





Transportation Safety Conference

A Deeper Dive into FMCSA Medical Exams

September 16, 2019

Presented by Kenji Saito, MD, JD

Chair, Medical Specialties, MaineGeneral Medical Center Medical Director, Workplace Health Regulatory Liaison, MaineGeneral Health

Adjunct Faculty, University of Pennsylvania Perlman School of Medicine Clinical Assistant Professor, Dartmouth College Clinical Assistant Professor of Preventive Medicine, University of New England



Conflict of Interest / Other Roles

- Employment: MaineGeneral. Chair Medical Specialties, Medical Director WPH and Regulatory Liaison
- Board of Directors
 - Founding Board Membmer, Kids' Chance of Maine <u>www.kidschance.org</u>
 - American College of Occupational and Environmental Medicine (ACOEM) <u>www.acoem.org</u>
 - New England College of Occupational and Environmental Medicine (NECOEM), Chair of Education and Webinar with Harvard School of Public Health www.necoem.org
- Academic Appointments: University of Pennsylvania School of Medicine, Dartmouth College, University of New England
- Faculty, MaineHealth Preventive Medicine Fellowship
- ACOEM:
 - Expert Panel for Eyes & MDGuidelines.com & Functional Outcomes
 - Past Chair: Health Informatics, Pharmaceutical Industry, RRG
 - Strategic Planning Committee, Financial Committee, OEM Competencies Task Force



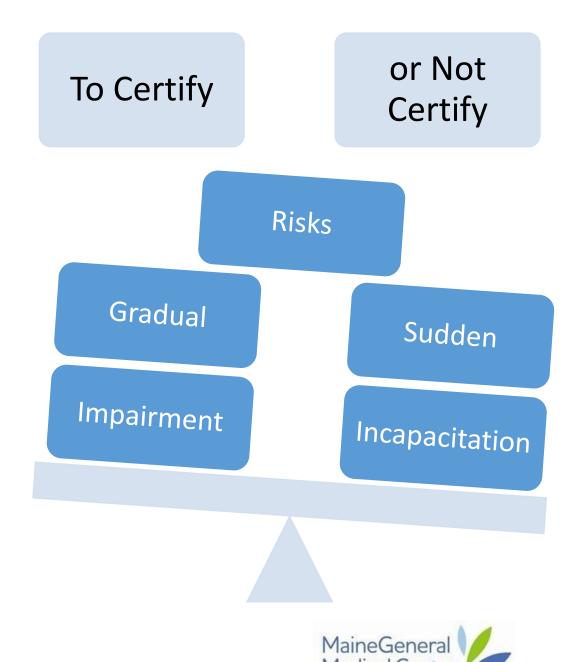
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- The materials presented today are for informational purposes only and not for the purpose of providing medical or legal advice and does not constitute a doctor-patient nor an attorney-client relationship
- The opinions expressed at or through this presentation are the opinions of the individual author and may not necessarily reflect the opinions of MaineGeneral, UPenn, Dartmouth, UNE, ACOEM, NECOEM and other academic or consultative relationships Dr. Saito may have with other entities



FMCSA Medical Exam

- A Fitness for Duty Evaluation during the validity period of the Medical Certificate
- The Risk of
 - Sudden
 - Gradual
- Impairment/Incapacitation



- Conditions that would absolutely disqualify a driver
 - Narcolepsy
 - Implantable cardioverter-defibrillator
 - Methadone
- Other conditions allow some discretion by the NRCME Medical Examiner
 - Must use their medical knowledge and current clinical best practice guidelines to determine whether a driver meets the physical qualification standards



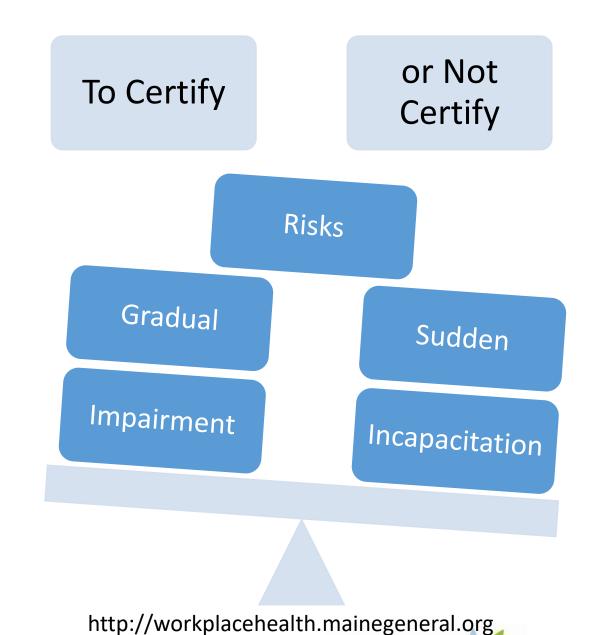
Discretion of NRCME providers

- Vision
- Diabetes
- Sleep Apnea
- Cardiovascular Health
- Medications

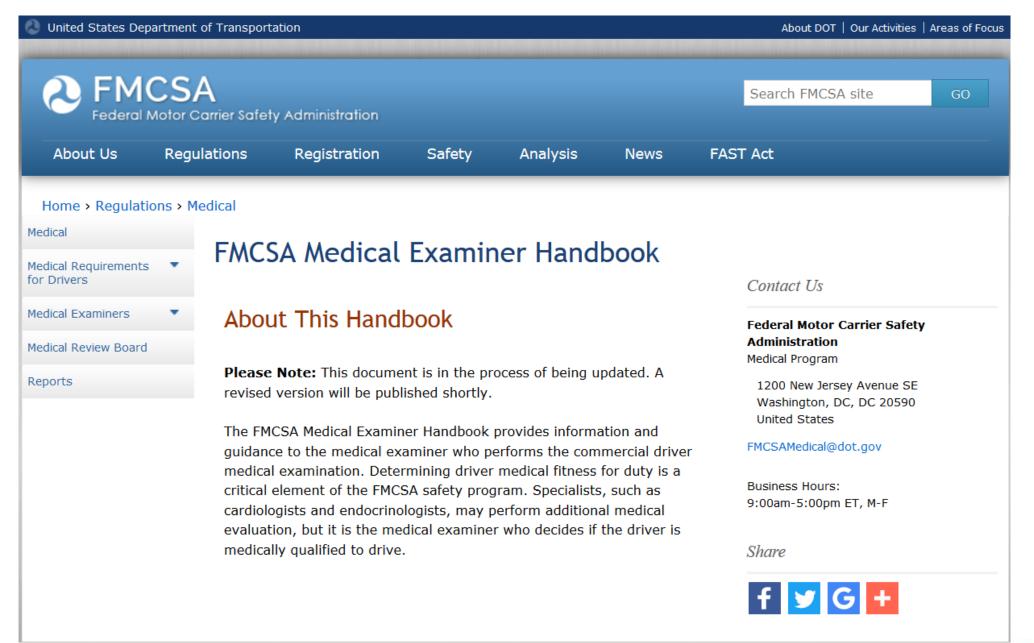


Discretion of NRCME providers

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MaineGeneral



NATIONAL REGISTRY OF CERTIFIED MEDICAL EXAMINERS

Federal Motor Carrier Safety Administration (FMCSA)

Medical Examiner Handbook 2019 Edition



Draft Handbook

- Last edition was 2014
- We will discuss important updates and changes in the 2019 draft update



MRB Meeting Dates and Topics

Meeting Date	Topic
June 25 – 26, 2018	Medical Examiner Handbook, Vision
September 26-27, 2017	Medical Examiner Handbook, Seizures
October 24-25, 2016	Medical Advisory Criteria, FDA Warnings, OSA, Driver Wellness
August 22-23, 2016	Obstructive Sleep Apnea
August 10, 2016 – Joint Meeting with MCSAC	Driver Health and Wellness Working Group -
Sept. 21-22, 2015 - Joint Meeting with MCSAC	Driver Health and Wellness
July 21-22, 2015	Diabetes Mellitus and Vision Standard
October 27, 2014 - Joint Meeting with MCSAC	Schedule II Controlled Substances
July 29-30, 2014	Schedule II Controlled Substances
September 11, 2013	Schedule II Medications
September 9-10, 2013 - Joint Meeting with MCSAC	Motorcoach Hours of Service; Schedule II Medications
February 2013	Bus Driver Fatigue
October 19, 2012	Field of Vision.
February 6, 2012 - Joint Meeting with MCSAC	Obstructive Sleep Apnea (OSA)
January 4-5, 2012	Obstructive Sleep Apnea (OSA)

MRB Meeting Dates and Topics

Meeting Date	Topic
December 2 and 5, 2011	OSA
June 30, 2011	updated Diabetes, cochlear implants, OSA
January 6, 2010	Parkinson's Disease, Multiple Sclerosis; Narcolepsy, Traumatic Brain Injury; Diabetes and Crash Risk
July 1, 2000	Psychiatric Disorders; Circadian Rhythm Disorders; Implantable Cardioverter Defibrillators and Cardiac Resynchronization
January 12, 2009	Stroke
October 6, 2008	Hearing, Vestibular Function; Psychiatric Disorders
July 18, 2008	Chronic Kidney Disease
April 7, 2008	Chronic Kidney Disease; Vision Deficiency
January 28, 2008	Obstructive Sleep Apnea; Seizures
July 26, 2007	Seizures
April 25, 2007	Cardiovascular
January 10, 2008	Schedule II Medication
November 1, 2006 -	Diabetes

- a. Identifies and defines the nature for Reconsideration ITDM Standard (10/15/18) b. States the FMCSA Response (3/5/19) 4.

 - ACOEM Final rule neither ensures safety nor offers a more consistent

 - e. Identifies the fi process to ensure that drivers with ITDM are at acceptable risk of crash

 The contract of the state o The doctor must the results in deg.

 Not necessary for ME to be licensed by the physical qualifications that is addressed by the physical qualifications. every condition that is addressed by the physical qualifications
- ME may request additional information

 Retinopathy progressing or sign threatening

 5. In addition, your application acknowledge that I must be otherwise qualified under 49 CFR 391.41(b)(1-12):

 I can legally operate a commercial motor vehicle in interstate. Reconsideration - https://www.resumming

otion

liabetes as of

ence of thy every 2 years of Diabetic am at least annually

- progressing or sight-
 - More frequent exams

Workplace Health

http://workplacehealth.mainegeneral.org MaineGeneral



ACOEM Request for Reconsideration ITDM Standard(10/15/18) FMCSA Response (3/5/19)

ACOEM - Driver who experiences severe hypoglycemic episode should be required to be reviewed by the certifying ME prior to returning to driving.

FMCSA Response

- TC can make individualized assessment
- Confident that TC would not sign form if driver not safe
- New exam not required but "final rule states that the requirement for a new medical examination could be applicable to the ITDM individual who experiences a severe hypoglycemic episode"
 - Motor Carrier bears responsibility to decide.

FMCSA Decision on Reconsideration - https://www.regulations.gov/document?D=FMCSA-2005-23151-1501



Interpretation to §391.45

- Question 3: Must a driver who is returning from an illness or injury undergo a medical examination even if his current medical certificate has not expired?
- **Guidance:** The FMCSRs do not require an examination in this case unless the injury or illness has impaired the driver's ability to perform his/her normal duties. However, the motor carrier may require a driver returning from any illness or injury to take a physical examination. But, in either case, the motor carrier has the obligation to determine if an injury or illness renders the driver medically unqualified.



You have been examined by an ophthalmologist or an optometrist in the last 3 4. months. The documentation required is a signed statement on letterhead by the

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Identifies and defines the n you have had the deficienc

This package has been removed due to the update of the Diabetes Standard. For more information please visit the New Diabetes Standard Overview Webinar.

otion

States the date of examinat

Vision Package

diabetes any

- Certifies that the visual def
- Identifies the visual acuity
- Identifies the field of vision fields, testing to at least 12 The doctor must submit the the results in degrees of fie
- Identifies if you have the a signals and devices showin
- Certifies that in his/her me the driving tasks required t
- 5. In addition, your application mu acknowledge that I must be otherv I can legally operate a commercial motor venture in interstant commercial.

- General Vision Package
- Indiana Residents Only
- Florida Residents Only

Hearing Package

- Federal Hearing Exemption Application
- Medical Release Form (Hearing) SAMPLE
- Medical Release Form

Seizure Package

- Federal Seizure Exemption Application
- Medical Release Form (Seizure) SAMPLE
- Medical Release Form

integration in the second seco MaineGeneral Medical Center

MCSA-5870

OMB Control Number: 2126-0006

Expiration Date: 11/30/2021

U.S. Department of Transportation Federal Motor Carrier Safety Administration

Individual's Name:	
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A Federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2126-0006. Public reporting for this collection of information is estimated to be approximately 8 minutes per response, including the time for reviewing instructions, gathering the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, Federal Motor Carrier Safety Administration, MC-RRA, 1200 New Jersey Avenue, SE, Washington, D.C. 20590.

INSULIN-TREATED DIABETES MELLITUS ASSESSMENT FORM

Name:	DOB:	
Driver's License Number (if applicable):	State:	

This individual is being evaluated either to determine whether he/she meets the physical qualification standards of the Federal Motor Carrier Safety Administration (FMCSA) to operate a commercial motor vehicle or because the individual has recently experienced a severe hypoglycemic episode. A treating clinician should complete this form to the best of his/her ability based on his/her knowledge of the individual's medical history. Completion of this form does not imply that a treating clinician is making a medical certification decision to qualify the individual to drive a commercial motor vehicle. Any determination as to whether the individual is physically qualified to drive a commercial motor vehicle will be made by a certified medical examiner on FMCSA's National Registry of Certified Medical Examiners.

FMCSA defines a treating clinician as a healthcare professional who manages, and prescribes insulin for, treatment of the individual's diabetes mellitus as authorized by the healthcare professional's applicable State licensing authority.

Instructions to the Individual:

When you are being evaluated prior to a medical certification examination, the certified medical examiner must receive this form and begin the examination no later than 45 calendar days after a treating clinician signs this form.

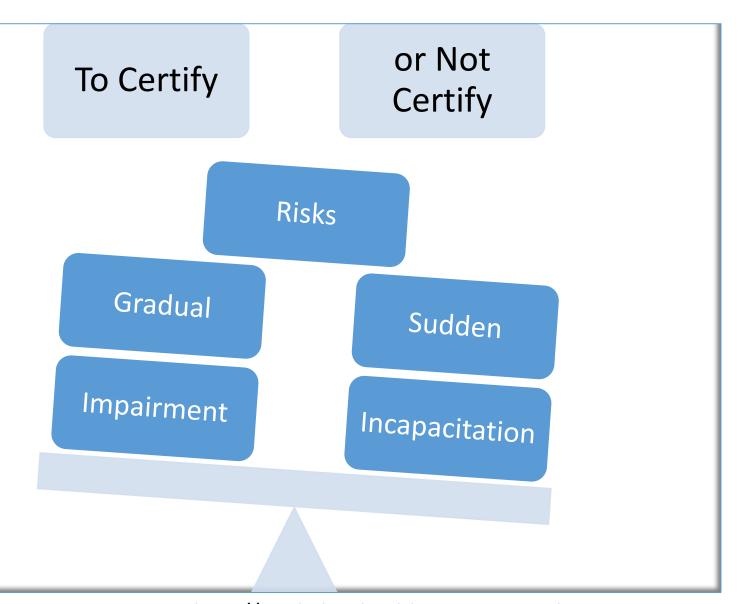
When you are being evaluated after a severe hypoglycemic episode, you must retain this form and give it to the certified medical examiner at your next medical certification examination.

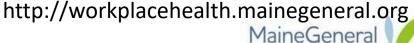
 We will discuss more about changes to the evaluation of diabetic drivers



Hypoglycemi

- ACOEM requested received response
 - ACOEM urged that Association's criter
 40 mg/dL irrespect
- FMCSA responses assessment





CDME Forum Questions

 Will share most current & relevant questions coming through the forum from medical examiners

Sleep Apnea in the "New" Medical Handbook

• More information will be forthcoming, but as of the creation of this handout in August 2019, below are the current status:

Sleep Apnea

49 CFR 391.41(b)(5) requires that an individual must have no established medical history or clinical diagnosis of a respiratory dysfunction likely to interfere with the ability to safely drive a CMV interstate commerce. The Medical Advisory Criteria (Appendix A to Part 391 Section E), identifies sleep apnea as one of several respiratory dysfunctions that may be detrimental to safe driving as this condition may interfere with driver alertness and may cause gradual or sudden incapacitation.

FMCSA reminds medical examiners that the Agency has no rules or regulatory guidance or criteria specifically on OSA screening, testing, and treatment beyond the existing requirements in 49 CFR 391.41(b)(5) and the 2000 medical advisory criteria which is not mandatory. The Agency relies on the use of sound screening approaches by certified medical examiners to identify which individuals are at greater risk for OSA and to refer only those individuals for diagnostic testing. In screening for OSA during the medical certification process, medical examiners may rely on their medical judgment and may consider relevant medical best practices, and expert recommendations. Medical examiners may confer with treating specialists, and request additional and current information to inform their medical certification determinations. FMCSA urges medical examiners educate CMV drivers regarding their risk factors and the health and safety impact of moderate to severe OSA during the medical certification process to explain clearly to drivers the basis for their medical certification decisions.

Key points to aid a medical examiner's decision on safe driving ability include using best practice methodology through experience and research to ensure driver and public safety:



Key points to aid a medical examiner's decision on safe driving ability include using best practice methodology through experience and research to ensure driver and public safety:

- Symptoms associated with sleep apnea include but are not limited to:
 - Loud snoring
 - Episodes of stopping to breath during sleep
 - Gasping for air during sleep
 - Awakening with a dry mouth
 - Morning headache
 - Insomnia
 - Excessive daytime sleepiness
 - Difficulty paying attention while awake
 - irritability
- Are there multiple risk factors? A high BMI by itself may not be sufficient to order a sleep study
- Risk factors include:
 - Hypertension (treated or untreated)
 - Type 2 diabetes (treated or untreated)
 - History of stroke, coronary artery disease, or arrhythmias
 - Rheumatoid Arthritis
 - Hypothyroidism (untreated)
 - Micrognathia or retrognathia
 - Loud Snoring
 - Small airway (Mallampati Classification of Class III or IV)
 - Neck size > 17 inches (male), >15.5 inches (female)
 - Age > 42 or male or post-menopausal female
 - BMI of 33 and above
- A medical examiner may certify a driver with an OSA diagnosis if the driver is being treated effectively
- A driver determined to be at risk for OSA may be certified for 90 days pending sleep study and treatment (if diagnosed with OSA) at the medical examiner's discretion
- To requalify, drivers must show effective treatment and compliance. Use of APAP for a minimum
 of 4 hours per night with 70% nightly usage is a recommended standard from the Medical Review
 Board. Trucking companies have the option of using their own standards.

 We will discuss what these changes mean and how it may impact your business

http://workplacehealth.mainegeneral.org



Cardiovascular Health

- Updates on Blood pressure guidance
- Joint National Committee 6, 7 and 8 recommendation for blood pressure
- How about others:
 - American College of Cardiology (ACC),
 - American Heart Association (AHA)
- 130/80 mm Hg vs. 140/90

Medication

What medications disqualify a CMV driver?

A driver cannot take a controlled substance or prescription medication without a prescription from a licensed practitioner.

If a driver uses a drug identified in 21 CFR 1308.11 (391.42(b)(12)) or any other substance such as amphetamine, a narcotic, or any other habit forming drug, The driver is medically unqualified.

There is an exception: the prescribing doctor can write that the driver is safe to be a commercial driver while taking the medication. In this case, the Medical Examiner may, but does not have to certify the driver.

Any anti-seizure medication used for the prevention of seizures is disqualifying.

The Medical Examiner has 2 ways to determine if any medication a driver uses will adversely affect safe operation of a CMV:

- 1. Review each medication prescription, non-prescription and supplement
- 2. Request a letter from the prescribing doctor

Last Updated: September 18, 2017



Medication

What medic 391.41 CMV Driver Medication Form, MCSA-5895 (optional)

A driver cannot take prescription from a li If a driver uses a dru substance such as ar driver is medically ur There is an exceptior commercial driver whout does not have to Any anti-seizure med The Medical Examine adversely affect safe 1. Review each medical

2. Request a letter fr

39141-cmv-driver-medication-form-mcsa-5895.pdf

About the 391.41 CMV Driver Medication Form, MCSA-5895 (optional):

The 391.41 CMV Driver Medication Form, MCSA-5895, requests additional information regarding medications prescribed by the treating physician as an optional tool for Medical Examiners to use in determining if a driver is medically qualified under 49 CFR 391.41.

Last Updated: September 10, 2017



U.S. Department of Transportation Federal Motor Carrier Safety Administration

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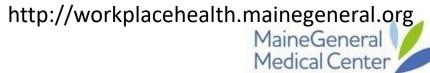
391.41 CMV DRIVER MEDICATION FORM

Driver Name:	DOB:	
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The above patient/driver is being evaluated to determine whether he/she meets the medical standards of the Federal Motor Carrier Safety Administration (FMCSA) to operate a commercial motor vehicle (CMV) in interstate commerce. During the medical evaluation, it was determined this individual is taking medication(s) that may impair his/her ability to safely operate a CMV. As the certified Medical Examiner (ME), I request that you review the regulations as noted below, complete this form, and return it to me at the mailing address, email address, or fax number specified below. The final determination as to whether the individual listed in this form is physically qualified to drive a CMV will be made by the certified ME.

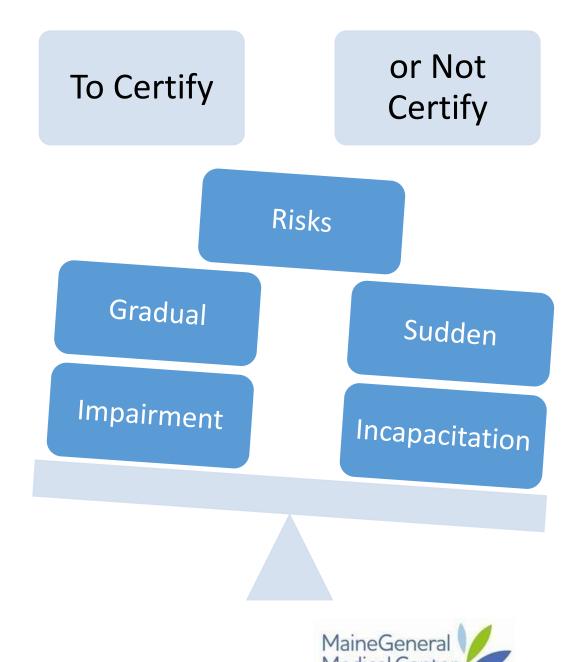
49 CFR 391.41, Physical Qualifications for Drivers: A person is physically qualified to drive a CMV if that person ... (12)(i) Does not use any drug or substance identified in 21 CFR 1308.11 Schedule I, an amphetamine, a narcotic, or other habit-forming drug. (ii) Does not use any non-Schedule I drug or substance that is identified in the other Schedules in 21 part 1308 except when the use is prescribed by a licensed medical practitioner, as defined in § 382.107, who is familiar with the driver's medical history and has advised the driver that the substance will not adversely affect the driver's ability to safely operate a CMV.

List all medications and dosages that you have prescribed to the above named individual.



FMCSA Medical Exam

- A Fitness for Duty Evaluation during the validity period of the Medical Certificate
- The Risk of
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Feedback

- Several experienced medical examiners were consulted and were asked to give feedback in response to specific questions
- The new handbook is more organized than previous publications
- Easier to understand
- Text altered in order to clarify language and make the information easier to read



Criticisms

- There were criticisms noted in the responses provided by the consulted medical examiners
- Many of the recommendations are still too imprecise and ambiguous
- The comments asked for more clear and specific guidelines



Feedback From medical examiners

- The examiners also commented that the 2019 FMCSA Medical Examiner Handbook, in comparison to the old handbook:
 - focuses more heavily on the responsibility given to a medical examiner regarding qualification decisions
 - more clearly defines the distinction between regulations and best practice recommendations
- Overall, the examiners surveyed found the new handbook to be a useful tool that allows medical examiners to make appropriate decisions regarding a driver's CMV qualifications

