

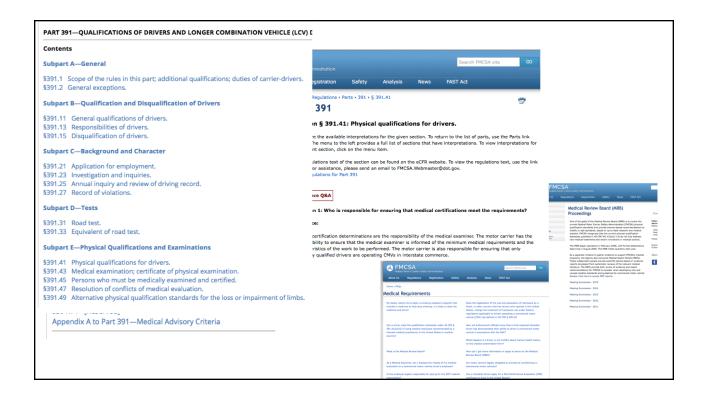
Department of Transportation Update:

Changes in the National Registry of Certified Medical Examiner's (NRCME) Guidelines for Commercial Drivers, Their Employers and Examiners

Natalie P. Hartenbaum, MD, MPH, FACOEM
President and Chief Medical Officer
OccuMedix, Inc.
WCI Annual Conference
August 20, 2018

Topics

- Introduction
- Status of NRCME Website
- Status of Medical Examiner Certification Integration
- VA Medical Examiners
- Medications
 - Drug Testing
- Obstructive Sleep Apnea
- Diabetes and other exemptions
- Other
- Cases with pertinent section



Responsibilities - Guidance Q & A

- 391.41 Question 1: Who is responsible for ensuring that medical certifications meet the requirements?
- Guidance:
- Medical certification determinations are the responsibility of the medical examiner.
 - Must understand difference between regulation (must) and guidance (may)
 - · Medical examiner is expected to use established best medical practice
 - Must consider driving and non-driving tasks

Responsibilities - Guidance Q & A

- 391.41 Question 1: Who is responsible for ensuring that medical certifications meet the requirements?
- Guidance:
- b. The motor carrier has the responsibility to ensure that the medical examiner is informed of the minimum medical requirements and the characteristics of the work to be performed.
 - · Minimal medical requirements taught through NRCME
 - Certification not limited to current position

Responsibilities - Guidance Q & A

- 391.41 Question 1: Who is responsible for ensuring that medical certifications meet the requirements?
- Guidance:
- c. The motor carrier is also responsible for ensuring that only medically qualified drivers are operating CMVs in interstate commerce.
 - ONLY required to maintain copy of MEC (currently)
 - · Not required to have MER
 - If you do, know what you are looking at
 - · May only perform CMV operations if able to meet FMCSRs
 - No restrictions

Responsibilities - Guidance Q & A

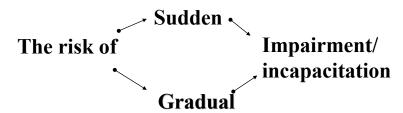
- 391.45 Question 3: Must a driver who is returning from an illness or injury undergo a medical examination even if his current medical certificate has not expired?
- Guidance:
 - · Examination not required
 - Unless injury or illness has impaired the driver's ability to perform his/her normal duties
 - However, the motor carrier may require a driver returning from any illness or injury to take a physical examination
 - Motor carrier has the obligation to determine if an injury or illness renders the driver medically unqualified.

Responsibilities - Guidance Q & A

- Question 4: May the medical examiner restrict a driver's duties?
- Guidance:
- No.
- Only conditions involve the use of corrective lenses or hearing aids, securement of a waiver or limitation of driving to exempt intracity zones
- A medical examiner who believes a driver has a condition not specified in §391.41 that would affect his ability to operate a CMV safely should refuse to sign the examiner's certificate.

Fitness for Duty Examination

Concern:



<u>From ME Handbook - Wh</u>en you determine that a driver is medically fit to drive and also able to perform non-driving responsibilities, you will certify the driver and issue a Medical Examiner's Certificate.

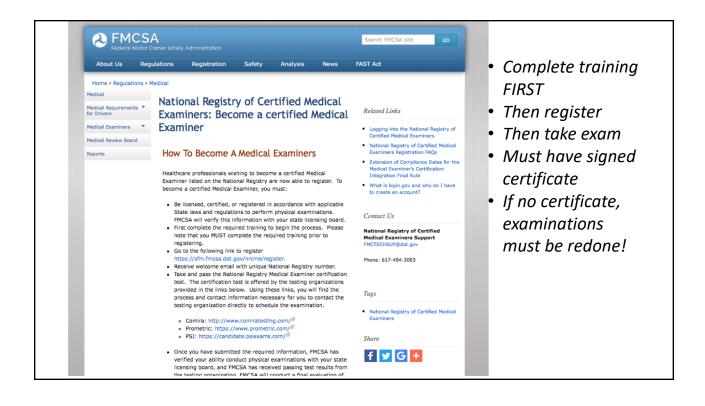
"Ability of the driver to operate a CMV safely"

- Both driving and non-driving tasks
- Examiner cannot place restrictions
 - No restrictions- driving nor non-driving tasks
 - Variances
- Concern is risk sudden or gradual impairment or incapacitation
 - Over the duration of certification

To determine that must have medical training to understand the diagnosis, treatment and prognosis of the medical conditions you are evaluating. Goes well beyond the NRCME training.(IMHO)

- Hacked in December 2017
- Ability to search for examiners restored first
- Then ability to add new examiners (new process)
- Examiner portal partially restored
- Examiners can upload determinations
 - Not yet for TPOs and MEAAs
- Glitches in system
- "Must" submit determinations by midnight following calendar day
- Will be adequate time to submit backlog





NRCME2 – Medical Examiner Certification Integration – Interim Final Rule

- Many state CDLIS not ready to receive feed from NRCME
- Examiners
 - Continue to issue paper medical examiner certificates through 2021
 - Never change for drivers without CDL issue paper certificates
 - · No delay in determination upload requirement
- CLP/CDL Applicants/Holders:
 - Provide copy of MEC to SDLA
 - Continue to carry MEC as proof of medical certification for the first 15 days
- Motor Carriers:
 - · Continue to verify examiner on NRCME
- Delay until June 22, 2021

NRCME Update – Refresher Training

- · Refresher training
 - 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.
 - No sooner than 9 years and no later than 10 years after the date of issuance of the medical examiner certification credential complete periodic retraining and pass the test required
- Only training offered by FMCSA will be acceptable
- No fee, no CME
- Not yet ready, will have adequate time to update
- Will be based on most frequent questions/issues

Adding VA Physicians* to NRCME

Qualified VA examiner means an advanced practice nurse, doctor of chiropractic, doctor of medicine, doctor of osteopathy, physician assistant, or other medical professional who is employed in the Department of Veterans Affairs; is licensed, certified, or registered in a State to perform physical examinations;

- · 390.123 Medical examiner certification for qualified Department of Veterans Affairs examiners.
- · 390.125 Qualified VA examiner certification training.
- · 390.127 Qualified VA examiner certification testing.
- 390.129 Issuance of the FMCSA medical examiner certification credential.
- 390.131 Requirements for continued listing of a certified VA medical examiner on the National Registry of Certified Medical Examiners.
- 390.133 Reasons for removal of a certified VA medical examiner from the National Registry of Certified Medical Examiners.
- 390.135 Procedure for removal of a certified VA medical examiner from the National Registry of Certified Medical Examiners.

Adding VA Physicians to NRCME

- VA examiner must complete training and pass examiner certification test
 - Developed/provided by FMCSA
 - Delivered through a web-based system operated by the Department of Veterans Affairs
- Once no longer employed by the VA, if the examiner wishes to conduct examinations
 - Must notify FMCSA within 30 days
 - Continue to meet requirements of 391.111
 - · No additional training or testing required

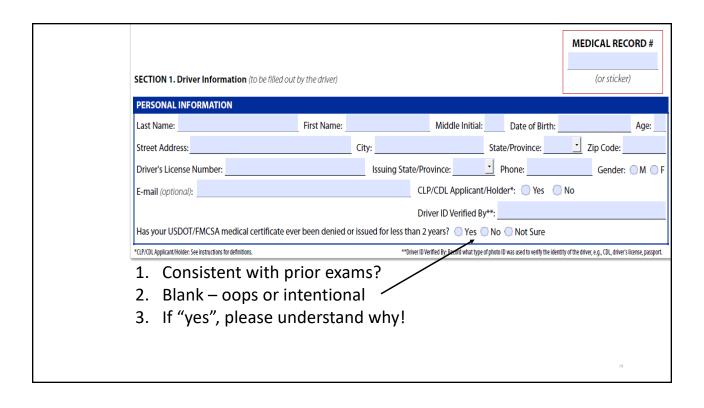
Adding VA Physicians to NRCME

- ONLY for veterans in VA Health System
 - Not family members will be system to monitor
- Training and testing yet to be developed
- May be some time until implemented
- Will be closely monitored by VA system

Medical Examination Report Form, MCSA-5875

- 1. Review old forms if available
- Can obtain medical records if new examinee (FMCSA – AOHC 2018)

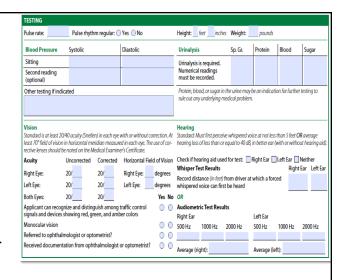




Driver Health History | Some the Market Science plants in the last last as the last as th

Testing

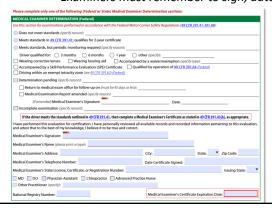
- Can note BMI, NC, etc
- Blood pressure GUIDANCE still exists
- Not required to enter uncorrected vision if wearing contacts.

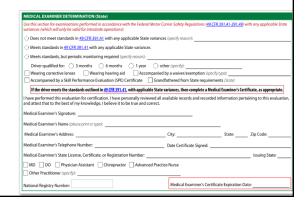


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Medical Examiner Determination Federal /State – PICK ONE

- Driver must TRULY be INTRAstate
- Examiner must know INTRAstate requirements for state where driver licensed
- · Not to be used as restriction
- · No determination pending on state
- Examiners must remember to sign, date and enter NR number





INTRASTATE-MEDICAL-VARIANCES¶						
State S	Intrastate Medical variance?	SDLA Contact information	Medical Conditions / Forms			
Alabama¤	Maybe¤	Alabama-Deptof-Public Safety¶ cdlmedicalmerger@dps.alabama.gov¤	"W-restriction-for-Alabama-issued-Medical-Waiver"??¤			
Alaska-¤	YES¤	Alaska-Department of Administration¶ Division of Motor Vehicles¶ doa.dmv.ads@alaska.gov¶ 907-428-1333¤	Vision♯			
Arizona¤	YES¤	Arizona Department of Transportation ¶ Motor Vehicle Services ¶ Medical Review Program ¶ MedicalReview@azdot.gov¤	Vision, Limb Impairment/Amputation, Diabetes¶ Intrastate variances - https://azdot.gov/mvd/driver-services/commercial-driver-license/MedicalReview/intrastate-waivers¤			
Arkansas¤	NO¤	Arkansas Dept. of Finance (dfa.arkansas.gov) ¶ 501-682-7100	н			
California¤	YES¤	California-Department of Motor-Vehicles¶ dmv.ca.gov¶	No formal variances but case by case. IF-DQ under- Federal, driver may submit to CA-DMV who review- for Intrastate:			

https://drive.google.com/open?id=0B0G2yEkESk2QWGhucGZmdVNSNUk

Determination Pending, DQ, Short Certification

- What are the implications for employer and driver
 - Current employee or new hire
 - Off the road or able to continue work/hire
 - Do they have current valid medical certificate
 - When does it expire
 - Cost of new examination/time
 - How long for information to be obtained
 - must submit determination by midnight following calendar day
 - Most recent certificate takes priority

Disqualification

- Driver has not completed appropriate waiting period
- Temporary/Long term condition which disqualifies
- Driver OFF the road NOW!
 - New determination takes precedence
 - More than one employer?
- New examination needed, can't update
- Driver does not meet medical criteria? Unsafe?
 Need/want more information

Short Certificate

- New hire some companies ok with 3 months, others not
- Is driver "safe" for duration of new certificate
- Needs new examination (can't update/amend)
- How long to obtain information
- No specific limit to the number of successive shortened medical examiner certificates, if examiner believes appropriate

Determination Pending

- May drive ONLY if current valid medical certificate
 - Can give less than 45 days
- Must enter 5850 report Determination Pending
- Do NOT issue MEC
- ONLY situation where examination can be "amended (updated)"
- Examination can be amended by different examiner in same office
 - · Must have and review original exam and all information
 - Submits new 5850
- Does examiner need/want more information, believes driver safe

Incomplete

- Driver can stop exam at any time
 - Examiner reports incomplete examination even if only blood pressure checked
- NOT for when examination is completed but attempt to avoid determination
- NOT because examiner waiting for information
- FMCSA maintains incomplete examination information

FMCSA will review when two or more conflicting certifications submitted

IMHO – Do not discuss determination or duration until examination complete IMHO – If driver presents for/has authorization for examination – DO IT!

*scope of practice may require termination of examination

Stages of CKD

Stage	Description	GFR ml/min/1.73m ²	Symptoms and signs*
1	Kidney damage with normal or increased GFR	>=90	BP +/-
2	Kidney damage with mild GFR fall	60-89	BP Lab +/-
3	Moderate fall in GFR	30-59	BP Lab + Symptoms +/-
4	Severe fall in GFR	15-29	BP Lab +++ Symptoms +
5	Established renal failure	<15 or dialysis	BP Lab +++ Symptoms ++

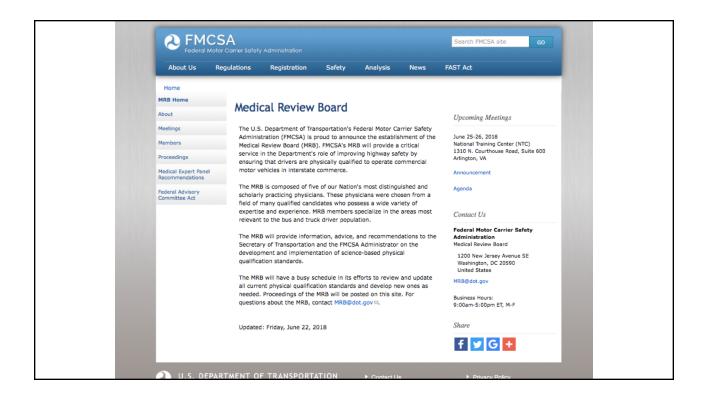
Exemptions

Vision, Insulin, seizure, Hearing

- Drivers Grandfathered into Waiver Program
 - Still about 107 drivers in the diabetes and 2,120 in the vision waiver programs
 - Will have old letter from FMCSA Examiner should review, if question authenticity, contact FMCSA
- Medical certification for drivers in waiver ("by operation of 49 CFR 391.64") or exemption programs should only be certified for only 1 year
 - Waivers/exemptions are good for 2 years, but the medical certification should only be for 1 year

Exemptions

- Insulin Exemption
 - Final Rule on eliminating the insulin exemption and moving the determination to the examiners is one step from publication.
 - Questionnaire for completion by treating clinician
 - Examiner will make qualification determination
- Vision Exemption elimination coming soon?



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 -Meeting of the MCSAC-MRB	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	Motorcoach Hours of Service; Schedule II Medications			
Joint MCSAC-MRB Meeting				
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	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, 2007,	Schedule II Medication			
November 1, 2006 -	Diabetes			

Medications

- No list of prohibited medications aside from;
 - Anti-seizure medication for control of seizures
 - Insulin Drivers can apply for exemption
 - Schedule 1 substances
- Methadone ? FAQs prohibited, Not in REGULATION in Appendix A
- Examiners and motor carriers encouraged to obtain practitioner's written statement
 - But are not required to accept statement of treating provider
- Optional Medication Form

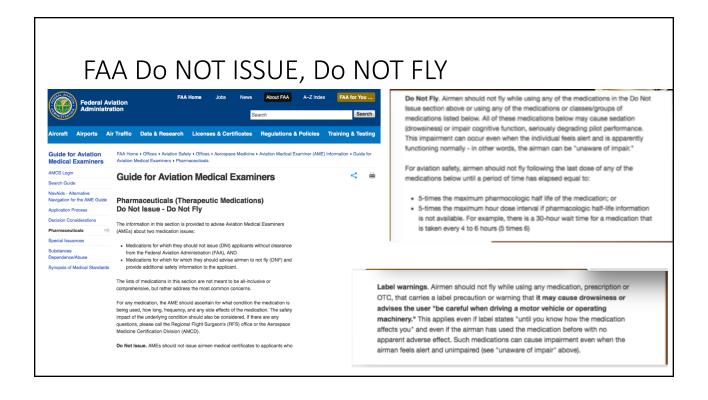
But, just because a medication is not prohibited does not mean it is safe

	391.41 CMV DRIVER MEDICATION FORM		
	Driver Name:	DOB:	
FMCSA Federal Motor Corner Safety Administration About Us Regulations Registration Safety Analysis News FAST tome > Regulations > Medical	Carrier Safety Administration (FMCSA) to operate the medical evaluation, it was determined this indiv operate a CMV. As the certified Medical Examin complete this form, and return it to me at the mailin	nine whether he/she meets the medical standards of the Federal Motor a commercial motor vehicle (CMV) in interstate commerce. During idual is taking medication(s) that may impair his/her ability to safely ser (ME), I request that you review the regulations as noted below, ng address, email address, or fax number specified below. The final this form is physically qualified to drive a CMV will be made by the	
Scal Beachiners Scal Beachiner	49 CFR 391.41, Physical Qualifications for Drivers: A poes not use any drug or substance identified in 21 CF forming drug, (ii) Does not use any non-Schedule I dru except when the use is prescribed by a licensed medical medical history and has advised the driver that the sub CMV. 1. List all medications and dosages that you have possible to the provider of the provider. 2. List any other medications and dosages that you a another treating health care provider. 3. What medical conditions are being treated with the description of the provider of the	nese medications? Intal and physical requirements of operating a CMV and with h "The Driver's Role" statement on page 2), my patient:	
	operate a CMV; and	n(s) that I prescribe that would adversely affect the ability to safely with the above medication(s) that would adversely affect the ability $_{Page\ l\ of\ 2}$	

Medication Recommendations (NOT from FMCSA)

- MRB/MCSAC
 - Recommendations: The MRB and MCSAC believe that a driver should not be qualified medically to operate a CMV while he/she is under treatment with narcotics or any narcotic derivative without exception.
 - While permitted he/she must not use the narcotic for a minimum of 8 hours (if using short-acting narcotics) or 12 hours (if using longacting narcotics) before resuming safety-sensitive duties
- ACOEM
 - Acute or chronic opioid use is not recommended for patients who perform safety-sensitive jobs.
- FAA Do not Issue/ Do Not Fly list

NOT ADOPTED BY FMCSA



Chantix - New FAQ

My doctor wants me to begin a smoking cessation program that includes a medicine to help stop smoking, is it okay to start the medicine and drive?

- The Federal Motor Carrier Safety Regulations (FMCSRs) does not include a list of prohibited medications.
- The Agency relies on the certifying medical examiner to evaluate and determine whether an underlying medical condition, medication, or combination of medications and substances used by an individual driver will impair his or her ability to safely operate a commercial motor vehicle (CMV).

Chantix - New FAQ

- Medical Examiners may disqualify a driver who takes any medication or combination of medications and substances that may impair or interfere with safe driving practices.
- All medications must be assessed to determine the potential risk of adverse side effects, which include but are not limited to: dizziness, drowsiness, and sleepiness, and the direct impact the potential side effects have on CMV driving and operation safety.

Chantix - New FAQ

- The medical examiner may confer with the treating medical specialist(s) who
 is familiar with the driver's health history.
- The final decision to certify the driver rests with the certifying medical examiner.
- The certifying medical examiner may consider utilizing the optional medication form when communicating with the treating prescribing clinician.
- This is applicable to ALL medications

Marijuana - New FAQs - 10/23/17

- Reminds examiners that Schedule I substances, including marijuana are not permitted
- Driver may not use marijuana even if is recommended
- Legalization of marijuana use by States and other jurisdictions - no change in DOT drug testing regulations
 - Dronabinol is not a Schedule I (Schedule III)
 - Epidiolex Cannabidiol approved for resistant seizures

Driver Advised to Use CBD Oil

- Purchased from internet and listed as THC free
- What would employer advise?
- What will examiner do if listed under OTC meds
- What about MRO if THC positive

CBD OIL (Cannabidiol) AND COMMERCIAL DRIVERS

- Use of CBD oil prohibited in CMV operators
- CBD extract Schedule I drug under the Controlled Substances Act
- CBD is distinguishable from THCA
 - Other cannabinoids, including THC, may be found in CBD products
 - Multiple FDA memos
- Memo on CBD products from SAMHSA recently sent to MROs and others.

(Revised) Mandatory Guidelines for Federal Workplace Drug Testing Programs - highlights

Substance Abuse and Mental Health Services Administration January 23, 2017

- <u>Allows</u> federal executive branch agencies;
 - Test for additional Schedule II drugs
 - To authorize collection of an alternate specimen (e.g., oral fluid) when donor unable to provide a sufficient urine
 - MROS to have routine request D,L stereoisomers of amphetamine and methamphetamine
- Does Not allow MRO to have routine request for additional opioids – nor-hydrocodone or nor nor-oxyxodone or THC-V

Final Rule: Procedures for Transportation Workplace Drug and Alcohol Testing Programs Changes

November 13, 2017

- · Testing for four semi-synthetic opioids
- Stop testing for MDEA, add MDA as initial analyte
- Eliminate blind specimen testing
- Add three more fatal flaws to the list of reasons when a laboratory would report a 'rejected for testing' specimen
- MROs have authority to conduct D,L stereoisomer and THC-V testing
- Timing for communicating significant safety risk has been modified
- · Process for verifying prescription specified
- Term Prescription clarified

What is a Legally Valid Prescription?

- Prescription must be "consistent" with Controlled Substances Act (CSA)
 - "A prescription is an order for medication which is dispensed to or for an ultimate user." (DOJ/DEA – Diversion Control)
- Prescription Requirements In order for a prescription to be valid, it must be;
 - Issued for a legitimate medical purpose
 - In the usual course of professional practice by a practitioner
 - Who has conducted at least one in-person medical evaluation of the patient or by a covering practitioner

What is a Legally Valid Prescription - DOT?

- Used for reason dispensed?
 - Not role of MRO (maybe)
- Appropriately prescribed or appropriate dose?
 - Not role of MRO
- How old is too old
 - Confusing

Prescriptions - How Old is Too Old?

- DEA does not have specifics
 - State may limit how old to fill/refill
- DOT silent (ish)
 - No "bright-line"
 - "MROs are highly qualified individuals who Part 40 requires to make judgment calls.
 - MROs must take into account differences in medications, and other case-specific factors".
- HHS Medical Review Officer Guidance Manual 2017

DHHS - Medical Review Officer Guidance Manual – 2017

Legitimate Use

MRO may consider;

"whether a medication was used during the time period for which it was legitimately prescribed.

If a donor's use was not medically authorized, the specimen will be reported as positive"



Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs

Part 40.135 - What does the MRO tell the employee at the beginning of the verification interview?

You must also advise the employee that, before informing any third party about any <u>medication</u> the employee is using pursuant to a legally valid prescription consistent with the Controlled Substances Act, you will allow 5 business days from the date you **report** the verified negative result for the employee to have the prescribing **physician** contact you to **determine**

if the medication can be changed to one that does not make the employee medically unqualified or does not pose a significant safety risk.

If, in your reasonable medical judgment, a medical qualification issue or a significant safety risk remains after you communicate with the employee's prescribing physician or after 5 business days, whichever is shorter, you must follow § 40.327. If, as the MRO, you receive information that eliminates the medical qualification issue or significant safety risk, you must transmit this information to any third party to whom you previously provided information under § 40.327.

Safety Concern - Employee Notice

"As of January 1, 2018, prior to the MRO reporting your information to a third party you will have up to five days to have your prescribing physician contact the MRO. You are responsible for facilitating the contact between the MRO and your prescribing physician.

Your prescribing physician should be willing to state to the MRO that you can safely perform your safety-sensitive functions while taking the medication(s), or consider changing your medication to one that does not make you medically unqualified or does not pose a significant safety risk."

Safety Concern - Thoughts

- 5 day pause for medication NOT medical conditions
 - What about ADD/ADHD and amphetamine
 - What about chronic pain and opioids
- Likely to discontinue or change
 - How long has individual been on medication (or similar)
 - What is it treating?

MRO /Examiner Role in Fitness for Duty

- Now more blurred
 - Except NRC
- MRO is not required to accept statement of provider that safe (but many will)
- Examiner is not required to accept statement that driver safe (but many will)
- What if one says yes and other no?
- Let the lawyers decide?
- Medical Marijuana (not dronabinol) is still not permitted

Employer Questions???? Discussion

For the test results showing opiates use on a legal prescription but with MRO safety concerns which remain unresolved, this appears to be a disqualifying test result even though listed as negative.

- Should follow up testing be done to verify no longer taking
- Fall under random or post-accident?
- · What if changed to different medication?
 - Should follow up testing be done?
 - · What if another safety concern

PDMPs and MRO / Examiners

- What is a PDMP
 - PDMPs serve multiple functions, including: patient care tool; drug epidemic early warning system; and drug diversion and insurance fraud investigative tool.
 - They help prescribers avoid drug interactions and identify drug-seeking behaviors or "doctor shopping."
 - PDMPs can also be used by professional licensing boards to identify clinicians with patterns of inappropriate prescribing and dispensing, and to assist law enforcement in cases of controlled substance diversion.

Office of National Drug Control Policy

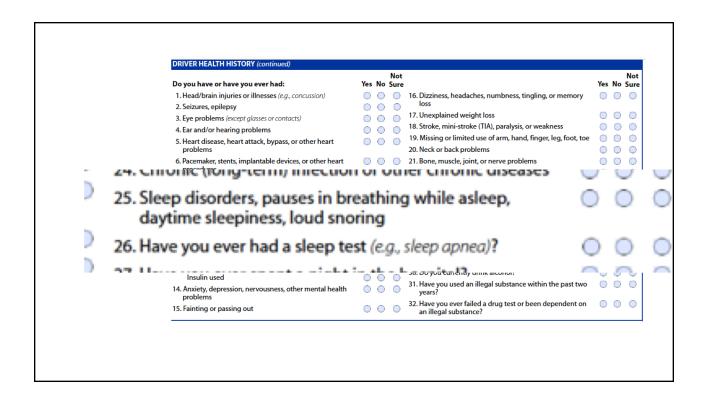
PDMPs and MRO / Examiners

Office of National Drug Control Policy

- "Protecting patient privacy is of the utmost importance.
- PDMPs ensure protection of patient information just as well as, if not better than, any other medical record.
- Law enforcement may not access patient-specific PDMP data unless they have an active investigation, and healthcare providers can access only the PDMP data relevant to their patients. "

PDMPs and MRO/ Examiners

- Read state laws carefully on who may access PDMP
 - California PDMP MUST NOT be used for any pre-employment or other evaluation, specifically including CDL. It is explicitly and exclusively for providers engaged in the treatment of patients. Criminal charges are cited as a possibility.
 - New York —information only used in relation to treatment of a person or dispensing of a controlled substance to a person who comes before the practitioner, pharmacist or designator in his or her professional capacity
 - Pennsylvania If prescribers improperly use the system, including knowingly or intentionally obtaining information for purposes other than for treatment or dispensation of controlled substances, they are subject to civil and/or criminal penal- ties. Failure to comply with the mandates set forth in Act 191 of 2014 could result in disciplinary action against one's professional license. Disciplinary actions of professional licenses fall under the purview of the Department of State."



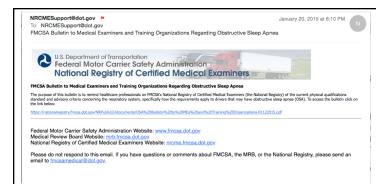
OSA Screening Recommendations/Rulemaking Cliff Notes Version

- Joint Task Force
 - BMI >35 AND neck circumference or HTN
- 2008 MEP BMI 33
- 2008 MRB BMI 30
- April 2012 Proposed Recommendations on Obstructive Sleep Apnea - Request for Comments

OSA Screening Recommendations/Rulemaking Cliff Notes Version

- Public Law 113–45. OCT. 15, 2013.
- 2016 MRB BMI 40 or 33-39 and 3 or more of other risk factors
- March 2016 ANPRM (FRA and FMCSA) Request for Comments
- August 2017 ANPRM withdrawn





2015 FMCSA – Do something

Plan to update the 2015

Bulletin to Examiners by end
of 2018

FMCSA Bulletin to Medical Examiners and Training Organizations Regarding Obstructive Sleep Apnea

The purpose of this bulletin is to remind healthcare professionals on FMCSA's National Registry of Certified Medical Examiners (the National Registry) of the current physical qualifications standard and advisory criteria concerning the respiratory system, specifically how the requirements apply to drivers that may have obstructive sleep apnea (OSA).

Current Physical Qualifications Standard for Respiratory Conditions

FMCSA's physical qualifications standards prohibit individuals from receiving a medical examiner's certificate to operate commercial motor vehicles in interstate commerce if they have an "established medical history or clinical diagnosis of a respiratory dysfunction likely

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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 Recommendation on OSA MRB Task 16-1 - October 2016

- Drivers with a BMI > 40 90 day conditional certification
 - Referred for sleep studies and treatment if indicated.
- Drivers should be immediately disqualified
 - Excessive fatigue or sleepiness while driving
 - Been in a sleep-related crash
 - Non-compliant with treatment.

https://www.fmcsa.dot.gov/advisory-committees/mcsac/mrb-task-16-01-letter-report

MRB Recommendation on OSA Task 16-1 - October 2016

Conditional certification - BMI 33 to 39 and 3 of following 11 risk factors;

- 1. Hypertension (treated/ untreated)
- 2. Type 2 diabetes (treated/ untreated)
- 3. Neck size male > 17 inches or female >15.5 inches
- 4. A history of stroke, CAD or arrhythmias
- 5. Loud snoring

- 6. Micrognathia or retrognathia
- 7. Witnessed apnea symptoms
- 8. Hypothyroidism
- 9. Age 42 or older
- 10. Male or post-menopausal female
- 11. Mallampati Scale score of class 3 or 4

Management of Obstructive Sleep Apnea in Commercial Motor Vehicle Operators: Recommendations of the AASM Sleep and Transportation Safety Awareness Task Force,

Primary Criteria for Evaluation by a Sleep Medicine Specialist

- 1. BMI \geq 40 kg/m2 or
- 2. BMI ≥ 33 kg/m2 and either
 - a. Hypertension requiring ≥ 2 medications for control or
 - b. Type 2 diabetes
- 3. Sleepiness-related crash or accident, off-road deviation, or rear-ending another vehicle by report or observation
- 4. Fatigue or sleepiness during the duty period

Management of Obstructive Sleep Apnea in Commercial Motor Vehicle Operators: Recommendations of the AASM Sleep and Transportation Safety Awareness Task Force

Secondary Criteria for Evaluation by a Sleep Medicine Specialist

- 1. Symptoms of OSA, which include but are not limited to:
 - Loud, habitual snoring
 - Witnessed apneas
 - Sleepiness during the major wake period*

Management of Obstructive Sleep Apnea in Commercial Motor Vehicle Operators: Recommendations of the AASM Sleep and Transportation Safety Awareness Task Force

- 2. BMI 28-33 kg/m2 with any of the following risk factors of OSA**
- · Small or recessed jaw
- Small airway (modified Mallampati classification of 3 or 4)
- Neck size ≥ 17 inches (men), ≥
 15.5 inches (women)
- Hypertension (especially if resistant)
- Type 2 diabetes, particularly if accompanied by obesity
- Cardiovascular disease
- Hypothyroidism (untreated)
- Age 42 years or older
- Family history of OSA
- Male, or postmenopausal female

- ME Handbook first posted in 2008
- Provided guidance MEs.
- MEs and stakeholders have have applied information as if regulation
- Removed from website in 2015.
- MEs should make physical qualification determinations on a case by case basis
- Revised MEH to be used in conjunction established best medical practices to make determination



Federal Motor Carrier Safety Administration (FMCSA)

Medical Examiner Handbook



ME Handbook - MRB Task 17-1 MRB Meeting 6/25-26/2018

III. <u>Task</u>

 The Agency tasks the MRB with reviewing and streamlining the MEH. This includes the removal of nonregulatory directive language and the update and removal of obsolete information.

ME Handbook MRB Meeting 6/25-26/2018

- Remove directive guidance
- Can guidance be included at all?
 - MEP recommendations, MRB recommendations, Evidence based reviews
 - If not included, can each section link to relevant "resources"?
 - If not included, can each section link to all MRB related documents
 - Will be easy to access chart of meeting topics
 - What about Waiting Period, Recommend to Disqualify, etc.
 - · Ok if aligned with medical advisory criteria

ME Handbook MRB Meeting 6/25-26/2018

- Remind examiners that once certified, driver can do any task
 - Certification not current position specific
- Training organizations SHOULD teach OPTIONAL resources of established best practice
- Intent to remove all medical education from handbook
 - Assume that LHCP, licensed by their state to perform physical examinations know how to do so.
 - Assume that LHCP know how to evaluate medical findings and diagnosis

ME Handbook MRB Meeting 6/25-26/2018

- Examiners SHOULD use established best medical practice and stay current
 - Documentation and decision making
- Bottom line understand what is regulation (must) vs guidance (may)
- Communicate accurately to driver and employer

IMHO

- We created this problem
- This is not a cookbook exam
- "MEs make physical qualification determinations on a case by case basis."
- Examiners MUST stay current with "established best medical practices."

Resources

- NRCME
 - https://www.fmcsa.dot.gov/regulations/medical/national-registry-certified-medicalexaminers
- FMCSA Medical Programs website
 - https://www.fmcsa.dot.gov/regulations/medical
- MRB Task 16-1 Recommendations on OSA
 - https://www.fmcsa.dot.gov/advisory-committees/mcsac/mrb-task-16-01-letter-report
- FMCSA Optional Medication Form
 - https://www.fmcsa.dot.gov/regulations/medical/39141-cmv-driver-medication-form-mcsa-5895-optional
- Federal Aviation Administration Do Not Issue/Do Not Fly
 - https://www.faa.gov/about/office org/headquarters offices/avs/offices/aam/ame/guide/ph arm/dni dnf/

Resources

- Mandatory Guidelines for Federal Workplace Drug Testing Programs
 Substance Abuse and Mental Health Services Administration January 23, 2017
 - https://www.gpo.gov/fdsys/pkg/FR-2017-01-23/pdf/2017-00979.pdf
- Final Rule: Procedures for Transportation Workplace Drug and Alcohol Testing Programs Changes. November 13, 2017
 - https://www.gpo.gov/fdsys/pkg/FR-2017-11-13/pdf/2017-24397.pdf
- Office of Drug & Alcohol Policy & Compliance List serve Notices
 - https://www.transportation.gov/odapc/ListServe Notices
- Department of Health and Human Services MRO Guidance Manual
 - https://www.samhsa.gov/sites/default/files/workplace/mro-guidance-manualoct2017 2.pdf