ME to record his or her unique National

Registry Number. The proposed rule would have allowed the ME to use existing medical examiner's certificate forms (without a box for the National Registry Number) for up to 4 years. Iowa opposed the use of obsolete forms.

FMCSA Response: FMCSA agrees there is no need to delay implementation of the updated medical examiner's certificate and has made changes to the final rule to require MEs to use the medical examiner's certificate with the National Registry Number for all examinations on or after a date 24 months after the effective date of this final rule. FMCSA has posted the current medical examiner's certificate on its public Web site since 2003, so MEs have not had to order supplies of paper copies. Therefore the two-year implementation date will not impose hardship or waste with regard to availability of the current certificate.

D. Costs and Benefits of the National Registry Program

1. Benefits

FMCSA requested comments on the costs and benefits of the proposed rule. The Indiana Statewide Association of Rural Electric Cooperatives (ISAREC) questioned the need for and the benefit of the National Registry, arguing that it might not be a good, targeted use of Agency resources. A private citizen questioned whether any study shows MEs make highways safer. Southern Company, a public utility company, opposed establishment of a National Registry and suggested instead that physicians should be given easy access to on-line directions and guidance to use any time.

In contrast, a chiropractor reported that in the past year, he had disqualified drivers who previously had been improperly qualified to drive by other MEs or required exemptions for blindness in one eye, insulin use, psychological conditions,

limb/appendage loss, implanted defibrillators, seizure disorders, and cardiovascular disorders. California noted a 2005 study that found that 10 percent of Medical Examination Reports (long forms) submitted and marked as qualified were actually from unqualified drivers, which, to the commenter, indicates that MEs misinterpreted the Agency standards.

The American Chiropractic Association and a comment signed by 147 chiropractors stated that the National Registry will both improve highway safety and reduce the number of erroneous driver disqualifications. They agreed that the ME certification program will raise the quality and conformity of the CMV driver physical examination. California and Iowa expressed similar opinions in stating that the training protocol will ensure that MEs are knowledgeable and capable of performing these examinations.

FMCSA Response: FMCSA is required by statute to establish the National Registry. As described in the regulatory evaluation, the Large Truck Crash Causation Study (LTCCS) data show that approximately 2.2 percent of crashes involve a crash where the truck driver was assigned the critical reason for the crash and the main contributing factor was the health or physical condition of the truck driver. ⁴ The LTCCS is the most comprehensive examination of truck-crash causation conducted in the United States. It is clear that driver health is a factor contributing to a significant number of crashes. Clearly, there are benefits from a program that would improve the screening of drivers, keep medically unqualified drivers off the road, and that would, therefore, in FMCSA's estimation, prevent 1,219 crashes per year.

⁴ Internal analysis of the LTCCS conducted by Agency data analysts. A description of the LTCCS, it's methodology, and the data is available at http://ai.fmcsa.dot.gov/ltccs/default.asp

It will not be possible to evaluate the effectiveness of training programs for MEs to be listed in the National Registry until after the training programs have been initiated. It is impossible to predict the degree to which the training program will improve ME screening of drivers. However, comments received from MEs who currently conduct driver physical evaluations, and evidence from the field from MEs and enforcement personnel indicate that many drivers who do not meet the Agency's physical qualification standards are being erroneously medically certified. The Agency expects the National Registry Program to reduce the number of errors committed by MEs. It will depend upon the effectiveness of training and the knowledge that MEs gain about Agency standards and guidelines.

CME programs have received extensive evaluations and have been shown to improve medical practitioner knowledge and skills, as well as patient outcomes.⁵ A comprehensive review of the effectiveness of CME programs sponsored by the U.S. Department of Health and Human Services demonstrated that these programs are effective in increasing participant knowledge, skills, and clinical practices, among other improvements.⁶ The National Registry Program is more rigorous than many CME programs because it includes a post-training knowledge assessment. Given that other CME programs have been shown to be effective, it is reasonable to expect, therefore, that the National Registry Program would attain some level of effectiveness.

2. Costs

⁵ Bordage G, Carlin B, Mazmanian PE. "Continuing medical education effect on physician knowledge: effectiveness of continuing medical education: American College of Chest Physicians Evidence-Based Educational Guidelines." *Chest.* 2009 and Neff JA, Weiner RV, Gaskill SP, Smith JA, Weiner M, Brown HP, Prihoda TJ, Newton E. "Preliminary Evaluation of Continuing Medical Education-Based Versus Clinic-Based Sexually Transmitted Disease Education Interventions for Primary Care Practitioners" *Teaching and Learning in Medicine.* 10(2) 74-82. 1998. ⁶ <u>Marinopoulos, S, Dorman T, Ratanawongsa N, Wilson LM, Ashar BH, Magaziner JL, Miller RG, Thomas PA, Prokopowicz GP, Qayyum R, Bass EB. *Effectiveness of Continuing Medical Education.* Evidence Report/Technology Assessment Number 149, Agency for Healthcare Research and Quality – US Department of Health and Human Services, 2007. Available online at: <u>http://www.ahrq.gov/downloads/pub/evidence/pdf/cme/cme.pdf</u></u>

We proposed developing the core curriculum specifications and administrative requirements for ME training— referred to as the Public-Private Partnership Model. We asked for comment on alternative training delivery methods and the ability of accredited training programs to adapt their continuing education programs to ensure quality and consistency of training.

We received many comments about the cost of ME training, testing, and certification. In 49 CFR 390.105, we require that all ME applicants complete training conducted by a private-sector training provider (administered by a nationally accredited medical professional organization that provides continuing education units). In 49 CFR 390.103(a)(3), we require that after completing mandatory training, an ME applicant must pass our ME certification test. In 49 CFR 390.111, we list requirements for continued listing on the National Registry, including periodic retraining every 5 years and recertification every 10 years. We anticipate that FMCSA will provide Web-based, periodic retraining at no cost to MEs. We estimate the annual costs of training and testing – including lost time to MEs – as varying between \$14 million and \$59 million (undiscounted) during the initial training phase.

Costs to Medical Examiners. Commenters presented various arguments concerning whether we had properly assessed the cost of the rule and which stakeholders would pay the cost of ME training and certification. Comcar Industries said we had "significantly understated" the cost impact of this rule on the trucking industry. A private citizen questioned whether we had properly evaluated what costs will increase after the National Registry is established. ISAREC, OOIDA, Virginia, and Wynne said that MEs would pass on cost increases to drivers or motor carriers and other employers of drivers.

A chiropractor, ATA, the National School Transportation Association (NSTA), OOIDA, and Wynne agreed that to recover their training investments, MEs in remote areas would impose higher physical examination fees over a smaller base of drivers. NSTA recommended that to prevent disparate examination fees across the country, FMCSA should limit the amount by which MEs can increase their physical examination fees to recover the cost of having to comply with the National Registry rule.

FMCSA Response: There will likely be a minimal increase in the cost charged by MEs to reflect the cost of becoming certified. In the regulatory evaluation, we estimated that becoming certified would cost approximately \$550 per examiner in out of pocket costs - \$440 for training and \$110 to take the certification test. Fees for driver examinations vary, but generally fall in the range of \$70 - \$100, assuming no specialized tests are required. As noted by one commenter, MEs in lower volume areas may already charge higher fees – up to \$170 per examination. At \$170 per examination, an ME would only have to conduct 3-4 examinations in order to recoup the out-of-pocket costs of certification. At the lower-end price of \$70 per examination, an ME would need to conduct a minimum of approximately 8 driver examinations to recoup the out-of-pocket costs of certification. In addition, many occupational health consortia and other organizations offer training on the CMV driver physical, and other ME training, free of charge, to physicians and other providers in their networks. It is unclear how many MEs would have access to these free courses, but at least some would bear little or no out-ofpocket costs for obtaining the required training.

The opportunity cost of time for an ME to attend certification training and testing was estimated at \$83 per hour, and the time commitment for certification was estimated

at 11.5 hours, for a total cost of approximately \$954. If an ME took on these costs, approximately 148 examinations at most would be needed to pay back the investment of time required to become certified. The NPRM proposed requiring MEs to repeat initial training every 12 years. This final rule eliminates this requirement for repeating the initial training but substitutes refresher training every 5 years, thereby reducing the cost to MEs for maintaining certification.

At a maximum, an ME would need to conduct approximately 26 examinations to compensate for the total cost of certification including both out-of-pocket costs and indirect costs of the time involved. The financial payoff for being able to continue conducting these examinations seems sufficient to induce most MEs who currently conduct 10 or more driver certifications per year to become certified. Based on the revenue generated by the examination, this volume would be sufficient to pay back both the value of time spent by an ME in training and out-of-pocket expenses in a little over 2 years.

The initial training required by this certification program is a fixed cost – a onetime expense. This is not a marginal cost that is incurred with each examination. In competitive markets, the cost of a service approaches its marginal cost, as fixed costs are averaged over multiple units of production. Given that there are MEs who evaluate hundreds of CMV drivers per year, the amount that initial certification costs would contribute to the per-unit cost of providing examinations would approach zero. We expect these higher volume MEs to set the market price for driver examinations. Those MEs who conduct fewer examinations would have pressure to match the prevailing price, or most drivers would go to an ME who charges a lower fee. We therefore expect a

minimal increase in the fees charged for these examinations. In addition, we expect that the MEs who choose to obtain training and be listed on the National Registry will see an increase in the volume of commercial driver examinations, because there may be fewer professionals eligible to conduct the driver examinations. Greater volume should help control cost increases because the cost of training will be spread across a greater number of examinations. As a result, a smaller price per examination increase would be necessary for MEs to recover their costs.

If training costs are incorporated into higher medical examination fees, this would not result in an increase in the total cost of the program, although it would result in a passthrough of these costs to the industry. If MEs pass some or all of the costs of the training on to the industry, the costs passed on would be borne by drivers and carriers rather than MEs, but whether these costs are passed on or absorbed by MEs would not change the total cost of the program. Therefore, the Agency feels it has fully accounted for the potential effects of the rule, although we cannot predict with a great deal of certainty how much of the associated costs would be absorbed by MEs rather than passed on to the industry.

Finally, the Agency disagrees that we should put a ceiling on the fees MEs are allowed to charge for physical examinations. Commenters are concerned both that there will be a shortage of MEs and that fees will increase. However, the ability to charge a higher fee for driver examinations increases the incentive that MEs have to obtain certification. Capping the fee too low would exacerbate any shortage in MEs, because it would reduce the financial incentive to become certified. In the interest of ensuring the

broadest geographic coverage possible for the National Registry, we do not agree that capping driver examination fees would be advisable.

It must be kept in mind that once this program reaches full implementation, all MEs who choose not to participate in this certification program will lose all revenue associated with conducting driver physical examinations. MEs face the choice of becoming certified to retain the current revenue stream they receive from driver examinations, or not becoming certified and losing this revenue to other professionals who are certified. The Agency believes that, for most MEs, preserving this revenue stream will outweigh any costs associated with becoming certified.

<u>Scarcity of Medical Examiners.</u> FMCSA requested comments on whether the proposed requirements may deter otherwise qualified MEs from performing these types of examinations and on ways to ensure that MEs are accessible to drivers in rural areas and areas where the demand for driver certification may be low. The Agency also asked for comments on additional costs drivers may incur to locate and travel to an ME for periodic examinations.

AAPA, AAOHN, Advocates, California, Virginia, and two individuals said that the cost of training and testing would diminish the number of physicians and others willing to become MEs. However, a physician with the Delaware Department of Health suggested that most physicians would find the costs of training and travel, certification, and recertification acceptable.

OOIDA also expressed concern that the burdensome and costly administrative obligations for listed MEs will discourage health care professionals from providing driver physical examinations. Administrative burdens would include the need for a computer

system that can interface with the Agency and personnel available to provide the Medical Examination Reports when requested. California requested that MEs be given sufficient notice prior to an onsite inspection and sufficient time to comply with a request for information.

Several commenters discussed the scarcity of MEs in rural areas and the resulting costs to CMV drivers. ATA, Arizona, Comcar Industries, ISAREC, National Academy of DOT Medical Examiners (NADME), OOIDA, Southern Company, Virginia, and Wynne said that a scarcity of MEs would burden truck drivers with having to travel long distances for physical examinations. ATA commented further that such travel likely would result in a loss of wages for the driver and loss of revenue to the motor carrier.

Commenters also argued that scarcity would result in difficulties in scheduling physical examinations. Commenters said many drivers will experience longer wait times and no walk-in opportunities for physical examinations. According to NSTA, difficulties in scheduling physical examinations could impede school bus service because newly hired drivers may be unable to receive physical examinations before the start of school.

Several commenters suggested actions we might take to avoid a scarcity of MEs. These suggestions included offering financial incentives to secure a local ME, permitting physical examinations by CMV drivers' family doctors, though not certified, having motor carriers take responsibility for finding physicians in their areas who are willing to become MEs, and extending the rule's implementation date if there are not sufficient numbers of MEs.

FMCSA Response: There are 3,140 counties or county-equivalent administrative units in the United States, according to the U.S. Census Bureau. Assuming

the Agency reaches its goal of certifying 40,000 MEs, there would certainly be a sufficient number of certified MEs to provide broad geographic coverage. Even half that number of certified MEs would be sufficient to provide comprehensive national coverage. It is unlikely that MEs would be evenly distributed throughout the Nation, but coverage should be sufficient to ensure reasonably convenient access in all but the most remote areas of the Nation. Lack of access to a certified ME would be likely to affect only a small number of drivers, especially considering that many of these drivers from rural areas would be delivering loads on a regular basis to larger towns and cities and, thus, have access to the broader ME populations in such areas. Given the mobile nature of the CMV driver occupation and the number of MEs we anticipate to join the National Registry, we do not believe that access to certified MEs will be an issue once the Registry is fully populated. In addition, we anticipate that the searchable National Registry may make it easier for drivers to find health care professionals who are qualified to conduct the driver physical certification examination. It is possible that in some areas where MEs are in short supply, such as rural areas, driver examination costs might increase, but the increase is not a certainty and is not likely to be large. Also, travel costs to drivers might increase due to drivers traveling further to find MEs.

<u>Mode of Training and Testing.</u> We proposed developing the core curriculum specifications and administrative requirements for ME training, which we would provide to private-sector training organizations for developing course content. We mentioned that training delivery could vary among providers and include self-paced, on-line training; the traditional classroom model; or a blended format. We also envisioned private-sector organizations administering a proctored and secure certification test, with the ME

applicant traveling to the test center. We asked for comment on alternative training and testing delivery methods and how FMCSA could offer training directly to MEs in a cost-effective manner.

ATA, Comcar Industries, ISAREC, MRB, NADME, NRCME Training Systems, OOIDA, and Schneider National endorsed on-line training as efficient and cost-effective. Schneider National also endorsed other cost-efficient technologies like videoconferencing, along with traditional classroom training.

A chiropractor said that live Web conferencing had the benefit of reducing costs and allowing conversation between a trainer and course attendees.

Delaware noted that some physicians favored an initial on-line Web-based product designed to educate new examiners, followed by on-site lectures and then initial testing, leading to qualification. However, OccuMedix stated that in-person, classroom training was optimal for initial certification since discussing case studies and in-person interacting with other ME candidates and faculty would be extremely beneficial.

Several of the commenters, including ATA, supported on-line testing. ATA said that on-line testing should be the preferred method of administration of the test to reduce costs. One commenter, a chiropractor, said that FMCSA should offer the test on its website.

FMCSA Response: The Agency agrees with comments that on-line training would reduce the cost associated with training. This rule does not preclude on-line training as a viable training, or the other suggested training formats, delivery methods. Allowing flexibility in alternative training delivery methods is one of the primary benefits of the Public-Private Partnership Model. While some organizations may charge for this

training, others (larger hospital systems, occupational health consortiums, professional associations, etc.) may offer training that is free of charge to group members. The Agency is aware of several ME training programs that are offered free to members of particular organizations. It is therefore likely that under the Public-Private Partnership Model a percentage of MEs would be able to obtain on-line training with no out-of-pocket costs or travel costs. At present, the Agency cannot estimate with any degree of certainty the number of MEs who might take advantage of on-line training, so we leave the travel costs estimates at the NPRM stage unchanged for the Public-Private Partnership Model. It is expected, however, that on-line training will reduce travel costs associated with this model.

The Agency agrees with commenters that allowing on-line testing will increase accessibility and decrease costs. This rule allows for secure online testing to be offered by testing organizations as an alternative or additional option to in-person testing. It requires online testing to be subject to specific security and privacy requirements due to the nature of the test and the need for authentication and security of the test. The Agency expects that, just as with on-line training, allowing for the increased flexibility provided by secure on-line testing in the final rule will reduce costs for MEs without adversely impacting the ability of the Agency to verify the qualifications of the MEs on the National Registry or compromising safety.

Estimates of Frequency of Driver Examinations. The NPRM estimated the number of MEs who would need to be certified by estimating that 3 million driver examinations are performed on interstate CMV drivers per year. All CMV drivers must be certified at least every 2 years, and some drivers are certified more frequently. We

specifically requested comments on how frequently drivers are examined more often than every 2 years. A chiropractor said that in 2008, his practice issued 41 percent of CMV medical certificates for less than 2 years. Schneider National said that of the approximately 650 medical examinations it performed each month, it issued about 50 percent of the medical certifications for less than 2 years. Comcar Industries reported that 39 percent of its drivers receive medical certificates for less than 2 years.

NSTA said FMCSA underestimated the number of drivers by not including intrastate drivers, because all States but two adopt the FMCSRs for intrastate drivers. NSTA also said that most States require school bus drivers to have a physical examination annually.

FMCSA Response: The Agency agrees that, given the estimates of the number of drivers who require certification more than once every two years, it is likely that more than 3 million drivers would be certified in a given year. However, we do not believe that this increase in the estimated number of drivers needing medical examinations per year is great enough to require more registered MEs than the 40,000 we used as the baseline for calculating the costs of the program. The increase in medical certifications does not, therefore, impact our estimate of the direct costs of the rule, which are based on the cost of training, certifying, and registering a given number of MEs. This rule does not change the regulations and guidelines that MEs use to determine how long drivers are certified.

In regard to counting intrastate-only driver examinations, FMCSA acknowledges the potential impact of certifying intrastate drivers and exempted school bus drivers on the number of driver examinations MEs on the National Registry will perform. However, for the purposes of estimating the costs of the program, as required by 49 U.S.C.

31136(c)(2)(A) and Executive Order 12866 (see Section VI below), we considered the direct impact of the rule, which is limited to interstate drivers.

E. Implementation of National Registry Program

1. Phased-in Implementation

The NPRM proposed phasing in the requirement for using MEs listed on the National Registry, with phase one requiring compliance for motor carriers with more than 50 drivers (so-called large carriers), and phase two requiring compliance for drivers not covered in phase one. Phase one would have begun 2 years after the rule's effective date; phase two would have begun 3 years after that date.

The majority of commenters to this section opposed the implementation schedule, while some offered alternatives to the proposed approach. ATA claimed that it is unfair to require drivers of large motor carriers to bear the costs of compliance for one year longer than drivers of smaller motor carriers. A joint comment from ABA and BISC voiced concern that the phased-in implementation schedule could result in only a limited number of MEs obtaining certification, which would make it difficult for drivers to locate an ME. The commenter recommended a single two-year implementation period, which it believed would provide adequate time for MEs to obtain certification. Comcar Industries added that the proposed implementation schedule demonstrates a lack of understanding of the transportation industry and is not realistic or reasonable. The commenter stated that we did not provide any valid reasons for proposing the approach and are unjustified in forcing the motor carriers to be responsible for implementation by requiring them to search for an ME when one may not be available in certain areas. Both ATA and Comcar Industries urged us to ensure that the National Registry is sufficiently populated

throughout the country before implementing the proposed requirements. NSTA said that the proposed phase-in schedule would cause hardships for rural school bus operations, because many school bus companies are not located in areas where there is easy access to MEs. NSTA suggested that we phase in the National Registry Program by either population density or by facility size from which buses are dispatched rather than by company size.

OOIDA claimed that the schedule was developed on flawed Agency assumptions. First, it stated that drivers employed by large carriers, just as their smaller independent counterparts, have the same likelihood of living in rural areas where MEs will not be concentrated. The commenter then suggested that there will always be a shortage of MEs in rural areas or other areas where the demand for examinations is low.

Dart Transit Company opposed the implementation schedule, suggesting that to actually improve highway safety, all motor carriers should be required to comply at the same time. California also recommended that the proposed requirements should be applicable to all participants on the effective date of the final rule. It noted that a driver could avoid compliance by claiming employment by a "small" carrier; a claim that the State SDLAs would be unable to verify.

Schneider National and a chiropractor suggested a "geographical" or "regional" approach to implementation. Schneider National claimed that ensuring there are a sufficient number of MEs in a particular region will reduce the traveling burden on a driver to obtain his or her examination. However, the chiropractor noted a potential drawback to implementing this geographic or regional approach, suggesting that MEs and

drivers may not receive adequate notice that they are in a regional area where they must follow the new requirements.

Finally, Delaware suggested that FMCSA create a matrix that would allow a State to determine by date when they must only accept medical certificates issued by certified examiners.

FMCSA Response: The Agency concurs with comments that the phase-in schedule would pose some issues, such as limiting the number of MEs in the first year. Additionally, FMCSA does not believe this would reflect the reality of the industry's distribution of drivers. In response, the Agency has eliminated the phase-in schedule from the final rule. The final rule will require that all drivers requiring certification under 49 CFR part 391, subpart E must be certified by an ME on the National Registry beginning 2 years after the effective date of this rule, regardless of the size of the employing carrier. The cost estimates based on the original phase-in period have been adjusted to account for this change in the accompanying regulatory evaluation.

2. Reviews of Performance of Medical Examiners

The NPRM proposed implementation of the SAFETEA-LU requirement that MEs electronically transmit to the FMCSA Chief Medical Examiner on a monthly basis the name of the CMV driver and a numerical identifier for any completed Medical Examination Report required under 49 CFR 391.43 (49 U.S.C. 31149(c)(1)(E)). OccuMedix, Dart Transit Company, and Advocates supported implementing a quality assurance program with a detailed removal process for non-compliant MEs. Advocates asserted we must ensure MEs fulfill the requirement to provide information about completed medical examinations on a regular basis. The commenter described our

proposed oversight as vestigial and hit-or-miss, expressing concern that we did not detail the approach to ensure that MEs actually are properly administering the physical examination.

Transportation Safety Services recommended that we address the problem area of many physician errors resulting from the physician's support staff incorrectly completing the paperwork. California requested that we provide a mechanism and authorize SDLAs to immediately report to FMCSA any health care professionals not on the National Registry who are performing driver examinations, and any MEs engaged in fraudulent or illegal activity.

Finally, a certified MRO recommended that we incorporate the Federal Transit Administration's approach for "Best Practices" awards for MEs that set model examples.

FMCSA Response: FMCSA intends to ensure that MEs comply with the requirement in this rule to electronically submit a completed MCSA-5850, CMV Driver Medical Examination Results, form monthly to FMCSA. The details of FMCSA's compliance and monitoring program will relate to FMCSA's future implementation of the provision of SAFETEA-LU (49 U.S.C. 31149(c)(2)), and therefore will not be part of this rulemaking.

FMCSA acknowledges that expanding the National Registry to include training and certification of auxiliary staff, whether health care professionals or administrative personnel, might be beneficial. However, in order to minimize the cost burden to the public, the Agency will not include these requirements in the final rule. MEs are reminded that they are responsible for reviewing and correcting any errors in the driver examination documentation.

States, other stakeholders, or the public may direct complaints about the performance of MEs as follows: If health care professionals not listed in the National Registry are known to be performing required driver examinations on or after 24 months from the effective date, or if MEs are believed to be engaged in fraudulent or illegal activity, FMCSA should be notified by: (1) writing the Office of Carrier, Driver and Vehicle Safety Standards, FMCSA, 1200 New Jersey Avenue, SE., Washington, DC 20590; (2) sending an e-mail to contactnrcme@dot.gov; or (3) calling an FMCSA-designated toll-free telephone number listed on the National Registry web site.

Finally, FMCSA does not anticipate creating a "best practice award" for MEs as part of the initial implementation of the National Registry Program. FMCSA may revisit this issue after the program has been fully implemented.

F. Issues Outside of the Scope of the Rulemaking

A number of respondents submitted comments on topics that were either outside the scope of what was proposed in the NPRM or were based on a misunderstanding of what the Agency proposed in this rulemaking. Many of these issues concern how FMCSA could prevent driver fraud in the medical certification process, track commercial driver examinations, require SDLAs to review Medical Examination Reports as part of the CDL, or establish specific medical examination requirements.

FMCSA Response: FMCSA acknowledges the policy concerns of the commenters. However, as stated in the NPRM, the legal and policy direction of this rulemaking is limited to requiring drivers to be examined by MEs that have been trained and certified to effectively determine whether they meet FMCSA physical qualification standards under 49 CFR part 391. FMCSA continues to believe this rulemaking

represents a major step in improving oversight capabilities by establishing the National Registry, ensuring that MEs are trained and qualified to perform driver examinations, removing MEs who do not meet program requirements from the National Registry, and requiring carriers and drivers to use only MEs on the National Registry.

The driver certification issues addressed by this rule complement the driver licensing issues that were addressed by the rule titled "Medical Certification Requirements as Part of the CDL" (December 1, 2008, 73 FR 73096), which established a system for interstate CDL drivers to provide medical certification status information to the SDLAs by providing the ME's certificates. It also required the SDLA to post that medical certification status information into the CDLIS driver record for licensing, enforcement, and employment decisions. The 2008 rule represented a significant first step in improving the oversight capabilities of medical certification status information for non-excepted, interstate CDL drivers.

Neither this final rule nor the 2008 rule are intended to address fraud perpetrated by drivers regarding their medical certification or to update SDLAs on disqualified drivers. While we acknowledge that these are important issues, these comments are outside the scope of this rule. However, as previously stated, FMCSA anticipates initiating a future rulemaking to expand medical certification information exchange with the States.

A third step toward improving oversight of the driver qualification process is the review and revision, as necessary, of the driver physical qualification standards. The Agency, with the advice of its Medical Review Board and its newly appointed Chief Medical Examiner, has begun the process, which will take several years to complete.

Changes to the standards and guidelines for driver qualification are beyond the scope of this rulemaking.

G. Comments on the Modified Information Collection

FMCSA published a request for public comments concerning a modification of the proposed information collection request under consideration on March 16, 2011 (76 FR 14366). FMCSA proposed a new information collection burden related to a requirement for employers of CMV drivers to verify the National Registry Number of the ME for each driver required to be examined by an ME on the National Registry, and to place a note relating to verification in the driver qualification file.

<u>Comment on the information collection burden.</u> One commenter, OOIDA, noted that the information collection burden would affect a large number of motor carriers and add to the already existing burden of recordkeeping obligations for both small motor carriers and owner-operators.

FMCSA Response: The Agency's regulations already require small carriers and owner-operators to comply with all of the regulations applicable to both carriers and drivers (see 49 CFR 390.11). The additional information collection burden from this verification requirement on an individual employer is minimal, amounting to a few minutes per driver. The Agency adopts the requirement for employers to verify the ME's National Registry Number for each of its drivers, as proposed.

<u>Comments beyond the scope of the information collection notice.</u> Multiple commenters, including several State organizations, stated that requiring employers to verify the National Registry Number would be redundant and unnecessary, because they believed the SDLAs would or should verify the qualifications of the MEs as part of the

process for posting medical status information on CDLIS. FMCSA is not requiring SDLAs to verify the National Registry Number. CDLIS only contains this information for CDL holders, and, as employers will be required to verify the ME numbers for both CDL holders and non-CDL holders, this would not be sufficient.

Several commenters, including AHAS, ATA, and OOIDA, noted that the Agency's proposal would not substantially deter driver fraud, and suggested alternate ways of addressing fraud. Several of these suggestions would, if adopted, increase the burden of this rulemaking on the employer or require additional public notice and comment rulemaking.

FMCSA Response: This rulemaking is one of several incremental steps towards a comprehensive medical certification oversight process that includes the ME, driver, and motor carrier. FMCSA believes that employer verification of an ME National Registry Number is one of several steps toward improving the driver medical certification process. Eliminating opportunities for fraud from the process is one of the goals for the medical certification oversight process. Though the Agency is unable to implement these various suggestions for fraud reduction in this final rule, they have been noted, and may be considered in a future rulemaking.

V. Section-by-Section Explanation of Changes from the NPRM

Part 350 Commercial Motor Carrier Safety Assistance Program

Section 350.341. FMCSA is revising this section so that States that receive MCSAP grants and that have in effect variances for physical qualification requirements for drivers operating CMVs in intrastate commerce will have the option of not establishing a separate registry of medical examiners trained and qualified to apply those

standards. Without this option, in order to comply with the general requirement of compatibility established by 49 U.S.C. 31102 and 49 CFR 350.201(a), such States would have the burden of establishing and administering a separate registry for such examiners applying different standards to intrastate-only CMV drivers. FMCSA does not believe it is necessary to place that burden on the States that may have such variances in effect. A State with variances in effect under 350.341(h)(1) and (2) that chooses to set up a separate registry of examiners qualified to apply those variances to intrastate drivers will not be allowed to use MCSAP funds for that purpose. Such use of MCSAP grant funds would not be consistent with the overall purpose of establishing a uniform standard for all CMV drivers nationwide.

Part 383 Medical recordkeeping

Section 383.73(o)(1)(iii)(E). FMCSA revises the list of items that the State must post to the CDLIS driver record by deleting the phrase "(if the National Registry of Medical Examiners, mandated by 49 U.S.C. 31149(d), requires one)" after "Medical examiner's National Registry identification number," because the National Registry Program implementation will indeed require such a number for certified MEs.

Part 390 Definitions

Section 390.5. The NPRM contained a phase-in schedule for implementation. In the final rule, however, the proposed phase-in has been eliminated and the revised definition applies beginning 2 years after the effective date of the final rule. Thereafter, every medical examination under subpart E of part 391 must be conducted by an ME listed on the National Registry. FMCSA revises the proposed definition of medical examiner to reflect that there is no phase-in schedule.

Subpart D of Part 390 -- National Registry of Certified Medical Examiners

Section 390.103. FMCSA adds an introductory phrase to paragraph (b) to clarify that it applies to a person who has ME certification. FMCSA adopts paragraph (a)(1) as proposed. We require the applicant for medical certification to have a legally permitted scope of practice (i.e., license, certification, or registration) that allows him or her to perform independently the requirements of § 391.43. FMCSA eliminates the reference to Appendix A from paragraph (a)(3) because Appendix A was not adopted in the final rule. As originally proposed in the NPRM, Appendix A specified contact information and required statements ME candidates would have to submit to testing organizations before the testing organizations would permit them to take the ME test. In paragraph (a)(3), FMCSA also prohibits an applicant who does not pass the certification test from retaking the test within 30 days, and requires an applicant to take the certification test no more than three years after completing the training.

Section 390.105. FMCSA deletes the provision on compliance with section 508 of the Rehabilitation Act for two reasons. First, this section only applies to Federal departments and agencies that provide electronic and information technology to their employees, or who use such technology to provide information and services to members of the public. Second, it is unnecessary in light of the provisions of section 504 of the Rehabilitation Act and Department regulations in 49 C.F.R. part 28.

<u>Section 390.107.</u> FMCSA makes changes to proposed § 390.107 <u>Medical</u> <u>examiner certification testing</u>. The Agency adds a new paragraph (b) (and changes the designation of the subsequent paragraphs as appropriate), to require additional security and privacy procedures for those testing organizations who intend to administer the test

on-line as an alternative or additional option to in-person testing. FMCSA also eliminates the reference to Appendix A of this part. The NPRM had proposed an Appendix A, but FMCSA did not adopt it in the final rule. A provision is added to make it clear that the test to be administered is the currently authorized test developed and furnished by FMCSA.

<u>Section 390.109.</u> FMCSA adopts § 390.109 <u>Issuance of the FMCSA medical</u> <u>examiner certification credential</u>, as proposed, except to specify compliance with the requirements of § 390.103(a) or (b) rather than compliance with the requirements of §§ 390.103 – 390.107.

Section 390.111. Although proposed paragraph (a)(5)(ii) would have required a certified ME to retake the initial training in alternating 6-year periods, this requirement was not adopted. Instead, the ME will be required to complete periodic training as specified by FMCSA every 5 years. The ME will still be required to take the certification test every 10 years in order to retain the certification.

Section 390.113. The final rule adds a general statement of the grounds for removal of an ME, based on 49 U.S.C. 31149.

Section 390.115. In the NPRM, this section described procedures for removal from the National Registry. Proposed paragraph (d) addressed requests for administrative review after an ME has been removed from the National Registry, but did not describe what would happen if the administrative review found that the removal of the ME was not valid. To correct this oversight, FMCSA adds text to paragraph (d)(2), which requires FMCSA to reinstate the ME and reissue a certification credential. The reinstated ME essentially must follow the requirements of § 390.111(a), which describes what the ME

must do to continue to be listed on the National Registry. Similarly, FMCSA adds the same text to paragraph (f), which describes applying for reinstatement on the National Registry after voluntary or involuntary removal. In addition to requiring a person who was involuntarily removed to complete corrective actions described in the notice of proposed removal, the rule requires reinstated MEs to follow the requirements of § 390.111(a).

Proposed paragraph (g) would have required that if a person is removed from the National Registry under paragraph (c) or (e), or a removal is affirmed under paragraph (d), then that person's listing is removed and the certification credential is no longer valid. FMCSA deletes the phrase "or a removal is affirmed under paragraph (d)," because a person who requests administrative review under paragraph (d) has already been removed from the National Registry under paragraph (c) or (e). That person's listing has been removed and his or her certification credential is no longer valid.

Finally, Director of Medical Programs is updated to Director, Office of Carrier, Driver and Vehicle Safety Standards throughout to reflect a change in FMCSA's organizational structure.

<u>Appendix A</u>. FMCSA does not adopt proposed Appendix A to part 390, Medical Examiner Application Data Elements. Instead of adopting proposed Appendix A, FMCSA will make available on its Web site the current minimum data elements that must be included in the application for medical examiner certification.

<u>Part 391</u>

Section 391.23. Amendments to paragraphs (m)(1) and (m)(2)(i)(B) of this section require the motor carrier to verify that a driver was certified by an ME on the National Registry beginning 2 years after the effective date of the rule.

Section 391.42. The NPRM contained a phase-in schedule for implementation. In the final rule, beginning 2 years after the effective date of the final rule, this section now requires that every medical examination under subpart E of part 391 must be conducted by an ME listed on the National Registry. For the reasons explained above in Section IV.E.1, FMCSA does not believe a phase-in period is necessary.

Section 391.43. The NPRM contained several proposed amendments to § 391.43, including an addition to the information required on a medical examiner's certificate. FMCSA adopts paragraph (a) as proposed to specify that, in accordance with the compliance schedule established in § 391.42, the medical examination must be performed by an ME listed on the National Registry under subpart D of part 390 of this chapter.

Proposed paragraph (g) would have required the ME to complete a medical examiner's certificate for drivers found to be physically qualified to drive a CMV. In the final rule, the paragraph is modified slightly to reflect the wording of the current paragraph, which was revised on December 1, 2008 (73 FR 73096) to include providing a copy of the medical examiner's certificate to the driver's employer. FMCSA adopts the proposed new requirement in paragraph (g)(3) that, once every calendar month, the ME must electronically transmit certain information to the FMCSA Director, Office of Carrier, Driver and Vehicle Safety Standards. (Director of Medical Programs is updated to Director, Office of Carrier, Driver and Vehicle Safety Standards to reflect a change in FMCSA's organizational structure.) The final rule specifies that the information must be

provided on Form MCSA-5850 and transmitted via a secure FMCSA-designated Web site.

FMCSA adopts proposed paragraph (h) to revise the medical examiner's certificate by adding a field for the ME to enter his or her unique National Registry Number. Under the proposed paragraph, MEs would have been allowed to use printed certificates they have on hand until 4 years after the effective date of the final rule. Because the MEs do not need to be listed on the National Registry until 2 years after the effective date of the rule, FMCSA believes additional time for using up old certificates is unnecessary and the final rule does not provide for the use of obsolete printed certificates.

FMCSA adopts proposed paragraph (i) to specify that the ME must retain the original (paper or electronic) completed Medical Examination Report and a copy or electronic version of the medical examiner's certificate, and make them available, along with related medical documentation, to an authorized representative of FMCSA or an authorized Federal, State, or local enforcement agency representative, within 48 hours of the request. The proposed paragraph would have required the records to be retained for 3 years, but the final rule retains the Med. Cert./CDL language, which specifies "at least 3 years from the date of the examination." Nothing in our 3-year retention requirement precludes longer retention which, in fact, may be required by States. In the case of an ME whose practice has closed, State law will govern the retention of medical records. Some States may require the ME's successor to retain drivers' medical records, or in the case of a deceased ME, the ME's estate may be responsible for retaining the records. Additionally, FMSCA has modified the medical examiner's certificate to include additional information.

Section 391.51. FMCSA amends this section to require the motor carrier to place a note in the driver qualification file relating to verification of ME listing on the National Registry beginning 2 years after the effective date of the final rule.

VI. Regulatory Analyses and Notices

Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures as supplemented by Executive Order 13563

The FMCSA has determined that this rulemaking action is a significant regulatory action under Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563 (76 FR 3821, January 18, 2011), and that it is significant under DOT regulatory policies and procedures.

This rule establishes a training, testing, and registration program that would certify medical professionals as qualified to conduct medical certification examinations of commercial drivers. Current regulations require all interstate commercial drivers (with certain limited exceptions) to be medically examined by a licensed health care provider to determine whether these drivers meet the FMCSA physical qualification requirements. All drivers must carry a medical examiner's certificate as proof that they have passed this physical qualification examination. The MEs who conduct said physical examinations must retain copies of the Medical Examination Reports of all drivers they examine. The Medical Examination Report lists the specific results of the various medical tests used to determine whether a driver meets the physical qualification standards set forth in subpart E of part 391 of the FMCSRs.

Before the adoption of this rule, there was no required training program for the medical professionals who conduct driver physical examinations, although the FMCSRs

required MEs to be knowledgeable about the regulations (49 CFR 391.43(c)(1)). The former rules required that any medical professional licensed by his or her State to conduct physical examinations could conduct driver medical certification exams. No specific knowledge of the Agency's physical qualification standards was required or verified by testing. As a result, some of the medical professionals who conduct these examinations may be unfamiliar with FMCSA physical qualification standards and how to apply them. These professionals may also be unaware of the mental and physical rigors that accompany the occupation of CMV driver, and how various medical conditions (and the therapies used to treat them) can affect the ability of drivers to safely operate CMVs.

This rule establishes the National Registry to ensure that all MEs who conduct driver medical certifications have been trained in FMCSA qualification standards and guidelines. In order to be listed on the National Registry, MEs are required to attend an accredited training program and pass a certification test to assess their knowledge of the Agency's physical qualification standards and guidelines and how to apply them to drivers. Upon passing this certification test, and meeting the other administrative requirements associated with the Program, MEs will be listed on the National Registry. Once this rule is fully implemented, only medical certificates issued to drivers by MEs on the National Registry will be considered valid by the Agency as proof of medical certification.

Alternatives

The regulatory evaluation that accompanied the NPRM for this rule considered three alternatives for implementing this Program. One alternative, referred to as the Public-Private Partnership Model, involved a partnership between the Agency and

various private-sector training and testing organizations that currently exist to provide continuing professional education and credentialing to medical professionals. This Public-Private Partnership Model was the Agency's preferred alternative. The majority of public comments to the docket during the notice and comment period for the NPRM supported the Public-Private Partnership Model over the other alternatives considered. This final rule implements the Public-Private Partnership Model. Under this partnership, the Agency will develop and provide guidance for the core curriculum specifications and the certification test and protocols. Any interested organization that can meet FMCSA requirements will be eligible to deliver training or testing. Training would therefore be delivered by private-sector professional associations, health care organizations, and other for-profit and non-profit training groups. Testing will be delivered by private-sector professional testing organizations. After completing one of these accredited training programs, passing the certification test, and agreeing to comply with FMCSA administrative requirements, MEs will be listed on the National Registry, and authorized to conduct CMV driver physical examinations. Once the National Registry is fully implemented, only physical examinations conducted by MEs on the National Registry will be recognized by FMCSA and enforcement personnel as proof of driver physical qualification.

The second alternative considered by the Agency at the NPRM stage was based on the Federal Aviation Administration's Aviation Medical Examiner program, referred to here as the Government Model. This alternative required the Agency to establish its own centralized training and testing program. As described in the regulatory evaluation accompanying the NPRM, this program would have required MEs to attend this Agency-

run program and pass a test administered by the Agency. Upon completion of the test, an ME would be eligible for listing on the National Registry. This program's components are essentially the same as the Public-Private Partnership Model, but all training and testing would have been conducted by the Agency rather than private-sector training and testing programs. This alternative would also have required all MEs to travel to the FMCSA facility or other regional training sites to receive the FMCSA training. This would have involved greater travel expenses for MEs when compared to the Public-Private Partnership Model, which has training programs distributed throughout the country as well as some vendors who would offer on-line training modules. However, this option would have given FMCSA optimal control over the training of MEs.

The third alternative, referred to as the MRO Model, was based on the current MRO program requirements set forth in 49 CFR part 40, subpart G. The DOT MRO training program grew out of the DOT drug and alcohol program, which monitors use of controlled substances and alcohol. MROs are trained and certified by accredited training programs operated by professional associations in cooperation with DOT. Only licensed MDs or DOs are eligible to be MROs. MROs review drug and alcohol test results for other safety-sensitive occupations such as airline mechanics, train operators, and ship's pilots.

The existing program specifies that MROs who oversee drug and alcohol testing for commercial drivers must attend a training and certification program that meets DOT standards. Each of these programs maintains its own registry of graduates rather than contributing names to a single Federal database. DOT does not administer the training curriculum or testing protocols for these programs. Thus, the Agency would exert less

control over a program based on the MRO model than under the other options discussed at the NPRM stage. In addition, MRO programs charge more for testing than would likely be charged for testing in the National Registry program. Long distance travel for the initial training and testing would also have been required under this alternative.

As noted, the Agency has chosen to adopt the Public-Private Partnership Model at the final rule stage. This alternative was estimated to have the lowest cost of the three alternatives considered, and would afford the greatest degree of flexibility, convenience, and training opportunity to MEs. Moreover, it was supported by the majority of comments that mentioned the various alternative models proposed in the NPRM. We summarize the estimated costs and benefits of the three models below. To a large extent, costs have not changed. However, the Agency has decided to drop the phase-in described in the NPRM in which drivers who work for carriers who employ 50 or more drivers would be required to comply with the rule one year earlier than drivers who work for smaller carriers or are owner-operators. The Agency concurs with comments received that the phase-in schedule would pose some issues, such as limiting the number of MEs in the first year. Additionally, FMCSA does not believe the phase-in would reflect the reality of the industry's distribution of drivers. Under this final rule, all drivers, regardless of the size carrier they work for, are required to obtain medical certification from a National Registry-certified ME within 2 years of the full implementation of the Program. This change has advanced the date at which all drivers must be certified by an ME on the National Registry, and as a result, a portion of the impacts that would be felt by drivers and the industry will be felt earlier than would have been the case with the phase-in. Related cost adjustments are described below in detail.

Summary of Costs and Benefits

The costs and benefits for all three alternatives are analyzed in this regulatory evaluation. It is anticipated that approximately 40,000 MEs will be needed for the NRCME to accommodate the demand for an estimated 2.6 million medical examinations per year, and to provide adequate access, both in terms of geographic coverage and relatively short appointment waiting times. All alternatives involve an initial training phase in which the 40,000 MEs receive training. This phase is expected to last 2 years. At the beginning of the third year the Agency requires drivers to be examined by MEs listed on the NRCME once their current medical certification expires. Under Alternative 1, the alternative adopted by this Final Rule, MEs are required to attend a training conducted by a private-sector organization. It is anticipated that this will result in training and testing fees that would have to be paid by MEs. Under Alternative 2, no training or testing fees would have been incurred by MEs, but the Agency would have borne the costs of providing the training and testing services. MEs would have borne the cost of long distance travel to the FMCSA training center under Alternative 2. Long distance travel to a designated training program was also anticipated under Alternative 3. Under Alternative 1 it is anticipated that training programs will be available throughout the country, and that some programs will offer online training courses, which will minimize the need for long distance travel.

It is also anticipated that by screening out physically unqualified drivers, this rule may require some drivers, who cannot meet the physical qualification standards, and would no longer be able to evade detection, to leave the industry and seek an alternative occupation. Carriers to would bear the cost of hiring replacement drivers. Recruiting new

drivers is an activity that consumes carrier resources, and there is therefore a cost associated with that activity. We therefore provide an estimate of the number of drivers who may be forced to retire from the occupation, and estimate the costs associated with recruiting an equal number of replacement drivers.

The 10-year total cost of the Public-Private Partnership Model is estimated at \$232 million, when discounted at a 7 percent discount rate. Undiscounted annual costs vary between \$14 million and \$59 million, with ME certification costs (training and testing costs plus lost time and travel costs) being the largest portion of the cost at approximately \$31.5 million in the highest-cost year. Alternative 2 has a total discounted 10-year cost of \$383 million, with undiscounted annual costs ranging between \$17 million and \$88 million. Alternative 3 has a total 10-year discounted cost of \$337 million, with undiscounted annual costs ranging between \$16 million and \$92 million. In all alternatives, the value of ME time spent in training is the largest portion of cost. The costs of the training/testing, including lost time and travel costs for MEs, is estimated to vary between \$63 million and \$131 million during the initial training phase, depending on the alternative, with Alternative 1 having the lowest cost. The lower cost associated with Alternative 1 is due to its minimization of travel and associated costs, both in expenses and lost time, to MEs.

Because all three alternatives are expected to improve the performance of MEs by equivalent amounts, total benefits are expected to be equivalent for all programs. These benefits are based on the reduction in CMV crashes that is likely to result from improved medical screening of drivers. It is estimated that physically impaired interstate drivers are responsible for approximately 9,687 of the roughly 440,000 commercial motor vehicle

crashes that occur annually. Although it is not anticipated that this program would completely eliminate these crashes, it is expected to prevent a portion of them. We estimate that this program may prevent up to one-fifth of these crashes annually, which would result in approximately 1,219 fewer crashes per year. The estimated annual benefit associated with avoiding these crashes is \$189 million per year, undiscounted. These full benefits are not realized until the program is fully phased in, which is several years after the establishment of the program. Nevertheless, at a 7 percent discount rate, the 10-year net benefits of this rule are estimated at approximately \$633.2 million to \$784.1 million over 10 years depending on the alternative. The Agency's chosen alternative has the highest net benefits at \$784.1 million.

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601-612) requires Federal agencies to consider the effects of the regulatory action on small business and other small entities and to minimize any significant economic impact. The term "small entities" comprises small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. Accordingly, DOT policy requires an analysis of the impact of all regulations on small entities, and mandates that agencies strive to lessen any adverse effects on these businesses. The Agency conducted an initial Regulatory Flexibility Analysis for the NPRM and found that the rule would not have a significant economic impact on a substantial number of small entities. No comments were received on that analysis from the public. I certify that this rule would not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This rulemaking will not impose an unfunded Federal mandate, as defined by the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532, et seq.), that would result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$143.1 million or more in any 1 year. The \$143.1 million figure was derived by inflation adjusting the \$100 million cap in the original Act from 1995 to 2010 dollars using the Consumer Price Index.

Executive Order 12988 (Civil Justice Reform)

This action meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Executive Order 13045 (Protection of Children)

FMCSA analyzed this action under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. We determined that this rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children.

Executive Order 12630 (Taking of Private Property)

This final rule does not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Executive Order 13132 (Federalism)

FMCSA analyzed this rule in accordance with the principles and criteria contained in Executive Order 13132. FMCSA has determined that this rulemaking will

have no significant cost or other effect on or for States. States will have policy-making discretion. Nothing in this document will preempt any State law or regulation. Therefore, this rule does not have sufficient federalism implications to warrant the preparation of a federalism assessment.

Executive Order 12372 (Intergovernmental Review)

The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this program.

Privacy Impact Assessment

FMCSA conducted a privacy impact assessment of this rule as required by section 522(a)(5) of division H of the Fiscal Year 2005 Omnibus Appropriations Act, Public Law 108-447, 118 Stat. 3268 (December 8, 2004) (set out as a note to 5 U.S.C. 552a). The assessment considers any impacts of the rule on the privacy of information in an identifiable form and related matters. FMCSA determined that this initiative will create impacts on privacy of information associated with implementation of this rule.

FMCSA only collects PII necessary for official purposes as stated in the National Registry final rule. In addition, FMCSA only obtains such PII by lawful and fair means and, to the greatest extent possible, with the knowledge or consent of the individual. The FMCSA Office of Information Technology adheres to the Fair Information Practice Principles (FIPPs) to assist the Agency in protecting the confidentiality and privacy of PII associated with the implementation of the National Registry final rule. These best practices incorporate standards and practices equivalent to those required under the Privacy Act of 1974 (5 U.S.C. 552a) and other Federal laws that are consistent with the

FIPPs. These practices include management, operational, and technical safeguards that are appropriate for the protection of PII. The entire privacy impact assessment is available for review in the docket.

Paperwork Reduction Act

This rule contains the following new information collection requirements. As required by the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3507(d)), FMCSA submitted the information requirements associated with the proposal to the Office of Management and Budget for its review.

Title: National Registry of Certified Medical Examiners (National Registry).

<u>Summary:</u> Under SAFETEA-LU, the Secretary of Transportation is required to establish and maintain a current national registry of medical examiners who are qualified to perform examinations and issue medical certificates that verify whether a CMV driver's health meets FMCSA standards. In addition, section 4116(b) of SAFETEA-LU requires that the medical examinations of CMV operators be performed by MEs who have received training in physical and medical examination standards, and, after the National Registry is established, are listed on the National Registry. SAFETEA-LU also requires MEs to electronically transmit the name of the applicant and FMCSA numerical identifier for any completed Medical Examination Report required under § 391.43 to the Chief Medical Examiner on a monthly basis.

Once the National Registry Program is implemented, FMCSA will accept medical examinations performed only by certified MEs listed on the National Registry, as required by law. The National Registry Program would require MEs to complete training developed from standardized curriculum specifications and pass a national certification

test. The procedures used to develop and maintain the quality of the Program are expected to be in accordance with national accreditation standards for certification programs established by the NCCA, the accreditation arm of the National Organization for Competency Assurance.

Requirements imposed on intrastate drivers and employers for 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 do mirror the Federal requirements; therefore, we are including intrastate drivers, which is consistent with other FMCSA information collections, to accurately reflect the burden of this information collection.

Close tracking and monitoring of certification activities and medical outcomes are crucial, and the rule addresses the information collection aspects of National Registry implementation. To this end, the rule requires MEs to submit four types of data:

1) <u>Medical Examiner Application and Test Results Data:</u> To be listed on the National Registry, MEs must first pass a certification test to ensure they demonstrate an established level of competency. FMCSA and private-sector testing organizations will collect data from MEs as the medical professionals apply to take this certification test. Data elements required of MEs at the time of application will include professional contact and identifying information such as job title, address, and training and State

licenses obtained. These data will be collected each time the ME applies to sit for the certification test and information will be updated with FMCSA as needed. Test results data will include total test score and responses for each test item. Private-sector testing organizations will regularly transmit medical examiner data and test results electronically to FMCSA for inclusion in a centralized, confidential database.

2) CMV Driver Medical Examination Results Data: Once every calendar month, each ME listed on the National Registry is required to complete and transmit to FMCSA Form MCSA-5850, CMV Driver Medical Examination Results, with the following information about each CMV driver examined during the previous month: name, date of birth, driver's license number and State, date of examination, an indication of the examination outcome (for example, medically qualified), whether intrastate driver only, and date of driver medical certification expiration. Data will be submitted electronically via a secure FMCSA-designated Web site. In order to continue to be listed on and to continue participation in the National Registry, MEs need to comply with this requirement on a monthly basis. MEs who examine drivers who operate only in intrastate commerce may report those driver examination results on the form and check the checkbox for "Intrastate Only". Data on intrastate only driver examinations will be used to provide information to State and local enforcement officials on medical examiner performance and driver physical qualifications.

3) Medical Examination Reports and Medical Examiner's Certificates: The National Registry Final Rule requires medical examiners to provide copies of Medical Examination Reports and medical examiner's certificates to authorized representatives, special agents, or investigators of the FMCSA or authorized 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.

It is necessary for medical examiners to provide Medical Examination Reports and medical examiner's certificates to an authorized representative, special agent, or investigator of FMCSA or an authorized State or local enforcement agency representative in order to determine ME compliance with FMCSA medical standards and guidelines in performing CMV driver medical examinations. Failure to comply with FMCSA medical standards and guidelines may result in removal from the National Registry. Medical examiner's certificates provide additional documentation to determine compliance with FMCSA medical standards and guidelines by linking the ME to both the medical examination and the driver medical certification decision. They also determine compliance by ensure the certification decision matches the information in the medical examination and that the certificate is completed correctly.

<u>4) Verification of National Registry Number by Motor Carriers</u>: Motor carriers will be required to verify the National Registry Number of the medical examiner for each driver required to be examined by a medical examiner on the National Registry and place a note relating to verification in the driver qualification file, as required by provisions in 49 CFR 391.23 and 391.51. This data collection requirement will also provide proof that the motor carrier has met its obligation to require drivers to comply with the regulations that apply to the driver (49 U.S.C. 31135(a) and 49 CFR 390.11).

<u>Respondents (Including the Number of)</u>: The likely respondents to this proposed information requirement are 40,000 MEs from medical professions who are believed to conduct the majority of current CMV driver medical examinations (APNs, DCs, DOs,

MDs, and PAs) and one or more national private-sector testing organizations that deliver the certification test. We are unable to estimate the number of private-sector organizations that might wish to perform testing.

<u>Frequency:</u> FMCSA estimates each of the respondents would provide ME test application data every 6 years and updated information as needed. FMCSA further estimates that each respondent would provide CMV driver examination data a maximum of 12 times per year. It is estimated that an average of approximately 20,000 MEs will apply to take the certification test annually for the first 2 years of National Registry implementation. It is estimated that one or more testing organizations will deliver the FMCSA medical examiner certification test to 20,000 MEs annually for the first 2 years following implementation of the National Registry Program. It is projected that MEs would file 4,623,000 medical examiner's certificates per year and that authorized representatives of FMCSA or authorized State or local enforcement agency representatives would request MEs to provide copies of the Medical Report Form and the medical examiner's certificate 2,100 times a year.

<u>Annual Burden Estimate:</u> This proposal would result in an annual recordkeeping and reporting burden as follows:

FMCSA estimates each of the respondents will provide medical examiner certification test results and application data every 6 years and updated information to FMCSA as needed. It is estimated that 20,000 medical examiner candidates will apply to take the certification test annually for the first 2 years of National Registry implementation, or an average of 13,333 applicants per year for the first 3 years of the program. FMCSA estimates that the total annual burden hours for the collection of the

medical examiner application data is 1,111 hours [13,333 applicants x 5 minutes/60 minutes per response = 1,111 hours]. This annual burden includes medical examiner candidate time for submitting the application data to the private-sector testing organizations.

It is estimated that it will take private-sector testing organization personnel 5 minutes per ME to collect and upload to FMCSA application data and test results. FMCSA estimates that the total annual burden hours for private-sector testing organizations to collect medical examiner application data and send ME application and test results data to FMCSA is 1,111 hours (13,333 applicants x 5 minutes/60 minutes per medical examiner = 1,111 hours).

FMCSA estimates that respondents would provide CMV driver examination data a maximum of 12 times per year and would file 4,623,000 medical examiner's certificates per year. It is projected that 40,000 certified MEs will be needed to perform the 4,623,000 CMV driver medical examinations required annually. The transmission of CMV driver examination data will require approximately 46,525 hours of medical examiner administrative personnel time on a yearly basis [40,000 registered medical examiners x 1 minute/60 minutes to file a report x 12 reports per year + 4,623,000 reports x 30 seconds/3600 seconds to enter each driver's examination data elements = 46,525 hours]. It is estimated that it will take medical examiner administrative personnel 30 seconds to file the medical examiner's certificate. This will require approximately 38,525 hours of administrative personnel time on a yearly basis [4,623,000 examinations x 30 seconds/3600 seconds per certificate = 38,525]. In addition, FMCSA estimates that half of motor carriers will request a copy of the medical examiner's certificate and that it

will take administrative personnel 1 minute to provide a copy of the medical examiner's certificate to a motor carrier. The annual time burden to the administrative personnel for providing motor carriers with a copy of the medical examiner's certificate is approximately 38,525 hours [4,623,000 examinations x .5 (50%) x 1 minute/60 minutes = 38,525 hours]. The annual time burden to medical examiner administrative personnel for transmitting CMV driver examination data to the FMCSA, filing medical examiner's certificates, and providing copies of the medical examiner's certificates to motor carriers is approximately 123,575 hours [46,525 hours to enter driver examination data elements and 38,525 hours for filing the medical examiner's certificate and 38,525 hours for filing the medical examiner's certificate and 38,525 hours].

FMCSA estimates that authorized representatives, special agents, or investigators of FMCSA or authorized State or local enforcement agency representatives will request MEs to provide copies of the Medical Examination Report and the medical examiner's certificate 2,100 times a year.

It is estimated that it will take ME administrative personnel 5 minutes to provide both the Medical Examination Report and the medical examiner's certificate to FMCSA or an authorized State or local enforcement agency representative upon request, so this will require approximately 175 hours of administrative personnel time on a yearly basis [2,100 requests x 5 minutes/60 minutes per response = 175 hours].

FMCSA estimates that motor carriers will verify the National Registry Number for 4,623,000 drivers per year who are medically certified. It is estimated that it will take motor carrier administrative personnel 4 minutes to verify the National Registry Number, write a note regarding the verification, and file the note in the Driver Qualification file, so

this will require approximately 308,200 hours of administrative personnel time on a yearly basis [4,623,000 verifications x 4 minutes/60 minutes per verification = 308,200 hours].

The total estimated annual time burden to respondents for the National Registry components is approximately 434,172 hours ⁷[2,222 hours for provision of medical examiner application and test results data (1,111 hours for medical examiners and 1,111 hours for testing organizations) + 123,575 hours for CMV driver examinations (46,525 hours to enter driver examination data elements + 38,525 hours for filing the medical examiner's certificate + 38,525 hours for providing medical examiner's certificates to motor carriers) + 175 hours for provision of Medical Examination Reports and medical examiner's certificates + 308,200 hours for verification of National Registry Number]. National Environmental Policy Act and Clean Air Act

The Agency analyzed this final rule for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.) and determined under our environmental procedures Order 5610.1, published March 1, 2004, in the <u>Federal</u> <u>Register</u> (69 FR 9680), that this action required an Environmental Assessment (EA) to determine if a more extensive Environmental Impact Statement was required. FMCSA prepared an EA and placed it in the docket for this rulemaking. The EA found that there are no significant negative impacts expected from the actions. Although congestion and air emission impacts are discussed in the EA, the impacts are minimal and are not expected to alter the Nation's highway congestion or air emissions from surface or air transportation vehicles. In addition, while not quantified in this analysis, minor benefits to the environment from reducing CMV crashes are expected.

⁷ The accompanying supporting statement also reflects the correction of a minor mathematical error.

We have also analyzed this rule under the Clean Air Act, as amended (CAA), section 176(c) (42 U.S.C. 7401 et seq.), and implementing regulations promulgated by the Environmental Protection Agency. Approval of this action is exempt from the CAA's general conformity requirement since it involves rulemaking and policy development and issuance.

Executive Order 13211 (Energy Effects)

We analyzed this action under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We determined that it is not a "significant energy action" under that Executive Order because it will not be likely to have a significant adverse effect on the supply, distribution, or use of energy.

Executive Order 12898 (Environmental Justice)

FMCSA evaluated the environmental effects of this final rule in accordance with Executive Order 12898 and determined that there are no environmental justice issues associated with its provisions and no collective environmental impact resulting from its promulgation.

Executive Order 13175 (Tribal Consultation)

FMCSA analyzed this action under Executive Order 13175, dated November 6, 2000, and believes that it will not have substantial direct effects on one or more Indian tribes; will not impose substantial compliance costs on Indian tribal governments; and will not preempt tribal law. Therefore, a tribal summary impact statement is not required.

List of Subjects

<u>49 CFR Part 350</u>

Grant programs-transportation, Highway safety, Motor carriers, Motor vehicle safety,

Reporting and recordkeeping requirements.

49 CFR Part 383

Administrative practice and procedure, Alcohol abuse, Drug abuse, Highway safety,

Motor carriers

49 CFR Part 390

Highway safety, Intermodal transportation, Motor carriers, Motor vehicle safety,

Reporting and recordkeeping requirements.

49 CFR Part 391

Alcohol abuse, Drug abuse, Drug testing, Highway safety, Motor carriers,

Reporting and recordkeeping requirements, Safety, Transportation.

In consideration of the foregoing, FMCSA amends title 49, Code of Federal

Regulations, parts 350, 383, 390, and 391, as follows:

PART 350 COMMERCIAL MOTOR CARRIER SAFETY ASSISTANCE

PROVISION

1. The authority citation for part 350 continues to read as follows:

Authority: 49 U.S.C. 13902, 31101–31104, 31108, 31136, 31140–31141, 31161, 31310–31311, 31502; and 49 CFR 1.73.

2. In § 350.341, add paragraph (h)(3) to to read as follows:

§ 350.341 What specific variances from the FMCSRs are allowed for State laws and regulations governing motor carriers, CMV drivers, and CMVs engaged in intrastate commerce and not subject to Federal jurisdiction?

* * * * *

(h) * * *

(3) The State may decide not to adopt laws and regulations that implement a registry of medical examiners trained and qualified to apply physical qualification standards or variances continued in effect or adopted by the State under this paragraph that apply to drivers of CMVs in intrastate commerce.

PART 383—COMMERCIAL DRIVER'S LICENSE STANDARDS;

REQUIREMENTS AND PENALTIES

3. The authority citation for part 383 continues to read as follows:

Authority: 49 U.S.C. 521, 31136, 31301 et seq., and 31502; secs. 214 and 215, Pub. L. 106–159, 113 Stat. 1748, 1766, 1767; sec. 4140, Pub. L. 109–59, 119 Stat. 1144, 1746; and 49 CFR 1.73.

4. Amend § 383.73 to by revising paragraph (o)(1)(iii)(E)to read as follows:

§ 383.73 State procedures.

* * * * * (o) * * * (1) * * * * (iii) * * *

(E) Medical examiner's National Registry Number issued in accordance with

§ 390.109;

* * * * *

PART 390--FEDERAL MOTOR CARRIER SAFETY REGULATIONS; GENERAL

5. Revise the authority citation for part 390 to read as follows:

Authority: 49 U.S.C. 504, 508, 31132, 31133, 31136, 31144, 31151, and 31502; sec. 114, Pub. L. 103–311, 108 Stat. 1673, 1677–1678; secs. 212 and 217, Pub. L. 106–159, 113 Stat. 1748, 1766, 1767; sec. 229, Pub. L. 106–159 (as transferred by sec. 4115 and amended by secs. 4130–4132, Pub. L. 109–59, 119 Stat. 1144, 1726, 1743–1744); sec. 4136, Pub. L. 109–59, 119 Stat. 1144, 1745; and 49 CFR 1.73.

6. Amend § 390.5 by revising the definition of "medical examiner" to read as follows:

§ 390.5 Definitions.

* * * * *

Medical examiner means the following:

(1) For medical examinations conducted before May 21, 2014, a person who is licensed, certified, and/or registered, in accordance with applicable State laws and regulations, to perform physical examinations. The term includes but is not limited to, doctors of medicine, doctors of osteopathy, physician assistants, advanced practice nurses, and doctors of chiropractic.

(2) For medical examinations conducted on and after May 21, 2014, an individual certified by FMCSA and listed on the National Registry of Certified Medical Examiners in accordance with subpart D of this part.

* * * * *

7. Add subpart D, consisting of §§ 390.101 through 390.115, to read as follows:

Subpart D--National Registry of Certified Medical Examiners

Sec.

390.101 Scope.

390.103 Eligibility requirements for medical examiner certification.

390.105 Medical examiner training programs.

390.107 Medical examiner certification testing.

390.109 Issuance of the FMCSA medical examiner certification credential.

390.111 Requirements for continued listing on the National Registry of Certified Medical Examiners.

390.113 Reasons for removal from the National Registry of Certified Medical Examiners.390.115 Procedure for removal from the National Registry of Certified MedicalExaminers.

Subpart D--National Registry of Certified Medical Examiners

§ 390.101 Scope.

The rules in this subpart establish the minimum qualifications for FMCSA certification of a medical examiner and for listing the examiner on FMCSA's National Registry of Certified Medical Examiners. The National Registry of Certified Medical Examiners Program is designed to improve highway safety and operator health by requiring that medical examiners be trained and certified to determine effectively whether an operator meets FMCSA physical qualification standards under part 391 of this chapter. One component of the National Registry Program is the registry itself, which is a national database of names and contact information for medical examiners who are certified by FMCSA to perform medical examinations of operators.

§ 390.103 Eligibility requirements for medical examiner certification.

(a) To receive medical examiner certification from FMCSA a person must:

(1) Be licensed, certified, or registered in accordance with applicable State laws and regulations to perform physical examinations. The applicant must be an advanced practice nurse, doctor of chiropractic, doctor of medicine, doctor of osteopathy, physician assistant, or other medical professional authorized by applicable State laws and regulations to perform physical examinations.

(2) Complete a training program that meets the requirements of § 390.105.

(3) Pass the medical examiner certification test provided by FMCSA and administered by a testing organization that meets the requirements of § 390.107 and that has electronically forwarded to FMCSA the applicant's completed test and application information no more than three years after completion of the training program required by paragraph (a)(2) of this section. An applicant must not take the test more than once every 30 days.

(b) If a person has medical examiner certification from FMCSA, then to renew such certification the medical examiner must remain qualified under paragraph (a)(1) of this section and complete additional testing and training as required by § 390.111(a)(5).

§ 390.105 Medical examiner training programs.

An applicant for medical examiner certification must complete a training program that:

(a) Is conducted by a training provider that:

(1) Is accredited by a nationally recognized medical profession accrediting organization to provide continuing education units; and

(2) Meets the following administrative requirements:

(i) Provides training participants with proof of participation.

(ii) Provides FMCSA point of contact information to training participants.

(b) Provides training to medical examiners on the following topics:

(1) Background, rationale, mission, and goals of the FMCSA medical examiner's role in reducing crashes, injuries, and fatalities involving commercial motor vehicles.

(2) Familiarization with the responsibilities and work environment of commercial motor vehicle operation.

(3) Identification of the operator and obtaining, reviewing, and documenting operator medical history, including prescription and over-the-counter medications.

(4) Performing, reviewing, and documenting the operator's medical examination.

(5) Performing, obtaining, and documenting additional diagnostic tests or medical opinion from a medical specialist or treating physician.

(6) Informing and educating the operator about medications and non-disqualifying medical conditions that require remedial care.

(7) Determining operator certification outcome and period for which certification should be valid.

(8) FMCSA reporting and documentation requirements.

Guidance on the core curriculum specifications for use by training providers is available from FMCSA.

§ 390.107 Medical examiner certification testing.

An applicant for medical examiner certification or recertification must apply, in, accordance with the minimum specifications for application elements established by FMCSA, to a testing organization that meets the following criteria:

(a) The testing organization has documented policies and procedures that:

(1) Use secure protocols to access, process, store, and transmit all test items, test forms, test data, and candidate information and ensure access by authorized personnel only.

(2) Ensure testing environments are reasonably comfortable and have minimal distractions.

(3) Prevent to the greatest extent practicable the opportunity for a test taker to attain a passing score by fraudulent means.

(4) Ensure that test center staff who interact with and proctor examinees or provide technical support have completed formal training, demonstrate competency, and are monitored periodically for quality assurance in testing procedures.

(5) Accommodate testing of individuals with disabilities or impairments to minimize the effect of the disabilities or impairments while maintaining the security of the test and data.

(b) Testing organizations that offer testing of examinees not at locations that are operated and staffed by the organizations but by means of remote, computer-based systems must, in addition to the requirements of paragraph (a) of this section, ensure that such systems:

(1) Provide a means to authenticate the identity of the person taking the test.

(2) Provide a means for the testing organization to monitor the activity of the person taking the test.

(3) Do not allow the person taking the test to reproduce or record the contents of the test by any means.

(c) The testing organization has submitted its documented policies and procedures as defined in paragraph (a) of this section and, if applicable, paragraph (b) of this section to FMCSA and agreed to future reviews by FMCSA to ensure compliance with the criteria listed in this section.

(d) The testing organization administers only the currently authorized version of the medical examiner certification test developed and furnished by FMCSA.

§ 390.109 Issuance of the FMCSA medical examiner certification credential.

Upon compliance with the requirements of § 390.103(a) or (b), FMCSA will issue to a medical examiner applicant an FMCSA medical examiner certification credential with a unique National Registry Number and will add the medical examiner's name to the National Registry of Certified Medical Examiners. The certification credential will expire 10 years after the date of its issuance.

§ 390.111 Requirements for continued listing on the National Registry of Certified Medical Examiners.

(a) To continue to be listed on the National Registry of Certified Medical Examiners, each medical examiner must:

(1) Continue to meet the requirements of this subpart and the applicable requirements of part 391 of this chapter.

(2) Report to FMCSA any changes in the application information submitted under§ 390.103(a)(3) within 30 days of the change.

(3) Continue to be licensed, certified, or registered, and authorized to perform physical examinations, in accordance with the applicable laws and regulations of each State in which the medical examiner performs examinations. (4) Maintain documentation of State licensure, registration, or certification to perform physical examinations for each State in which the examiner performs examinations and maintain documentation of and completion of all training required by this section and § 390.105. The medical examiner must make this documentation available to an authorized representative of FMCSA or an authorized representative of Federal, State, or local government. The medical examiner must provide this documentation within 48 hours of the request for investigations and within 10 days of the request for regular audits of eligibility.

(5) Maintain medical examiner certification by completing training and testing according to the following schedule:

(i) No sooner than 4 years and no later than 5 years after the date of issuance of the medical examiner certification credential, complete periodic training as specified by FMCSA.

(ii) No sooner than 9 years and no later than 10 years after the date of issuance of the medical examiner certification credential:

(A) Complete periodic training as specified by FMCSA; and

(B) Pass the test required by \$ 390.103(a)(3).

(b) FMCSA will issue a new medical examiner certification credential valid for 10 years to a medical examiner who complies with paragraphs (a)(1) through (4) of this section and who successfully completes the training and testing as required by paragraphs (a)(5)(i) and (ii) of this section.

§ 390.113 Reasons for removal from the National Registry of Certified Medical Examiners.

FMCSA may remove a medical examiner from the National Registry of Certified Medical Examiners when a medical examiner fails to meet or maintain the qualifications established by this subpart, the requirements of other regulations applicable to the medical examiner, or otherwise does not meet the requirements of 49 U.S.C. 31149. The reasons for removal may include, but are not limited to:

(a) The medical examiner fails to comply with the requirements for continued listing on the National Registry of Certified Medical Examiners, as described in § 390.111.

(b) FMCSA finds that there are errors, omissions, or other indications of improper certification by the medical examiner of an operator in either the completed Medical Examination Reports or the medical examiner's certificates.

(c) The FMCSA determines the medical examiner issued a medical examiner's certificate to an operator of a commercial motor vehicle who failed to meet the applicable standards at the time of the examination.

(d) The medical examiner fails to comply with the examination requirements in § 391.43 of this chapter.

(e) The medical examiner falsely claims to have completed training in physical and medical examination standards as required by this subpart.

§ 390.115 Procedure for removal from the National Registry of Certified Medical Examiners.

(a) <u>Voluntary removal</u>. To be voluntarily removed from the National Registry of Certified Medical Examiners, a medical examiner must submit a request to the FMCSA Director, Office of Carrier, Driver and Vehicle Safety Standards. Except as provided in

paragraph (b) of this section, the Director, Office of Carrier, Driver and Vehicle Safety Standards will accept the request and the removal will become effective immediately. On and after the date of issuance of a notice of proposed removal from the National Registry of Certified Medical Examiners, as described in paragraph (b) of this section, however, the Director, Office of Carrier, Driver and Vehicle Safety Standards will not approve the medical examiner's request for voluntary removal from the National Registry of Certified Medical Examiners.

(b) <u>Notice of proposed removal</u>. Except as provided by paragraphs (a) and (e) of this section, FMCSA initiates the process for removal of a medical examiner from the National Registry of Certified Medical Examiners by issuing a written notice of proposed removal to the medical examiner, stating the reasons that removal is proposed under § 390.113 and any corrective actions necessary for the medical examiner to remain listed on the National Registry of Certified Medical Examiners.

(c) Response to notice of proposed removal and corrective action. A medical examiner who has received a notice of proposed removal from the National Registry of Certified Medical Examiners must submit any written response to the Director, Office of Carrier, Driver and Vehicle Safety Standards no later than 30 days after the date of issuance of the notice of proposed removal. The response must indicate either that the medical examiner believes FMCSA has relied on erroneous reasons, in whole or in part, in proposing removal from the National Registry of Certified Medical Examiners, as described in paragraph (c)(1) of this section, or that the medical examiner will comply and take any corrective action specified in the notice of proposed removal, as described in paragraph (c)(2) of this section.

(1) <u>Opposing a notice of proposed removal</u>. If the medical examiner believes FMCSA has relied on an erroneous reason, in whole or in part, in proposing removal from the National Registry of Certified Medical Examiners, the medical examiner must explain the basis for his or her belief that FMCSA relied on an erroneous reason in proposing the removal. The Director, Office of Carrier, Driver and Vehicle Safety Standards will review the explanation.

(i) If the Director, Office of Carrier, Driver and Vehicle Safety Standards finds FMCSA has wholly relied on an erroneous reason for proposing removal from the National Registry of Certified Medical Examiners, the Director, Office of Carrier, Driver and Vehicle Safety Standards will withdraw the notice of proposed removal and notify the medical examiner in writing of the determination. If the Director, Office of Carrier, Driver and Vehicle Safety Standards finds FMCSA has partly relied on an erroneous reason for proposing removal from the National Registry of Certified Medical Examiners, the Director, Office of Carrier, Driver and Vehicle Safety Standards will modify the notice of proposed removal and notify the medical examiner in writing of the determination. No later than 60 days after the date the Director, Office of Carrier, Driver and Vehicle Safety Standards modifies a notice of proposed removal, the medical examiner must comply with this subpart and correct any deficiencies identified in the modified notice of proposed removal as described in paragraph (c)(2) of this section.

(ii) If the Director, Office of Carrier, Driver and Vehicle Safety Standards finds FMCSA has not relied on an erroneous reason in proposing removal, the Director, Office of Carrier, Driver and Vehicle Safety Standards will affirm the notice of proposed removal and notify the medical examiner in writing of the determination. No later than 60

days after the date the Director, Office of Carrier, Driver and Vehicle Safety Standards affirms the notice of proposed removal, the medical examiner must comply with this subpart and correct the deficiencies identified in the notice of proposed removal as described in paragraph (c)(2) of this section.

(iii) If the medical examiner does not submit a written response within 30 days of the date of issuance of a notice of proposed removal, the removal becomes effective and the medical examiner is immediately removed from the National Registry of Certified Medical Examiners.

(2) Compliance and corrective action.

(i) The medical examiner must comply with this subpart and complete the corrective actions specified in the notice of proposed removal no later than 60 days after either the date of issuance of the notice of proposed removal or the date the Director, Office of Carrier, Driver and Vehicle Safety Standards affirms or modifies the notice of proposed removal, whichever is later. The medical examiner must provide documentation of compliance and completion of the corrective actions to the Director, Office of Carrier, Driver and Vehicle Safety Standards. The Director, Office of Carrier, Driver and Vehicle Safety Standards. The Director, Office of Carrier, Driver and Vehicle Safety Standards may conduct any investigations and request any documentation necessary to verify that the medical examiner has complied with this subpart and completed the required corrective action(s). The Director, Office of Carrier, Driver and Vehicle Safety Standards will notify the medical examiner in writing whether he or she has met the requirements to continue to be listed on the National Registry of Certified Medical Examiners.

(ii) If the medical examiner fails to complete the proposed corrective action(s) within the 60-day period, the removal becomes effective and the medical examiner is immediately removed from the National Registry of Certified Medical Examiners. The Director, Office of Carrier, Driver and Vehicle Safety Standards will notify the person in writing that he or she has been removed from the National Registry of Certified Medical Examiners. Examiners.

(3) At any time before a notice of proposed removal from the National Registry of Certified Medical Examiners becomes final, the recipient of the notice of proposed removal and the Director, Office of Carrier, Driver and Vehicle Safety Standards may resolve the matter by mutual agreement.

(d) <u>Request for administrative review</u>. If a person has been removed from the National Registry of Certified Medical Examiners under paragraph (c)(1)(iii), (c)(2)(ii), or (e) of this section, that person may request an administrative review no later than 30 days after the date the removal becomes effective. The request must be submitted in writing to the FMCSA Associate Administrator for Policy and Program Development. The request must explain the error(s) committed in removing the medical examiner from the National Registry of Certified Medical Examiners, and include a list of all factual, legal, and procedural issues in dispute, and any supporting information or documents.

(1) <u>Additional procedures for administrative review</u>. The Associate Administrator may ask the person to submit additional data or attend a conference to discuss the removal. If the person does not provide the information requested, or does not attend the scheduled conference, the Associate Administrator may dismiss the request for administrative review.

(2) <u>Decision on administrative review</u>. The Associate Administrator will complete the administrative review and notify the person in writing of the decision. The decision constitutes final Agency action. If the Associate Administrator decides the removal was not valid, FMCSA will reinstate the person and reissue a certification credential to expire on the expiration date of the certificate that was invalidated under paragraph (g) of this section. The reinstated medical examiner must:

(i) Continue to meet the requirements of this subpart and the applicable requirements of part 391 of this chapter.

(ii) Report to FMCSA any changes in the application information submitted under § 390.103(a)(3) within 30 days of the reinstatement.

(iii) Be licensed, certified, or registered in accordance with applicable State laws and regulations to perform physical examinations.

(iv) Maintain documentation of State licensure, registration, or certification to perform physical examinations for each State in which the examiner performs examinations maintain documentation of completion of all training required by § 390.105 and § 390.111. The medical examiner must also make this documentation available to an authorized representative of FMCSA or an authorized representative of Federal, State, or local government. The medical examiner must provide this documentation within 48 hours of the request for investigations and within 10 days of the request for regular audits of eligibility.

(v) Complete periodic training as required by the Director, Office of Carrier,Driver and Vehicle Safety Standards.

(e) <u>Emergency removal</u>. In cases of either willfulness or in which public health, interest, or safety requires, the provisions of paragraph (b) of this section are not applicable and the Director, Office of Carrier, Driver and Vehicle Safety Standards may immediately remove a medical examiner from the National Registry of Certified Medical Examiners and invalidate the certification credential issued under § 390.109. A person who has been removed under the provisions of this paragraph may request an administrative review of that decision as described under paragraph (d) of this section.

(f) <u>Reinstatement on the National Registry of Certified Medical Examiners</u>. No sooner than 30 days after the date of removal from the National Registry of Certified Medical Examiners, a person who has been voluntarily or involuntarily removed may apply to the Director, Office of Carrier, Driver and Vehicle Safety Standards to be reinstated. The person must:

(1) Continue to meet the requirements of this subpart and the applicable requirements of part 391 of this chapter.

(2) Report to FMCSA any changes in the application information submitted under § 390.103(a)(3).

(3) Be licensed, certified, or registered in accordance with applicable State laws and regulations to perform physical examinations.

(4) Maintain documentation of State licensure, registration, or certification to perform physical examinations for each State in which the person performs examinations and maintains documentation of completion of all training required by §§ 390.105 and 390.111 . The medical examiner must also make this documentation available to an authorized representative of FMCSA or an authorized representative of Federal, State, or

local government. The person must provide this documentation within 48 hours of the request for investigations and within 10 days of the request for regular audits of eligibility.

(5) Complete training and testing as required by the Director, Office of Carrier, Driver and Vehicle Safety Standards.

(6) In the case of a person who has been involuntarily removed, provide documentation showing completion of any corrective actions required in the notice of proposed removal.

(g) Effect of final decision by FMCSA. If a person is removed from the National Registry of Certified Medical Examiners under paragraph (c) or (e) of this section, the certification credential issued under § 390.109 is no longer valid. However, the removed person's information remains publicly available for 3 years, with an indication that the person is no longer listed on the National Registry of Certified Medical Examiners as of the date of removal.

PART 391--QUALIFICATIONS OF DRIVERS AND LONGER COMBINATION

VEHICLE (LCV) DRIVER INSTRUCTORS

8. Revise the authority citation for part 391 to read as follows:

Authority: 49 U.S.C. 504, 508, 31133, 31136, and 31502; sec. 4007(b), Pub. L. 102–240, 105 Stat, 1914, 2152; sec. 114, Pub. L. 103–311, 108 Stat. 1673, 1677; sec. 215, Pub. L. 106–159, 113 Stat. 1748, 1767; and 49 CFR 1.73.

- 9. Amend § 391.23 by:
- a. Revising paragraph (m)(1);

b. Removing ", and" at the end of paragraph (m)(2)(i)(A) and adding in its place a period;

c. Redesignating paragraph (m)(2)(i)(B) as (m)(2)(i)(C) and adding a new paragraph (m)(2)(i)(B).

The revision and addition read as follows:

§ 391.23 Investigation and inquiries.

* * * * *

(m)* * *

(1) The motor carrier must obtain an original or copy of the medical examiner's certificate issued in accordance with § 391.43, and any medical variance on which the certification is based, and, beginning on or after May 21, 2014 verify the driver was certified by a medical examiner listed on the National Registry of Certified Medical Examiners as of the date of issuance of the medical examiner's certificate, and place the records in the driver qualification file, before allowing the driver to operate a CMV.

- (2) * * *
- (i) * * *

(B) Beginning on or after May 21, 2014, that the driver was certified by a medical examiner listed on the National Registry of Certified Medical Examiners as of the date of medical examiner's certificate issuance.

* * * * *

10. Add § 391.42 to read as follows:

§ 391.42 Schedule for use of medical examiners listed on the National Registry of Certified Medical Examiners.

On and after May 21, 2014, each medical examination required under this subpart must be conducted by a medical examiner who is listed on the National Registry of Certified Medical Examiners.

11. Amend § 391.43 by revising paragraphs (a), (g), and (h), and adding paragraph (i) to read as follows:

§ 391.43 Medical examination; certificate of physical examination.

(a) Except as provided by paragraph (b) of this section and as provided by § 391.42, the medical examination must be performed by a medical examiner listed on the National Registry of Certified Medical Examiners under subpart D of part 390 of this chapter.

* * * * *

(g) Upon completion of the medical examination required by this subpart:

(1) The medical examiner must date and sign the Medical Examination Report and provide his or her full name, office address, and telephone number on the Report.

(2) If the medical examiner finds that the person examined is physically qualified to operate a commercial motor vehicle in accordance with § 391.41(b), he or she must complete a certificate in the form prescribed in paragraph (h) of this section and furnish the original to the person who was examined. The examiner must provide a copy to a prospective or current employing motor carrier who requests it.

(3) Once every calendar month, beginning May 21, 2014, the medical examiner must electronically transmit to the Director, Office of Carrier, Driver and Vehicle Safety Standards, via a secure FMCSA-designated Web site, a completed Form MCSA-5850, Medical Examiner Submission of CMV Driver Medical Examination Results. The Form

109

must include all information specified for each medical examination conducted during the previous month for any driver who is required to be examined by a medical examiner listed on the National Registry of Certified Medical Examiners.

(h) The medical examiner's certificate shall be substantially in accordance with the following form.

MEDICAL EXAMINER'S CERTIFICATE					
I certify that I have examinedin accordance with the Federal Motor Carrier Safety					
Regulations (49 CFR 391.41-391.49) and with knowledge of the driving duties, I find this person is qualified, and, if applicable, only when:					
 □ wearing corrective lenses □ wearing hearing aid 	 ☐ driving within an exempt intracity zone (49 CFR 391.62) ☐ accompanied by a Skill Performance Evaluation Certificate (SPE) 				
□ accompanied by awaiver/exemp					
The information I have provided regarding this physical examination is true and complete. A complete examination form with any attachment embodies my findings completely and correctly, and is on file in my office.					
SIGNATURE OF MEDICAL EXAMINER	TELEPHONE			DATE	
MEDICAL EXAMINER'S NAME (PRINT)	Image: MD Image: Chiropractor Image: DO Image: Chiropractice Nurse Image: Physician Assistant Image: Other Practitioner				
MEDICAL EXAMINER'S LICENSE OR CERTIFICATE NO./ISSUING STATE	NATIONAL REGISTRY NO.				
SIGNATURE OF DRIVER	INTRASTATE ONLY	CDL	DRIV	'ER'S LICENSE NO.	STATE
	□ YES □ NO	□ YES □ NO			
ADDRESS OF DRIVER					
MEDICAL CERTIFICATION EXPIRATION DATE					

(i) Each original (paper or electronic) completed Medical Examination Report and a copy or electronic version of each medical examiner's certificate must be retained on file at the office of the medical examiner for at least 3 years from the date of examination. The medical examiner must make all records and information in these files available to an authorized representative of FMCSA or an authorized Federal, State, or local enforcement agency representative, within 48 hours after the request is made.

12. Amend § 391.51 by:

a. Removing "and" at the end of paragraph (b)(7)(iii);

b. Removing the period at the end of paragraph (b)(8) and adding in its place "; and";

c. Removing "and" at the end of paragraph (d)(4);

d. Removing the period at the end of paragraph (d)(5) and adding in its place "; and"; and

e. Adding paragraphs (b)(9) and (d)(6).

The additions read as follows:

§ 391.51 General requirements for driver qualification files.

* * * * *

(b) * * *

(9) A note relating to verification of medical examiner listing on the National Registry of Certified Medical Examiners required by § 391.23(m).

* * * * *

(d) * * *

(6) The note relating to verification of medical examiner listing on the National Registry of Certified Medical Examiners required by § 391.23(m).

Issued on: April 10, 2012

Anne S. Ferro Administrator

Appendix A Guidance for the Core Curriculum Specifications

The guidance for the core curriculum specifications is intended to assist training organizations in developing programs that would be used to fulfill the proposed requirements in the Federal Motor Carrier Safety Administration's (FMCSA) final rule for the National Registry of Certified Medical Examiners (National Registry). The final rule states that a medical examiner must complete a training program. FMCSA explained in the preamble to the final rule that training providers and organizations must follow the core curriculum specifications in developing training programs for medical examiners who apply for listing on the Agency's National Registry. This training prepares medical examiners to:

- Apply knowledge of FMCSA's driver physical qualifications standards and advisory criteria to findings gathered during the driver's medical examination; and
- Make sound determinations of the driver's medical and physical qualifications for safely operating a commercial motor vehicle (CMV) in interstate commerce.

The rule, 49 CFR 390.105(b), lists eight topics which must be covered in the core curriculum specifications. The core curriculum specifications are arranged below by numbered topic, followed by guidance to assist training providers in developing programs based on the core curriculum specifications.

Guidance for Each of the Core Curriculum Specifications

(1) Background, rationale, mission and goals of the FMCSA medical examiner's role in reducing crashes, injuries and fatalities involving commercial motor vehicles. Mission and Goals of Federal Motor Carrier Safety Administration (FMCSA)

• Discuss the history of FMCSA and its position within the Department of Transportation including its establishment by the Motor Carrier Safety Improvement Act of 1999 and emphasize FMCSA's Mission to reduce crashes, injuries and fatalities involving large trucks and buses.

Role of the Medical Examiner

• Explain the role of the medical examiner as described in 49 CFR 391.43.

(2) Familiarization with the responsibilities and work environment of commercial motor vehicle (CMV) operations.

The Job of CMV Driving

- Describe the responsibilities, work schedules, physical and emotional demands and lifestyle among CMV drivers and how these vary by the type of driving.
- Discuss factors and job tasks that may be involved in a driver's performance, such as:
 - Loading and unloading trailers;

- Inspecting the operating condition of the CMV; and
- Work schedules:
 - irregular work, rest, and eating patterns / dietary choices.

(3) Identification of the driver and obtaining, reviewing, and documenting driver medical history, including prescription and over-the-counter medications. Driver Identification and Medical History:

Discuss the importance of driver identification and review of the following elements of the driver's medical history as related to the tasks of driving a CMV in interstate commerce.

- Inspect a State-issued identification document with the driver's photo to verify the identity of the individual being examined; identify the commercial driver's license or other types of driver's license.
- Identify, query and note issues in a driver's medical record and/or health history as available, which may include:
 - specific information regarding any affirmative responses in the history;
 - any illness, surgery, or injury in the last five years;
 - o any other hospitalizations or surgeries;
 - any recent changes in health status;
 - o whether he/she has any medical conditions or current complaints;
 - o any incidents of disability / physical limitations;
 - current medications and supplements, and potential side effects, which may be potentially disqualifying;
 - his/ her use of recreational/addictive substances (e.g., nicotine, alcohol, inhalants, narcotics or other habit-forming drugs);
 - disorders of the eyes (e.g., retinopathy, cataracts, aphakia, glaucoma, macular degeneration, monocular vision);
 - disorders of the ears (e.g., hearing loss, hearing aids, vertigo, tinnitus, implants);
 - cardiac symptoms and disease (e.g., syncope, dyspnea, chest pain, palpitations, hypertension, congestive heart failure, myocardial infarction, coronary insufficiency, or thrombosis);
 - pulmonary symptoms and disease (e.g., dyspnea, orthopnea, chronic cough, asthma, chronic lung disorders, tuberculosis, previous pulmonary embolus, pneumothorax);
 - sleep disorders (e.g., obstructive sleep apnea, daytime sleepiness, loud snoring, other);
 - o gastrointestinal disorders (e.g., liver disease, digestive problems, hernias);
 - genitourinary disorders (e.g., kidney stones and other renal conditions, renal failure, hernias);
 - diabetes mellitus:
 - current medications (type, potential side effects, duration on current medication);
 - complications from diabetes; and

- presence and frequency of hypoglycemic / hyperglycemic episodes/reactions;
- o other endocrine disorders (e.g., thyroid disorders, interventions / treatment);
- musculoskeletal disorders (e.g., amputations, arthritis, spinal surgery);
- neurologic disorders (e.g., loss of consciousness, seizures, stroke / transient ischemic attack, headaches/ migraines, numbness / weakness); or
- psychiatric disorders (e.g., schizophrenia, severe depression, anxiety, bipolar disorder, or other conditions) that could impair a driver's ability to safely function.

(4) Performing, reviewing and documenting the driver's medical examination.

Physical Examination (Qualification/Disqualification Standards (§ 391.41 and 391.43))

- Explain the FMCSA physical examination requirements and advisory criteria in relationship to conducting the driver's physical examination of the following:
 - Eyes (§ 391.41(b)(10))
 - equal reaction of both pupils to light;
 - evidence of nystagmus and exophthalmos;
 - evaluation of extra-ocular movements.
 - Ears (§ 391.41(b)(11))
 - abnormalities of the ear canal and tympanic membrane;
 - presence of a hearing aid.
 - Mouth and throat (\$ 391.41(b)(5))
 - conditions contributing to difficulty swallowing, speaking or breathing;
 - Neck (§ 391.41(b)(7))
 - range of motion;
 - soft tissue palpation / examination (e.g., lymph nodes, thyroid gland).
 - Heart (§ 391.41(b)(4)and (b)(6))
 - chest inspection (e.g., surgical scars, pacemaker / implantable automatic defibrillator);
 - auscultation for thrills, murmurs, extra sounds, and enlargement;
 - blood pressure and pulse (rate and rhythm);
 - additional signs of disease (e.g., edema, bruits, diaphoresis, distended neck veins.
 - Lungs, chest, and thorax (§ 391.41(b)(5))
 - respiratory rate and pattern;
 - auscultation for abnormal breath sounds;
 - abnormal chest wall configuration / palpation.
 - Abdomen (§ 391.41(a)(3)(i) and 391.43(f))
 - surgical scars;
 - palpation for enlarged liver or spleen, abnormal masses or bruits / pulsation, abdominal tenderness, hernias (e.g., inguinal, umbilical, ventral, femoral or other abnormalities).
 - Spine (§ 391.41(b)(7))
 - surgical scars and deformities;

- tenderness and muscle spasm ;
- loss in range of motion and painful motion;
- spinal deformities.
- Extremities and trunk (§ 391.41(b)(1), (b)(4) and (b)(7))
 - gait, mobility, and posture while bearing his/her weight; limping or signs of pain ;
 - loss, impairment, or use of orthosis;
 - deformities, atrophy, weakness, paralysis, or surgical scars;
 - elbow and shoulder strength, function, and mobility ;
 - handgrip and prehension relative to requirements for controlling a steering wheel and gear shift;
 - varicosities, skin abnormalities, and cyanosis, clubbing, or edema;
 - leg length discrepancy; lower extremity strength, motion, and function
 - other abnormalities of the trunk.
- Neurologic status (§ 391.41(b)(7), (b)(8) and(b)(9))
 - impaired equilibrium, coordination or speech pattern (e.g., ataxia);
 - sensory or positional abnormalities;
 - tremor;
 - radicular signs;
 - reflexes (e.g., asymmetric deep-tendon, normal / abnormal patellar and Babinski).
- Mental status (§ 391.41(b)(9))
 - comprehension and interaction;
 - cognitive impairment;
 - signs of depression, paranoia, antagonism, or aggressiveness that may require follow-up with a mental health professional.

(5) Performing, obtaining and documenting diagnostic tests and obtaining additional testing or medical opinion from a medical specialist or treating physician. <u>Diagnostic Testing and Further Evaluation</u>

- Describe the FMCSA diagnostic testing requirements and the medical examiner's ability to request further testing and evaluation by a specialist.
 - Urine test for specific gravity, protein, blood and glucose (§ 391.41(a)(3)(i));
 - Whisper or audiometric testing (§ 391.41(b)(11));
 - Vision testing for color vision, distant acuity, horizontal field of vision and presence of monocular vision (§ 391.41(b)(10));
 - Other testing as indicated to determine the driver's medical and physical qualifications for safely operating a CMV.
 - Refer to a specialist a driver who exhibits evidence of any of the following disorders (§ 391.43(e) and (f)):
 - vision (e.g., retinopathy, macular degeneration);
 - cardiac (e.g., myocardial infarction, coronary insufficiency, blood pressure control);

- pulmonary (e.g., emphysema, fibrosis);
- endocrine (e.g., diabetes);
- musculoskeletal (e.g., arthritis, neuromuscular disease);
- neurologic (e.g., seizures);
- sleep (e.g., obstructive sleep apnea);
- mental / emotional health (e.g., depression, schizophrenia); or
- other medical condition(s) that may interfere with ability to safely operate a CMV.

(6) Informing and educating the driver about medications and non-disqualifying medical conditions that require remedial care.

Health Counseling

- Inform course participants of the importance of counseling the driver about:
 - possible consequences of non-compliance with a care plan for conditions that have been advised for periodic monitoring with primary healthcare provider;
 - possible side effects and interactions of medications (e.g., narcotics, anticoagulants, psychotropics) including products acquired over-thecounter (e.g., antihistamines, cold and cough medications or dietary supplements) that could negatively affect his/her driving;
 - the effect of fatigue, lack of sleep, poor diet, emotional conditions, stress, and other illnesses that can affect safe driving;
 - if he/she is a contact lens user, the importance of carrying a pair of glasses while driving;
 - if he/she uses a hearing aid, the importance of carrying a spare power source for the device while driving;
 - if he/she has a history of deep vein thrombosis, the risk associated with inactivity while driving and interventions that could prevent another thrombotic event;
 - o if he/she has a diabetes exemption, that he/she should:
 - carry a rapidly absorbable form of glucose while driving;
 - self-monitor blood glucose one hour before driving and at least once every four hours while driving;
 - comply with each condition of his/her exemption;
 - plan to submit glucose monitoring logs for each annual recertification;
 - corrective or therapeutic steps needed for conditions which may progress and adversely impact safe driving ability (e.g., seek follow-up from primary care physician);
 - steps needed for reconsideration of medical certification if driver is certified with a limited interval, e.g., the return date and documentation required for extending the certification time period.

(7) Determining driver certification outcome and period for which certification should be valid.

Assessing the Driver's Qualifications and Disposition

- Explain how to assess the driver's medical and physical qualification to operate a CMV safely in interstate commerce using the medical examination findings weighed against the physical and mental demands associated with operating a CMV by:
 - Considering a driver's ability to
 - move his/her body through space while climbing ladders; bend, stoop, and crouch; enter and exit the cab;
 - manipulate steering wheel;
 - perform precision prehension and power grasping;
 - use arms, feet, and legs during CMV operation;
 - inspect the operating condition of a tractor and/or trailer;
 - monitor and adjust to a complex driving situation; and
 - consider the adverse health effects of fatigue associated with extended work hours without breaks;
 - Considering identified disease or condition(s) progression rate, stability, and likelihood of gradual or sudden incapacitation for documented conditions (e.g., cardiovascular, neurologic, respiratory, musculoskeletal and other).

Medical Certificate Qualification/Disqualification Decision and Examination Intervals

- Discuss the medical examiner's obligation to consider potential risk to public safety and the driver's medical and physical qualifications to drive safely when issuing a Medical Examiner's Certificate, when to qualify/disqualify the driver and how to determine the expiration date of the certificate by:
 - using the requirements stated in the FMCSRs, with nondiscretionary certification standards to disqualify a driver
 - with a history of epilepsy;
 - with diabetes requiring insulin control (unless accompanied by an exemption);
 - when vision parameters (e.g., acuity, horizontal field of vision, color) fall below minimum standards unless accompanied by an exemption;
 - when hearing measurements with or without a hearing aid fall below minimum standards;
 - currently taking methadone;
 - with a current clinical diagnosis of alcoholism; or
 - who uses a controlled substance including a narcotic, an amphetamine, or another habit-forming drug without a prescription from the treating physician;
 - using clinical expertise, disqualify a driver when evidence shows a driver has a medical condition that in your opinion will likely interfere with the safe operation of a CMV;
 - certifying a driver for an appropriate duration of certification interval;
 - if he/she has a condition for which the medical examiner is deferring the driver's medical certification or disqualifying the driver, informing the driver of the reasons which may include:

- a vision deficiency (e.g., retinopathy, macular degeneration);
- the immediate post-operative period;
- a cardiac event (e.g., myocardial infarction, coronary insufficiency);
- a chronic pulmonary exacerbation (e.g., emphysema, fibrosis);
- uncontrolled hypertension;
- endocrine dysfunctions (e.g., insulin-dependent diabetes);
- musculoskeletal challenges (e.g., arthritis, neuromuscular disease);
- a neurologic event (e.g., seizures, stroke, TIA);
- a sleep disorder (e.g., obstructive sleep apnea); or
- mental health dysfunctions (e.g., depression, bipolar disorder).

(8) FMCSA reporting and documentation requirements.

Documentation of Medical Examination Findings

Demonstrate the required FMCSA medical examination report forms, appropriate methods for recording the medical examination findings and the rationale for certification decisions including:

- Medical Examination Report Form
 - identification of the driver;
 - use of appropriate Medical Examination Report form;
 - assurance that driver completes and signs driver's portion of the Medical Examination Report form;
 - specifics regarding any affirmative response on the driver's medical history;
 - height/weight, blood pressure, pulse;
 - o results of the medical examination, including details of abnormal findings;
 - audiometric and vision testing results;
 - presence of a hearing aid and whether it is required to meet the standard;
 - if obtained, funduscopic examination results;
 - the need for corrective lenses for driving;
 - presence or absence of monocular vision and need for a vision exemption;
 - if driver has diabetes mellitus and is insulin dependent, the need for a diabetes exemption;
 - o other laboratory, pulmonary, cardiac testing performed; and
 - \circ the reason(s) for the disqualification and/or referral.
- Other supporting documentation
 - if driver has current vision exemption, include the ophthalmologist's or optometrist's report;
 - if a driver has a diabetes exemption, include the endocrinologist's and ophthalmologist's/optometrist's report;
 - treating physician's work release;
 - if obtained, specialist's evaluation report;

- if the driver has a current Skill Performance Evaluation Certificate, include it; and
- results of Substance Abuse Professional evaluations for alcohol and drug use and/or abuse for a driver with
 - alcoholism who completed counseling and treatment to the point of full recovery.
- Medical Examiner's Certificate
 - o certification status, which may require:
 - waiver / exemption;
 - wearing corrective lenses;
 - wearing a hearing aid; or
 - a Skill Performance Evaluation Certificate;
 - complete and accurate documentation on medical certification card including:
 - the examiner's name, examination date, office address, and telephone number and Medical Examiner signature; and
 - the driver's signature.