The expanding role of the MRO
Opportunity or slippery slope?
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The views expressed in this presentation are my own and do not necessarily reflect those of my employer nor the various agencies involved in drug testing regulations or ACOEM.

I have no known conflicts of interest.
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What are the current responsibilities of MROs in DOT programs

- For the DOT including FMCSA
- 49 CFR Part 40
- Subpart G
- 40.123
What are the current responsibilities of MROs in DOT programs

- You must determine whether there is a legitimate medical explanation for confirmed positive, adulterated, substituted, and invalid drug tests results from the laboratory.
- This is the third responsibility on a list of 8 responsibilities for MRO.
- Tends to be the one most frequently done.
What are the current responsibilities of MROs in DOT programs

- Can you name the first listed responsibility of the MRO?
What are the current responsibilities of MROs in DOT programs

- Acting as an independent and impartial “gatekeeper” and advocate for the accuracy and integrity of the drug testing process.
Be sure that the person you are dealing with is indeed the ONE person you want to be dealing with.
What are the current responsibilities of MROs in DOT programs

- The remaining responsibilities
What are the current responsibilities of MROs in DOT programs

- Providing a quality assurance review of the drug testing process for the specimens under your purview. This includes, but is not limited to:
What are the current responsibilities of MROs in DOT programs

1) Ensuring the review of the CCF on all specimen collections for the purposes of determining whether there is a problem that may cause a test to be cancelled (see §§40.199–40.203). As an MRO, you are not required to review laboratory internal chain of custody documentation. No one is permitted to cancel a test because you have not reviewed this documentation;
(2) Providing feedback to employers, collection sites and laboratories regarding performance issues where necessary.
Current Responsibilities

- (3) Reporting to and consulting with the ODAPC or a relevant DOT agency when you wish DOT assistance in resolving any program issue. As an employer or service agent, you are prohibited from limiting or attempting to limit the MRO's access to DOT for this purpose and from retaliating in any way against an MRO for discussing drug testing issues with DOT.
What are the current responsibilities of MROs in DOT programs

- While you provide medical review of employees' test results, this part does not deem that you have established a doctor-patient relationship with the employees whose tests you review.
- You must act to investigate and correct problems where possible and notify appropriate parties (e.g., HHS, DOT, employers, service agents) where assistance is needed, (e.g., cancelled or problematic tests, incorrect results, problems with blind specimens).
What are the current responsibilities of MROs in DOT programs

- You must ensure the timely flow of test results and other information to employers.
- You must protect the confidentiality of the drug testing information.
- You must perform all your functions in compliance with this part and other DOT agency regulations.
One has gained some attention recently

- Timely flow of test results and other information to employers
- MRO newsletter in Spring 09 had an article on what to tell the employer and the potential pitfalls if that information is misused.
- DOT says need to tell about other medical issues that cause significant risk to public safety
(a) As the MRO, you must, except as provided in paragraph (c) of this section, report drug test results and medical information you learned as part of the verification process to third parties without the employee's consent if you determine, in your reasonable medical judgment, that:
(1) The information is likely to result in the employee being determined to be medically unqualified under an applicable DOT agency regulation.
(2) The information indicates that continued performance by the employee of his or her safety-sensitive function is likely to pose a significant safety risk.

(b) The third parties to whom you are authorized to provide information by this section include the employer, a physician or other health care provider responsible for determining the medical qualifications of the employee under an applicable DOT agency safety regulation, a SAP evaluating the employee as part of the return to duty process (see §40.293(g)), a DOT agency, or the National Transportation Safety Board in the course of an accident investigation.

(c) If the law of a foreign country (e.g., Canada) prohibits you from providing medical information to the employer, you may comply with that prohibition.
The FHWA expects MROs to properly investigate the facts concerning a CMV driver’s claim that a positive controlled substance test result was caused by a prescription written by a knowledgeable, licensed medical practitioner or the use of an over-the-counter substance that was obtained in a foreign country without a prescription. This investigation should be documented in the MRO’s files.

If the CMV driver lawfully obtained a substance in a foreign country without a prescription which is a controlled substance in the United States, the MRO must also investigate whether a knowledgeable, licensed medical practitioner provided instructions to the CMV driver that the use of the “over-the-counter” substance would not affect the driver’s ability to safely operate a CMV.
In the course of an interview for a non-negative test a medication may come up as being taken that presents a significant safety risk.

This may be the explanation for the positive test or it may be another medication with significant safety risks.
Significant safety risk

- Listed in Schedule I

- Schedule II drugs have to be looked at closely
Significant safety risk

- Many medications are listed in the PDR as having side effects that can cause drowsiness or other side effects impacting safety.
- The MRO has to decide which are “significant”
Results consistent with legitimate drug use. If the MRO determines that there is a legitimate medical explanation for a positive confirmatory drug test result, and that the use of a drug identified through testing was in the manner and at the dosage prescribed, and the results do not reflect a lack of reliability or trustworthiness, then the donor has not violated the licensee's or other entity's FFD policy. The MRO shall report to the licensee or other entity that no FFD policy violation has occurred. The MRO shall further evaluate the positive confirmatory test result and medical explanation to determine whether use of the drug and/or the medical condition poses a potential risk to public health and safety as a result of the individual being impaired while on duty. If the MRO determines that such a risk exists, he or she shall ensure that a determination of fitness is performed.
Hints from other programs

In the latest revision to the Guidelines, dated November 25, 2008 (73 FR 71858 with an effective date of May 1, 2010), the new regulations will permit the certification of Instrumented Initial Test Facilities (IITF) and will expand the drug testing profile to include new drug analytes: methylenedioxymethamphetamine (MDMA) commonly known as "ecstasy," methylenedioxyamphetamine (MDA), and methylenedioxyethylamphetamine (MDEA) which are close chemical analogues of MDMA.
Tests that result in findings of adulteration and substitution require review by a qualified MRO. The employee will also be offered the opportunity to have the split specimen tested. The MRO must follow the same procedures for verification of a confirmed positive drug test including providing an explanation of the laboratory finding, addressing technical questions raised by the employee, and offering the employee the opportunity to present a legitimate medical explanation for the laboratory result. The employee has the burden of proof and must demonstrate that the adulterant entered the specimen through physiological means. The same burden of proof and demonstration requirement must be met for substituted specimens as well. [40.215]

The MRO has full discretion in the use of his/her professional judgment to determine a legitimate medical explanation for an adulterated or substituted specimen. If a reasonable explanation may exist, the MRO must direct the employee to have a medical evaluation by a “referral physician” that has expertise in the medical issues raised. The employee must also demonstrate in a controlled environment how the results were possible. The final determination of whether there is a legitimate medical explanation is that of the MRO. [40.215]

(2001)
Amendments to Part 40

- Return to duty testing
- MRO needs to help advise employer
From the FTA Drug and Alcohol Regulation Update Winter 2009

Further similar in Spring 2009
To meet the NTSB expectation, the FTA must develop a standardized methodology to collect the information on the role that Rx/OTC medications play in transit industry fatal accidents and establish a meaningful way to analyze and report the findings. As a first step in this effort, FTA is currently undertaking a study to assess the current status of Rx/OTC policies within the transit industry and to determine the extent to which transit systems collect and maintain data regarding the role Rx/OTC medications play in fatal accidents. As part of this effort, each transit system is requested to complete two online questionnaires. The first questionnaire solicits information
The first questionnaire solicits information regarding your transit system’s accident investigation procedures, data collection methodologies, and methods used to determine the role Rx/OTC medications play in accidents. This questionnaire is designed to obtain preliminary data from a wide array of transit systems. This form should be completed by the person within your organization that addresses safety, risk management or accident investigations. Follow-up interviews will be conducted with a select group of transit systems. You can complete this questionnaire by going to http://transitsafety.volpe.dot.gov/survey1
The second questionnaire solicits information regarding your transit system’s Rx/OTC policy. This form should be completed by your Drug and Alcohol Program Manager, medical personnel or the person who addresses employee fitness-for-duty issues. The information obtained from this questionnaire will be used to update the Prescription and Over-the-Counter Medication Toolkit. You can complete this questionnaire by going to http://transit-safety.volpe.dot.gov/survey2.
Clues

- “Strike Force” focused on school bus drivers this past fall
- Increasing comments on the “distracted” driver
A challenge that might provide a clue to future change

- Timely flow...
- (a particular company’s) MRO reviews the results of the drug screening within two hours of receiving them, consults with the donor candidate when necessary, and the results are forwarded immediately to our client.
Another challenge- from Pipeline

- Through interpretation of this section, the Department has permitted the administrative review to be conducted by staff persons working under the direct supervision of the MRO. While allowing this delegation of MRO responsibility, the Department never intended nor can it condone a practice which allows for MROs to appoint outside "agents" to perform this review. The MRO should have direct supervisory relationship with the reviewer and not simply have access to the "process" of the administrative review. Conversely, a C/TPA cannot contract for the MRO to only review positive drug test results leaving the review or processing of negatives to the consortium or third party administrator.

- Regulation References:
  - 49 CFR 40.33

(emphasis added)
Mine Safety and Health Administration
30 CFR Parts 56, 57, and 66
Alcohol- and Drug-Free Mines: Policy, Prohibitions, Testing, Training, and Assistance; Proposed Rule

In addition to prohibiting the use, and requiring testing for illicit drugs or the “SAMHSA–5;” MSHA is proposing that the unauthorized use of the following controlled substances also be prohibited: barbiturates, benzodiazepines (e.g., Valium, Librium, Xanax), methadone, propoxyphene (e.g., Darvon), and synthetic and semi-synthetic opioids (i.e., hydrocodone, hydromorphone, oxymorphone, oxycodone).

(2008)
The NPRM in its preamble and in section 66.101, essentially indicate that the MRO's interpretation of a laboratory positive drug test result should include, in addition to a determination that the individual has a valid, current prescription for the substance found in the urine drug test, a determination of whether the urine drug test results are consistent with the individual using the medication as prescribed. (e.g. at the recommended dosage and intervals) Making a determination of dosage and administration time/interval is based on the urine drug test quantitative levels of drug detected, or even the metabolite(s), parent drug ratios, is not a recommended practice in drug test interpretation. There are so many variables, most of which the MRO cannot accurately determine, that impact dose-response relationships. Likewise any attempt to make a sound judgment about impairment or intoxication at the time of the collection of the urine specimen based on the urine drug test result is also fraught with uncontrolled variables beyond the MRO's purview.

(Comments by Dr. Donna Smith, First Lab, Nov 2008)
Other concerns that impact MRO

- HIPPA issues and MRO
- Federal has release inherent
- Non regulated does not have such built in
- Releases should be obtained
Other Concerns

- MROs are increasingly being asked to provide program guidance
- MROs are increasingly being asked to do training for supervisors
- MROs continue to be involved in presenting to industry leaders
- MROs continue to be directly involved with implementations
- MROs are involved in random selection process
City of Boulder has ordinance prohibiting random testing
For school bus drivers, must follow federal rules
For school bus drivers must have a negative test pre endorsement to drive school bus
No state specific regs
No state level regs
State level-Montana

- Limits random testing
- Must follow federal rules
(5) Medical Review Officer (MRO): A licensed physician (medical doctor or doctor of osteopathy), certified by either the American College of Occupational and Environmental Medicine or The American Association of Medical Review Officers to include a minimum of twelve hours of continuing medical education annually, responsible for receiving laboratory results generated by an employer's drug testing program. The MRO shall be an agent of the employer.
Drug test results can only go to a licensed physician or their designee.

Applies to both workplace and clinical drug testing.
San Francisco has an ordinance prohibiting drug testing

No employer may demand, require, or request employees to submit to, to take or to undergo any blood, urine, or encephalographic test in the body as a condition of continued employment. Nothing herein shall prohibit an employer from requiring a specific employee to submit to blood or urine testing if: (a) The employer has reasonable grounds to believe that an employee's faculties are impaired on the job; and (b) The employee is in a position where such impairment presents a clear and present danger to the physical safety of the employee, another employee or to a member of the public;
Iowa law requires you to send results of drug tests to the parent/guardian of anyone under 18.
State Level-Oklahoma

- Requires an MRO in the process
- Similar to federal definition
State Level- Maine

- Prohibits observed testing for non-regulated tests
Late Breaking News

- Just published in Federal Register
- Thursday February 4, 2010
- 49 CFR Part 40
- [Docket OST–2010–0026]
- RIN 2105–AD95
- Public Comments due by April 5, 2010
LATE BREAKING NEWS

• DOT is required by the Omnibus Transportation Employees Testing Act to follow the HHS requirements for the testing procedures/protocols and drugs for which we test.

• Primary laboratory proposals include:
  • Testing for MDMA (aka. Ecstasy);
  • Lowering cutoff levels for cocaine and amphetamines
  • Conducting mandatory initial testing for heroin (6MAM)
  • Authorizing employers to use HHS-Certified Instrumented Initial Test Facilities to conduct initial drug testing

• We also propose bringing a number of our testing definitions in-line with those of HHS.
Late Breaking News

- Instrumented initial test facilities
- Local, lab based, initial testing sections of drug testing labs
- Non negatives have to go to certified lab for confirmation testing
In addition DOT will limit Instrumented Initial Test Facilities and MRO relationships to the same as laboratory and MRO relationships.
DOT estimates increase of 10% of amphetamines and cocaine using lower cut off levels
The HHS Mandatory Guidelines will require that nationally recognized MRO certification entities or subspecialty boards for medical practitioners in the field of medical review must have their qualifications, training programs, and examinations approved by HHS on an annual basis.
The DOT is seeking comment on whether part 40 should require these groups to be approved. Would the DOT program be better served if we sought a shared approval process with the HHS?
In addition, the DOT is seeking comments on whether part 40, at 49 CFR Part 40.121(d), should be amended by removing the requirement that MROs must complete 12 Continuing Education Units (CEUs) pertaining to DOT and MRO practices every three years, and instead require MROs to be recertified every five years by an MRO certification board or subspecialty board. We believe this is a cost neutral proposition, and may even prove less costly because many MROs obtain both the 12 CEUs every 3 years and the MRO recertification every 5 years.
DOT seeks comments about what types of MRO records should be covered under the record keeping requirements. Is it normal practice for an MRO to include in his or her paperwork personal notes and conversations with laboratory personnel? What other types of records would MROs normally be required to keep as part of this paperwork requirement?
Late Breaking News

Asking for MROs to provide comment upon what they believe are records DOT inspectors or auditors could expect to see when reviewing MROs records as part of the overall compliance audit of a DOT regulated employer.
SUMMARY

- There are many responsibilities of the MRO already in place
- Not all of them are done by many MROs
- The NRC already calls for the MRO to be more directly involved in deciding if a fitness for duty evaluation is needed
- There are clues in several other programs.
Questions?

- Thank you for your attention
- Please consider joining the MRO list
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- Or e mail me
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American Occupational Health Conference
AOHC 2010
Orlando

Rosen Shingle Creek
Sunday, May 2, 2010 - Wednesday, May 5, 2010
Pre-conference Courses
Friday, April 30, 2010 and Saturday, May 1, 2010.