

Commercial Driver Medical Examination (DOT) Update

MARCOEM 2019
October 13, 2019
Natalie P. Hartenbaum, MD, MPH
President and Chief Medical Officer
OccuMedix, Inc



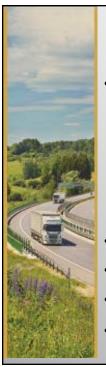
Agenda

- NRCME
 - Registration, Refresher Training, NRCME2 Forms, new FAQs
- Diabetes Standard
 - Confusion and controversy
- Vision Exemption
 - Quick no change

- Medication
 - Form, Marijuana/CBD, FMCSA Clearinghouse
- Obstructive Sleep Apnea
 - Not much new
- Draft ME Handbook
- Resources

WAAAAY TOO MUCH GOING ON





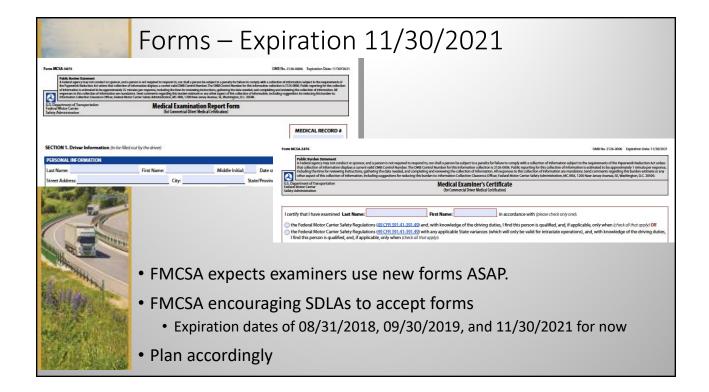
NRCME Update – Refresher Training

- · Refresher training
 - 4-5 yrs after date of issuance of the ME certification credential
 - Complete periodic training as specified (and provided) by FMCSA.
 - 9-10 yrs after issuance of the ME certification credential
 - · Complete periodic retraining and pass the test required
- Refresher Only training offered by FMCSA will be acceptable
- · No fee, no CME
- Getting close(?????), will have adequate time to complete
- Will be based on most frequent questions/issues, not on Draft ME Handbook



NRCME2 – Medical Examiner Certification Integration Interim Final Rule – June 21, 2018

- Many state CDLIS not ready Delay until June 22, 2021
- Examiners
 - Issue paper MEC through 2021
 - No change (ever) for drivers w/o CDL issue paper MEC
 - No delay in determination upload requirement
 - Midnight following calendar day
- Motor Carriers:
 - Continue to verify examiner on NRCME





New FAQs

Q. How may a Medical Examiner comply with 49 CFR 391.43(i) if he or she changes employment and the Medical Examiner's records are maintained by the previous employer?

A. The Medical Examiner would advise FMCSA of the location of the records and the range of dates during which examinations were conducted for that employer. The Agency would then contact the previous employer to obtain the necessary information



New FAQs

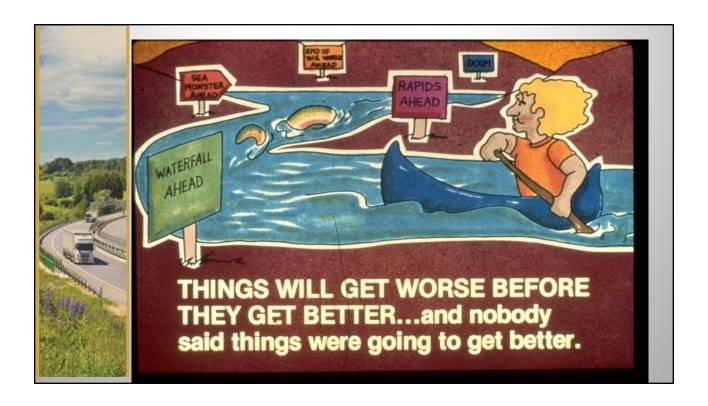
Q. May a Medical Examiner's employers maintain the required records at the employer's centralized medical records department or electronic health record system in lieu of the individual Medical Examiner's office?



New FAQs

A. Yes, according to 49 CFR 391.43(i), each original (paper or electronic) completed Medical Examination Report Form, MCSA-5875, and Medical Examiner's Certificate, Form MCSA-5876, must be retained on file at the Medical Examiner's office for a period of at least 3 years from the date of examination.

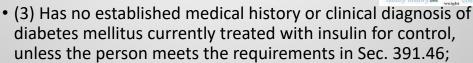
The Medical Examiner's employer may maintain all required records on behalf of the Medical Examiner in a centralized medical records department or within its electronic health record system, as long as the Medical Examiner may request and obtain the records and can provide the scanned records upon request to FMCSA or an authorized Federal, State, or local enforcement agency.





Revised Diabetes Standard September 19, 2018

- Sec. 391.41 Physical qualifications for drivers.
- * * * *
- (b) * * *



system

food sign

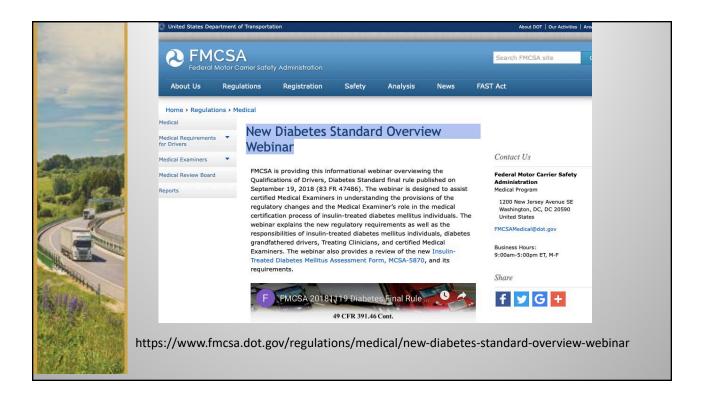
insulin

research

Had been;

(3) Has no established medical history or clinical diagnosis of diabetes mellitus currently <u>requiring</u> insulin for control

Diabetes Exemption "officially " ended 2/21/19 - Federal Register announcement





Sec. 391.46 Physical qualification standards for an individual with diabetes mellitus treated with insulin for control

- ME determines if driver meets physical qualification standards in §391.41 (all)
 - Must *consider* information in Form, MCSA-5870



Sec. 391.46 Physical qualification standards for an individual with diabetes mellitus treated with insulin for control

- Utilizing <u>independent</u> medical judgment* apply following qualification standards
 - Not physically qualified if not maintaining stable insulin regimen and (?or) not properly controlling his or her diabetes mellitus
 - Not physically qualified -permanent basis
 - Severe non- proliferative or proliferative diabetic retinopathy

May obtain additional information from TC or other information *ME makes final determination



American Diabetes Association Recommendation on Dilated Eye Examinations Subsequent exams

- If no evidence of retinopathy for one or more annual eye exams
 - · Exams every 2 years may be considered
- If any level of diabetic retinopathy is present
 - Dilated retinal examinations for patients with type 1 or 2 DM at least annually by ophthalmologist or optometrist.
- If retinopathy is progressing or sight-threatening
 - Examinations will be required more frequently.

Solomon SD, Chew E, Duh EJ, et. al. Diabetic Retinopathy: A Position Statement by the American Diabetes Association. Diabetes Care 2017 Mar; 40(3): 412-418. http://care.diabetesjournals.org/content/40/3/412



Sec. 391.46 Physical qualification standards for an individual with diabetes mellitus treated with insulin for control

- (e) Severe hypoglycemic episodes.
 - (1) Individual with ITDM who experiences a severe hypoglycemic episode is prohibited from operating a CMV and must report to and be evaluated by TC as soon as "reasonably practicable"
 - Severe hypoglycemic episode "requires the assistance of others or results in LOC, seizure, or coma"



Sec. 391.46 Physical qualification standards for an individual with diabetes mellitus treated with insulin for control

- Prohibition continues until TC
 - Determined that the cause has been addressed;
 - Determined that the individual is maintaining a stable insulin regimen and proper control of his or her diabetes mellitus; and
 - Completes a new Form, MCSA-5870
- Individual (**driver**) retains Form and provides to ME at next medical examination.
- No requirement under 391.46 for ME to evaluate but...



§391.45 - Persons who must be medically examined and certified:

"(c) Any driver whose ability to perform his/her normal duties has been impaired by a physical or mental injury or disease";



§391.45(c) *Persons who must be medically examined and certified -* Interpretation

"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."



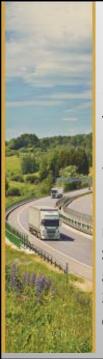
ACOEM Request for Reconsideration ITDM Standard(10/15/18) FMCSA Response (3/5/19)

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



FMCSA Response – Severe Hypoglycemic Episode

"Whether a new medical examination is required will depend on the specific circumstances and whether the episode results in a physical or mental injury or disease that impairs the individual's ability to perform his or her normal duties. As motor carriers bear the responsibility to ensure that employed drivers are medically qualified to operate a commercial motor vehicle, motor carriers are not prohibited by the Federal Motor Carrier Safety Regulations from establishing local reporting policies and procedures for obtaining re-evaluation under 49 CFR 391.45 for employees concerning potentially impairing medical conditions"



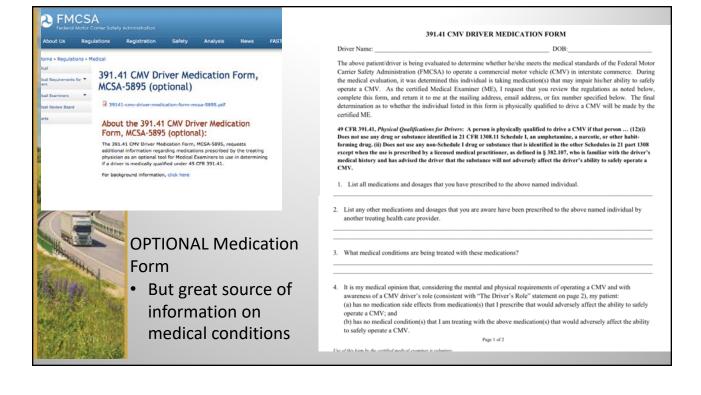
Annual Certification for Non-insulin Treated Diabetics

- Annual certification is not a "requirement"
 - Never was!!!
- Final Rule noted
 - Not imposing the "requirement for annual certification," for non-ITDM individuals
 - Certified MEs are trained that they may issue shortduration MECs, MCSA-5876, for medical conditions that require frequent monitoring or where additional medical information is needed".



Annual Certification for Non-insulin Treated Diabetics

- Still in FAQs that "drivers with specific medical conditions require more frequent certification:"
 - Determination by examiner that condition requires more frequent monitoring, such as diabetes mellitus or sleep disorders".



Medication Medical Marijuana Indication for treatment Phin Mgm + Prequency # of pills prescribed p	
indication for treatment Pain man	t
- Rread	MA
Dose# of plus prescribed p	er month
How frequently used if ordered as needed A-M: Only	
/ //	
Taken during work hours: (yes) no	
PLEASE ATTACH A PRINTOUT OF ALL CONTROLLED SUBSTAI EITHER FROM NYS PMP REGISTRY OR ELECTRONIC HEALTH	NCES PRESCRIBED, RECORD.
Comments	
[certify that, in my professional judgment, this medication will no	ot affect his/her ability to
safely operate a commercial motor vehicle.	
A	
M. Chang above the	
Physician's Stamp- phone #	<u> </u>
No. 1995 Secretar Anni Principal Secretar Secret	



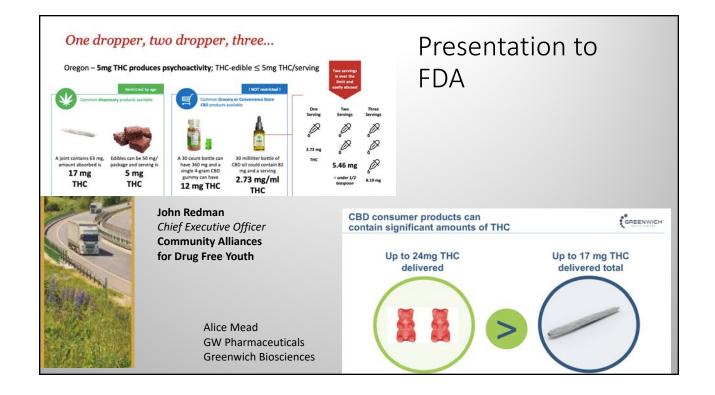
Medication/CBD

- Marijuana recreational or medical prohibited
- CBD not automatically disqualifying if used legally under Federal law BUT...
 - Used under Hemp laws or state (May not be consistent with Federal Law)
 - Cultivated as required under Federal Lay
 - · Concentration meets criteria under Federal law
 - Or as labeled
 - Not labeled for health benefits
 - Not added to food
- Driver beware not a valid explanation on a drug test.
- Employer may set criteria (depends on state)



CBD — Concentration of THC under STATE Law High CBD — Low THC Laws

- Georgia contains no more than 5% THC
- Mississippi cannabis extract, oil, or resin that contains less than 0.5% THC.
- North Carolina hemp extract must be composed of less than 0.9% THC
- South Carolina CBD oil that is less than 0.9% THC
- Tennessee CBD oil that is less than 0.9% THC
- Texas cannabis oil that is no more than 0.5% THC
- Virginia oil must contain no more than 5% THC.
- States may also have limitations on use (diagnosis) and dispensing

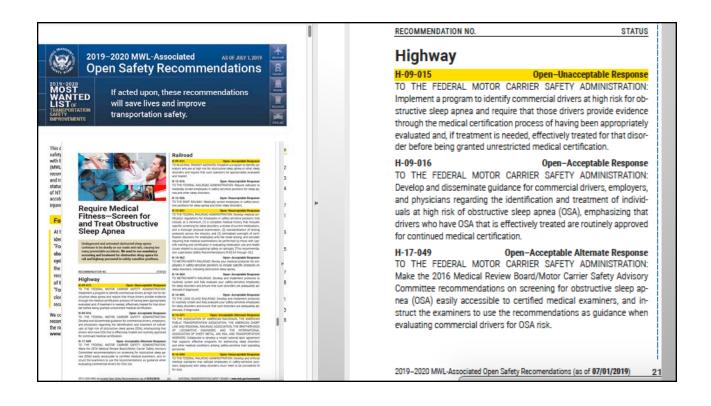






FMCSA Drug and Alcohol Clearinghouse

• Examiners (nor MROs) will have access to review violations





OSA ANPRM Withdrawal - August 8, 2017

"'The Agency reminds medical examiners that there are no FMCSA rules or other regulatory guidance beyond what is referenced in this paragraph above (2015 Bulletin and 2016 MRB recommendations) with guidelines for screening, diagnosis, and treatment of OSA in CMV drivers. Medical certification determinations for such drivers are made by the examiners based on the examiner's medical judgment rather than a Federal regulation or requirement."



MRB –June 2019 meeting

Meeting Dates	Topic
July 15-16, 2019	National Training Center (NTC)
	1310 N. Courthouse Road
	Arlington, VA
	Announcement DRAFT Medical Examiners handbook rev. 7-1-19 Agenda, July 15-16, 2019 Medical Review Board FMCSA Educational Video Series - MEDICATIONS I Joseph Sentef MD, MPH, MBA, MRO Chief Medical Officer FMCSA Educational Video Series - MEDICATIONS II Joseph Sentef MD, MPH, MBA, MRO Chief Medical Officer Medical Examiners Handbook Task Statement 17-1 FINAL Task Statement 15-2 Vision Standards 7-15-15 Comments - Truckers for a Cause on draft-medical-examiners-handbook-rev-7-1-19 Handbook Questionnaire Results

NATIONAL REGISTRY

Federal Motor Carrier Safety Administration (FMCSA) Medical Examiner Handbook



- ME Handbook first posted in 2008
- Provided guidance MEs.

https://www.fmcsa.dot.gov/medical-review-board-mrb-meeting-topics

- MEs and stakeholders have have applied information as if regulation
- Removed from website in 2015.

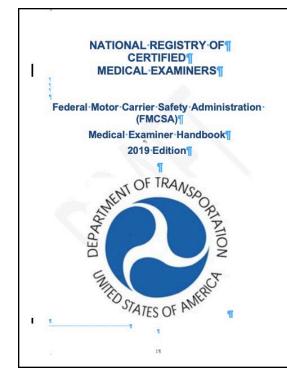


No longer endorsed by FMCSA but still a reasonable resource for the ME to use as a STARTING point in making a certification determination. NOT a REQUIREMENT!!!!!!!

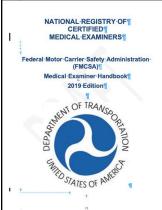


MRB Task 17-1 - Recommendations to the Agency on the Revision of the Federal Motor Carrier Safety Administration (FMCSA) Medical Examiners Handbook (MEH)

- Reviewing and streamlining the MEH
- Removal of non-regulatory directive language
- Update and removal of obsolete information
- Expected completion end of 2017
- Issue was that many examiners saw content of ME Handbook as REQUIREMENT

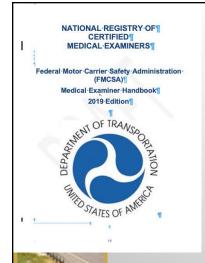


- Significantly shorter 75 v 260
- Mostly narrative
- No clear
 - Waiting period
 - Recommend to disqualify
 - Recertification recommendation
- Included Advisory Criteria for some but not all standards
 - Will include





- Did not include interpretations or FAQs
 - But suggested
- A lot of "read between lines"
 - But does everyone have "read between lines" vision?
- Needs better organization and crossreferencing
- Focuses on sudden death or sudden incapacitation
 - Suggested to add- Sudden or gradual impairment or incapacitation

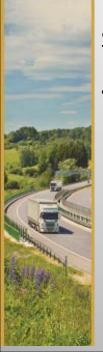


- Does not include;
 - "You should not certify the driver until the etiology is confirmed and treatment has been shown to be adequate/effective, safe, and stable" (Old Handbook)



General

- "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 include:"
 - But not every examiner will be aware of EBM or have experience



Statements - Additional Medical Information

 "Specialists, such as cardiologists may provide additional medical information, but it is the medical examiner who ultimately decides if the driver is medically qualified to drive".



Statements – Additional Medical Information

 "Consistent with best practices for any medical condition, in applying the physical qualification standards, the ME may consult with the individual's treating provider for additional information concerning the driver's medical history and current condition, make appropriate referrals to other medical providers, or request medical records, all with appropriate consent."



Statements

Criteria Guidance

- FMCSA provides medical guidance and advisory criteria to provide recommendations and information to assist medical examiners in applying the regulations. These recommendations and guidance often are based on expert review or considered best practice. Unlike regulations, the recommendations and other guidance are not legally binding. Rather, such guidance is strictly advisory, not mandatory and intended to provide information that helps to support the application of the standards in the regulations or to serve as a reference. Accordingly, the examiner may or may not choose to follow these recommendations.
 - Suggested to add "but should document reason for not following"



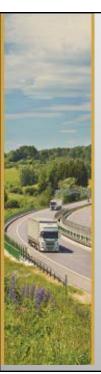
Part III - Examination Guidelines

- "Other sources of guidance, which can be used by the medical examiner include, but are not limited to, medical expert panel reports, medical reports from literature, and Medical Review Board (MRB) recommendations."
 - But are they taught in training programs should be!
 - No link to MRB proceedings or reports



Statements

- When you determine that a driver is medically fit to drive and also able to perform non-driving responsibilities (my emphasis), you will certify the driver and issue a Medical Examiner's Certificate.
- You are to retain the driver medical records for a minimum of 3 years
 - Will add or consistent with state law
- An employer can only be provided a copy with the driver's consent
 - Will add reference to HIPAA compliant release



Vision

- Disqualifying Vision
 - Monocular vision except with an exemption
 - Failure to meet any part of the vision testing criteria with one eye or both eyes
- Medical Advisory Criteria
 - Use of telescopic lenses is not acceptable

Will clarify "monocular vision" as defined by FMCSA



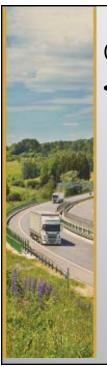
Vision

- Instructions on how to perform Snellen visual acuity, types of Snellen charts, how to perform peripheral vision testing, etc.
 - Will be removed.
- Discussed if video needed to demonstrate testing peripheral vision
 - ? How about video on how to perform abdominal exam, palpate for aneurysm, etc
 - Should ME Handbook be teaching how to do exam or...
 - "Must be licensed by state to perform physical examination"....
 - Doesn't that imply "knows how to do examination"?



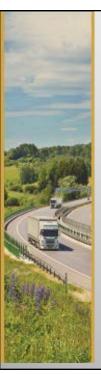
Blood Pressure

- Should only be taken by examiner
 - Not rely on BP from treating provider
- Categories of BP NOT on form
 - Should guidance should be updated?
 - JNCV III, other guidance?
 - · Would need to go through Rulemaking
- BP Certification/Recertification Recommendation Table in Draft Handbook incorrect
 - Will be updated to be consistent with MAC



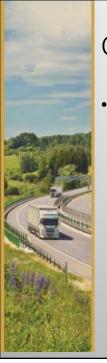
Cardiovascular - AAA

- "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:
 - Includes a 3-month waiting period for aneurysm repair
 - Includes aneurysms less than 4 cm that are asymptomatic and are not considered restrictive
 - Includes aneurysms greater than 4 cm but less than 5 cm that are asymptomatic and have cardiovascular clearance should not be considered restrictive"
 - Does not include specific language that >5cm should disqualify



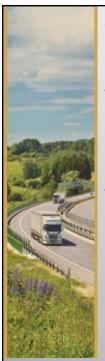
Cardiovascular – ICD

 ICDs treat but do not prevent arrhythmias. Therefore, the driver remains at risk for syncope. The management of the underlying disease is not effective enough for the driver to meet cardiovascular qualification requirements. Combination ICD/pacemaker devices are also ineffective in preventing incapacitating cardiac arrhythmia events.



Cardiovascular - ICD

- Having an ICD or ICD/pacemaker combination device is **disqualifying** in that federal regulation 391.41(b)(4) states that a driver "has no current clinical diagnosis of myocardial infarction, angina pectoris, coronary insufficiency, thrombosis, or any other cardiovascular disease of a variety known to be accompanied by syncope, dyspnea, collapse, or congestive heart failure.
 - But had been told that ICD falls under LOC (391.41(b)(8)



Cardiovascular –

"Cardiovascular Tests for Educational Purposes"

- Echocardiogram
 - "Based on best practices methodology, a driver should have an LVEF greater or equal to 40% with no associated pulmonary hypertension"
- Exercise Tolerance Test (ETT) Based on best practices methodology -
 - Able to exercise to a workload capacity greater than 6 Metabolic Equivalents (METs) (through Bruce protocol stage II or equivalent)
 - Attain a heart > 85% of predicted maximum (unless on beta blockers)
 - Have a rise in systolic blood pressure greater than or equal to 20 mm
 HG without angina,
 - Have no significant ST segment depression



Cardiovascular – MI

- Current opinion among clinicians (?) state that post-MI drivers may safely return to any occupational task provided there is no exercise-induced myocardial ischemia or left ventricular dysfunction.
- Key points
 - "Consider a recovery period of 2 months based on best practices if the driver is asymptomatic, has no electrocardiogram ischemic changes and tolerates medications"
 - "Consider medical clearance from a cardiovascular specialist"
- Nothing about ETT prior to RTW or periodic (also not mentioned for Angina) but...



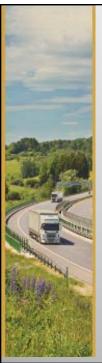
Cardiovascular – CABG

- Key points
 - The driver should have a reasonable recovery period of 3 months
 - · Having a healed sternum
 - Being asymptomatic and tolerating cardiovascular medications with no orthostatic symptoms
 - Having been examined and approved by a cardiologist for medical fitness to drive
 - At 5 years post-CABG surgery because of the risk of re-occlusion over time, it would be reasonable for the driver to obtain an annual exercise test or an imaging stress test, if indicated
- AND



Cardiovascular – Percutaneous Coronary Intervention

- Key points...
 - A one week recovery period is reasonable to assure that no acute complication occurs at the vascular access site
 - Having no injury to the vascular access site
 - Individuals with stents should have an exercise tolerance test (ETT) every other year
 - Removed recommendation for ETT 3-6 months after (Cardiac MEP 2007)



Obstructive Sleep Apnea

"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.



Obstructive Sleep Apnea

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."

- Notes that high BMI by itself may not be sufficient to order sleep study
 - But may note that extremely high BMI might be
- Asks if multiple risk factors
 - Then lists those from 2016 MRB Recommendations.
 - Includes BMI of 33 and above



Obstructive Sleep Apnea

- Then includes;
 - 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.
 - What will EEOC say?



Disqualify - search

- Use of telescopic lenses is not acceptable
- BP >180/110 Under certify Disqualified
- Having an ICD or ICD/pacemaker combination device is disqualifying in that federal regulation 391.41(b)(4) states that...
- The confirmed diagnosis of hypertrophic cardiomyopathy is disqualifying in that federal regulation 391.41(b)(4) states that...
- A confirmed diagnosis of restrictive cardiomyopathy is disqualifying in that federal regulation 391.41(b)(4) states that...



Disqualify - search

- A driver with moderate aortic stenosis that is asymptomatic and the driver has no disqualifying findings and/or conditions (i.e. angina, heart failure, atrial fibrillation, LV ejection fraction under 40%, thromboembolism)
- Spinal cord injury resulting in paraplegia is disqualifying.
- Being able to tolerate treatment without disqualifying side effects (i.e. sedation or impaired coordination)
- Tolerating treatment without disqualifying side effects such as suicidal behavior or ideation



Concerns

- Very dependent on what training programs teach?
 - Most do NOT teach or even mention content of the MEP/MRB/EBR
- Does not mention content from MEP or EBR on Parkinson's Disease, Multiple Sclerosis, Chronic Kidney Disease, Narcolepsy (not mentioned as disqualifying), Circadian Rhythm Disorders.
- Does not uniformly include;
 - "You should not certify the driver until etiology is confirmed and treatment has been shown to be adequate, effective, safe, and stable"
 - "Not certifying the driver until the medication has been shown to be adequate/effective, safe, and stable"

MRB Meeting Dates and Topics		
Meeting Date	Topic	
July 15 – 16, 2019	Medical Examiner Handbook, Vision and Vision	
	Exemption	
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 -Meeting of the	Driver Health and Wellness Working Group -	
MCSAC-MRB		
Sept. 21-22, 2015 Joint Meeting	Driver Health and Wellness	
with MCSAC		
July 21-22, 2015	Diabetes Mellitus and Vision Standard	
NUMBER OF SECURITY AND ASSESSMENT OF SECURITY ASSESSMENT OF SE		

MRB Meeting Dates and Topics		
Meeting Date	Topic	
October 27, 2014 Joint Meeting	Schedule II Controlled Substances	
with MCSAC		
July 29-30, 2014	Schedule II Controlled Substances	
September 11, 2013	Schedule II Medications	
September 9-10, 2013	Motorcoach Hours of Service; Schedule II	
Joint MCSAC-MRB Meeting	Medications	
February 2013	Bus Driver Fatigue	
October 19, 2012 -	Field of Vision.	
February 6, 2012 MCSAC and MRB	Obstructive Sleep Apnea (OSA)	
January 4-5, 2012 -	Obstructive Sleep Apnea (OSA)	

MRB Meeting Dates and Topics		
Meeting Date	Торіс	
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	

MRB Meeting Dates and Topics		
Meeting Date	Topic	
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, 2007,	Schedule II Medication	
November 1, 2006 -	Diabetes	
18 July 18 18 18 18 18 18 18 18 18 18 18 18 18		



MOC

- FMCSA requires all drivers with a BMI >40 to have a diagnostic sleep study - F
- Examiners are prohibited from requiring drivers to submit their glucose logs - F
- The contents of the proposed ME Handbook should be utilized now F