MRO ALERT

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Updating the Technical, Legal and Procedural Aspects of MRO Practice

In this issue

New DOT Rule Presents Safety Concerns for MROs and Employers as well as Implementation Challenges for All

Spasmodic Launch into Opioid Testing

By Theodore F. Shults MS JD

As 2017 winds down, the year can only be described as challenging. As measured in terms of its death toll, we are at the height of the worst drug-use epidemic in both US and world history.

With the addition of prescription opioids to federally mandated testing and a new requirement from DOT for the MRO to hold any safety concerns they may have regarding prescription drug use for five business days to allow the donor to get their treating physician to contact the MRO, one thing is very clear: MROs do not charge enough for all the management and time it takes to properly verify results.

Regardless of the merits of this new requirement, I am concerned that political and special interest kibitzing may to be the cause of the spasmodic release of the updated HHS mandatory guidelines and DOT's publication of its new rule with its truncated implementation date of January 1, 2018. Especially since the new DOT rule contained a significant surprise as mentioned above: a required hold of up to five business days on MROs' relaying safety concerns to employers based on prescription drug use. This new provision has raised many questions and concerns with MROs and employers. There was no indication in the proposed rule that DOT was contemplating this significant change in MRO practice. Also, there has been no time for software and business practice implementation. (Too bad we do not have a spasmodic launch into Oral Fluid testing).

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With respect to drug testing beyond the safety concerns, we continue to hear complaints and frustration from private employers who currently test for expanded opioid panels and receive negative results from their MROs, while ending up with employees who are clearly strung out on opioids. The combination of synthetic urine and the uncertainty around the use of new and old prescriptions effectively undermines the efficacy of testing programs.

As a timely confirmation of the shortcomings of drug testing, we see newspaper articles about positive, post-accident drug tests for Amtrak workers involved in a deadly accident last year. Remember that it was the drug-related Amtrak accident in Maryland in 1987 that launched the federal mandatory drug testing program in the first place.

Next, we learn from 60 Minutes that pharmaceutical companies and wholesale drug distributors successfully lobbied congress to pass a bill that clipped the wings of the DEA's ability to block the massive distribution of pain medications (massive = millions of pills) to small, rural pharmacies that fueled pill mills. Plus, the senator who sponsored the legislation was then tapped to be the new head of the DEA … at least until the 60 Minutes program aired. (The position was vacant because the previous head of the agency had resigned apparently in disgust).

This much-too-easy manipulation of the legislative agenda explains a lot of the chronic deficiencies, how the opioid epidemic got so large and why we have such obvious limitations in mandatory federal drug testing programs. There is a lot of money in drugs, legal and illegal. Now, in addition to all the deaths we have suffered, we are looking at decades of litigation against manufacturers, distributers, pharmacies, et al. (I suspect that more than one person is working on drafting new legislation that will block these lawsuits).

I remain, however, sympathetic to all of the federal civil servants whom I have had the privilege to work with. I know that it is frustrating for them also. Now the focus is on how to make what we have work as best as possible.

This issue will cover the new DOT rule, current guidance and some of the challenges presented. It also contains an open letter sent from an MRO to the director of the Office of Drug and Alcohol Policy and Compliance (ODAPC). Next month we will cover the problematic question: How much risk is reasonable? Or, how do we best determine safety concerns?

The "New" DOT Part 40 Rule Includes Significant Changes

Below is DOT's "official" Part 40 Summary of Rule Changes. It is followed by DOT's Notice on Part 40 DOT Policies; DOT's Notice on Federal Drug Testing Custody and Control Form; DOT's Drug Testing Employee Notice; and finally three "fatal flaws" adopted by DOT's new rule.

Part 40 Final Rule - DOT Summary of Changes

Today, November 13, 2017, the Department of Transportation (DOT) published a final rule in the Federal Register (82 FR 52229). The rule, among other items, added four semi-synthetic opioids (i.e., hydrocodone, oxycodone, hydromorphone, oxymorphone). It also added methylenedioxyamphetamine (MDA) as an initial test analyte and removed the testing for methylenedioxyethylamphetaime (MDEA).

When is the final rule effective?

The final rule is effective January 1, 2018.

What does this mean for employees?

You will *also* be tested for four semi-synthetic opioids (i.e., hydrocodone, oxycodone, hydromorphone, oxymorphone). Some common names for these semi-synthetic opioids include OxyContin®, Percodan®, Percocet®, Vicodin®, Lortab®, Norco®, Dilaudid®, Exalgo®. In addition, you will no longer be tested for MDEA.

What does this mean for employers and Consortium/Third Party Administrators (C/TPA)?

As an employer or C/TPA, you will no longer be required to submit blind specimens to laboratories.

What does this mean for urine collectors?

The shy bladder process has been modified so that the collector will discard any specimen provided during the collection event when the employee does not provide a sufficient specimen by the end of the three-hour wait period.

What does this mean for laboratories?

As an HHS-certified laboratory you will:

- Add four semi-synthetic opioids — hydrocodone, oxycodone, hydromorphone and oxymorphone — to your DOT testing panel;
- Add MDA as an initial test analyte;
- Remove testing for MDEA;
- Add three more fatal flaws to the list of reasons when a laboratory would report a 'rejected for testing' specimen; and
- Need to modify the reports [in Appendix B & C] you provide to employers and the DOT.

What does this mean for Medical Review Officers (MROs)?

Several of your MRO drug test review processes have been modified. For example:

- The term 'prescription' has been clarified;
- You have authority to conduct D,L stereoisomer and THC-V testing; and
- The timing when you communicate a significant safety risk has been modified.

What does this mean for alcohol technicians?

The list of NHTSA-approved Alcohol Screening Devices and Evidential Breath Testing Devices will appear on ODAPC's website.

What does this mean for service agents?

Collectors, alcohol testing technicians, MROs, and Substance Abuse Professionals will be required to subscribe to ODAPC's list-serve.

Unauthorized use of DOT-branded items (such as logos or emblems) on a service agent's website, publications, etc., could be a basis for the DOT to initiate a Public Interest Exclusion proceeding.

What are some of the other changes to Part 40?

- The DOT added a new section reiterating that, in the DOT testing program, only urine specimens can be collected and analyzed at HHS-certified laboratories.
- The DOT added language further emphasizing the existing DOT prohibition on the use of DNA testing on DOT drug-testing specimens.
- The final rule made minor modifications to certain section headings.
- The final rule moved the list of Substance Abuse Professional certification organizations from the rule text to ODAPC's website.
- The final rule moved the MIS instructions from Appendix H to ODAPC's website.
- Outdated compliance dates were removed and links were updated.
- Appendices B, C, D, and H were updated.

Where can I find a copy of the final rule?

You can view the final rule on ODAPC's web site.

Note: This document informally summarizes some of the important effects of the rule, but it is not a substitute for the rule and should not be relied upon to determine legal compliance with the rule. ODAPC encourages affected entities, including employers and service agents, to review the final rule.

Part 40 DOT Policies Notice

DOT Drug Testing: Employer DOT Policies: the Part 40 Changes

The DOT Agencies & United States Coast Guard (USCG) have provided guidance to DOT-regulated employers about what their DOT policies will need to contain about the changes to 49 CFR Part 40, which are effective January 1, 2018.

1. The Federal Transit Administration, Federal Motor Carrier Safety Administration, Federal Aviation Administration, Pipeline and Hazardous Materials Safety Administration, Federal Railroad Administration, and USCG take this position:

There is no need for employers to make any changes if their current DOT policies refer to adhering to "... Part 40." However, there are exceptions when an employer's DOT policy lists the following optional information:

- If sub-categories of drugs tested under the 5-panel are listed – for example, if a policy lists "Opiates (codeine, heroin, & morphine)" and/or "Amphetamines (amphetamine, methamphetamine, MDMA, MDA, MDEA)," then "Opiates" needs to change to "Opioids (codeine, heroin, morphine, oxycodone, oxymorphone, hydrocodone, hydromorphone)" and "MDEA" will need to be removed from the list under "Amphetamines." If however, employers would like to delete the sub-categories of drugs, doing so will also be acceptable.

- Likewise, if cut-off levels are listed in current policies, employers must update those cut-off levels. Again, employers may simply delete the cut-off levels completely and be in compliance if the DOT policy refers to adhering to "... Part 40."
- While these DOT Agencies and USCG suggest that employers provide written notice to employees about their updated DOT policies, doing so is an employer's prerogative.

2. This document replaces the previous Employer DOT Policies - Part 40 Changes notice from 2010.

(Updated: Monday, December 4, 2017)

DOT Guidance on Federal Drug Testing Custody and Control Forms

On Monday November 13, 2017, the Department of Transportation (DOT) published a final rule in the Federal Register. The final rule, among other items, added four semi-synthetic opioids (i.e., hydrocodone, oxycodone, hydromorphone, oxymorphone) to our drug testing panel. It also added methylenedioxyamphetamine (MDA) as an initial test analyte and removed the testing for methylenedioxyethylamphetaime (MDEA).

When is the final rule effective?

The final rule is effective January 1, 2018.

Is there a revised CCF because of the additional drugs being added?

Yes, the Office of Management and Budget (OMB) approved a revised Federal Drug Testing Custody and Control Form (CCF). The revised CCF can be viewed here.

How will I know the difference between the revised and 'old' CCF?

The 'old' CCF is the one that has been used under the DOT-regulated program since 2010.

The revised CCF includes the following changes:

- In Step 1D:
  - Removal of the checkbox, the letters "DOT" and hash line in front of the text "Specify DOT Agency."
- In Step 5A:
  - Addition of four new analytes: oxycodone (OXYC), oxymorphone (OXYM), hydrocodone (HYC), and hydromorphone (HYM),
  - Removal of the analyte methylenedioxyethylamphetamine (MDEA).

When can I begin using the revised CCF?

- DOT-regulated employers and their service agents (collectors, laboratories, Medical Review Officers (MROs)) are authorized to use the revised CCF beginning January 1, 2018.
- As a laboratory, to avoid confusion about opioids testing prior to January 1, 2018 for DOT-regulated clients, and to allow you to deplete your existing supplies of old CCFs, we recommend as a best practice, that you not mail any revised CCFs to your DOT-regulated clients or their service agents until after January 1, 2018.

As a collector, after January 1, 2018 can I still use the 'old' CCF?

- Yes, OMB authorized, and you may choose to use, the 'old' CCF until June 30, 2018. When using the 'old' CCF between January 1, 2018, and June 30, 2018, a 'memorandum for the record' is not required. After June 30, 2018, if

you use the 'old' CCF, you must complete a 'memorandum for the record' per §40.205(b)(2).

- After January 1, 2018, you may begin using the revised CCF. However, after June 30, 2018, you are required to use the revised CCF.
- We recommend that you monitor your existing supply of 'old' CCFs and coordinate the delivery of the new CCF with the testing laboratory.

If I use the 'old' CCF after January 1, 2018, what do I need to do differently?

- As a collector or MRO, there is nothing you need to do differently.
- As a laboratory, before transmitting a confirmed positive result for Oxycodone, Oxymorphone, Hydrocodone, and/or Hydromorphone to the MRO, in Step 5A of Copy 1, check the "positive" box and write in the specific drug analyte in the "Remarks" section.

Note: This document informally summarizes some of the important effects of the rule, but it is not a substitute for the rule and should not be relied upon to determine legal compliance with the rule. ODAPC encourages affected entities, including employers and service agents, to review the final rule.

(Updated: Friday, December 1, 2017)

DOT Drug Testing Part 40: Employee Notice

This is a reminder that the U.S. Department of Transportation (DOT) drug testing program will soon require testing for four semi-synthetic opioids (i.e., hydrocodone, oxycodone, hydromorphone, oxymorphone). The change is effective January 1, 2018.

What does this mean for the employees?

Beginning January 1, 2018, in addition to the existing DOT drug testing panel (that includes marijuana, cocaine, amphetamines, phencyclidine (PCP), and opiates), you will also be tested for four semi-synthetic opioids (i.e., hydrocodone, oxycodone, hydromorphone, oxymorphone). Some common names for these semi-synthetic opioids include OxyContin®, Percodan®, Percocet®, Vicodin®, Lortab®, Norco®, Dilaudid®, Exalgo®.

If you test positive for any of the semi-synthetic opioid drugs, then as with any other drug test result that is confirmed by the laboratory, the Medical Review Officer (MRO) will conduct an interview with you to determine if there is a legitimate medical explanation for the result. If you have a valid prescription, you should provide it to the MRO, who will determine if the prescription is valid. If a legitimate medical explanation is established, the MRO will report the result to your employer as a 'negative'. If not, the MRO will report the result to your employer as 'positive'.

As it has been the requirement in the past, when your employer receives a 'positive' drug test result, your employer is to immediately remove you from performing safety-sensitive functions and provide you with a list of qualified Substance Abuse Professionals (SAP) available in your area. In order to return to performing safety-sensitive functions for any DOT-regulated employer, you must complete the return-to-duty process that will include an evaluation by a SAP, who will require education and/or treatment. The SAP will determine if you successfully completed the prescribed education and/or treatment. Before an employer can return you to safety-sensitive work,

the employer must get a negative result on a directly observed return-to-duty drug test. After you return to safety-sensitive work, you must be subject to directly observed follow-up testing for 12-60 months depending on the SAP's recommendations.

Do I need to tell anyone about my prescribed medications?

Your employer may have a policy that requires you to report your prescribed medications to them. So check with your employer. If your job function has DOT-regulated medical standards (truck/bus driver, airline pilot, mariner), the DOT agency regulation may require you to report your prescribed medications to those who approved your medical qualifications.

What should I tell my prescribing physician?

If you are taking any prescription medications, consider this to be a reminder to have a conversation with your prescribing physician to discuss your safety-sensitive work. Be proactive in ensuring that your prescribing physician knows what type of transportation-related safety-sensitive work you currently perform. For example, don't just provide a job title but describe your exact job function(s) or ask your employer for a detailed description of your job function that you can give to your prescribing physician. This is important information for your prescribing physician to consider when deciding whether and what medication to prescribe for you. It is important for you to know whether your medications could impact your ability to safely perform your transportation-related work.

Will the MRO report my prescribed medication use/medical information to a third party?

Historically, the DOT's regulation required the MRO to report your medication use/medical information to a third party, (e.g. your employer, health care provider responsible for your medical qualifications, etc.), if the MRO determines in his/her reasonable medical judgement that you may be medically unqualified according to DOT Agency regulations, or if your continued performance is likely to pose a significant safety risk. The MRO may report this information even if the MRO verifies your drug test result as 'negative'.

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.

Note: This document informally summarizes some of the effects of recent changes to the Procedures for Transportation Workplace Drug and Alcohol Testing Programs that are important for transportation employees, but it should not be relied upon to determine legal compliance with those procedures.

(Updated: Monday, December 11, 2017)

The Three New "Fatal Flaws"

These "fatal flaws" were proposed in the HHS Mandatory Guidelines and adopted by DOT's new rule.

Specifically, the flaws proposed to be added were:

1) there is no CCF;

2) two separate collections were performed using one CCF; and

3) there was no specimen submitted to the laboratory with the CCF.

Numbers 1 and 3 are pretty obvious, and simply codify what the laboratories have practiced. Number 2 is not obvious and is somewhat problematic. Here is the typical situation where "two collections" (separate voids) have occurred and only one CCF has been submitted. The most common cause is that the first urine is temperature out of range (TOR) and the second observed collection has been performed. Then it turns out that the donor has only the one copy of the CCF provided by his or her employer and the collection site does not have a DOT CCF that will go to the right laboratory or has no spare CCF at all. So now the first TOR specimen is sent with the second observed collection which may be well annotated as to why it does not have its own CCF. Guess which one is positive? The second one. However, because it does not have its own CCF it is now a cancelled test.

Letter and Comment from MRO to Director of ODAPC

From: Greg Elam
Sent: November 21, 2017
Subject: Final Rule

Dear Ms. Kelly,

I have been practicing full time as an MRO for 22 years. I have been certified through AAMRO the entire time, having taken numerous courses and exams along the way. I am also a Certified Medical Examiner under the FMCSA and am very familiar with the disqualifying conditions for CMV drivers.

I have received the final rule published on November 13, 2017 addressing the 49 CFR Part 40 rules. I have reviewed them and ask that my comments be heard.

The new rule as published has a glaring issue that was not mentioned in the NPRM published on January 23, 2017 and therefore no comment period before this was issued as a final rule!

The issue involves the 5-day waiting period before the MRO can report a safety concern to the employer after overturning a laboratory confirmed positive test.

This compromises safety! Requiring a five-day waiting period increases the time for an untoward event in the interim and thus the employer's and MRO's liability. There are illustrative cases but see Turney v Taylor Clinic in Anniston, Alabama for one.

This rule is already in place and in the preamble to the final rule it was noted: "We have no reason to believe this process is not effective." If the process is working, why change it?

This is already the rule but I can count on one hand the number of times a physician has reached out to me to discuss. The prescribing physician is busy seeing patients and thus is loath to contact another physician questioning his judgment. I read we are not allowed to question the treatment but that is how it is perceived in the real world and aren't we doing that by requesting a different medication? This is effectively practicing medicine in an arena where we do not have a doctor-patient relationship. Nonetheless, we do report that now, immediately, and let the employer coordinate the fitness-for-duty issues. That is working and the employers are very familiar with that. Adding the 5-day waiting period just kicks the can down the road but it ultimately ends back in the employer's lap — plus a load of additional liability.

The additional time for the MRO has not been adequately accounted for in the cost estimate. The time is being underestimated in my opinion. The MRO will have to keep a log of the "5-day waiting charts" and speak to many people including the employer twice and the employee's physician and/or staff at least once, doubling the time spent on each case. Even if the MRO does not report a safety concern because the employee's physician agrees to change a medication, how does the MRO document and confirm that? Otherwise, it would make the MRO responsible if the employee goes back to work and has an accident if the employer has not been notified of a safety concern!

This brings up a host of scenarios that put the responsibility of fitness-for-duty issues solely on the MRO. We are not trained for that and have never been required to be. There are a variety of people in many different circumstances practicing as MROs and this rule seems to imply there is some consistent standard that is used for people in safety sensitive jobs in different operating agencies. This is the employer's responsibility and placing more on the MRO is misguided. If you insist on this course of action, I ask you promulgate the fitness-for-duty training standards for MROs.

And what about the employers who require their employees to let them know of any medications as allowed under some operating agencies like FMCSA? Will that become the de facto role of the MRO?

Making this a rule on the eve of an influx of positive test results for opioids creates a perfect storm!

There are many more eloquent who I hope will comment.

I respectfully ask this be addressed through the proper channels by issuing a NPRM and reviewing the comments before making a final decision.

Sincerely,

Greg

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DOT's Five-Day Waiting Period

MRO Experiences and Issues with Respect to New Requirement to Hold Back Reporting of Safety Concerns to Speak with Donor's Treating Physician

- Only 10-20 % of treating physician who are contacted by their patient ever call the MRO, and when they do they push back pretty hard on the MRO for questioning their practice and judgment.
- Many MROs have told me that they do not anticipate changing their opinion based solely on the treating physician stating that the patient is OK.
- As for the 80-90% of donors whose treating physician does not call the MRO, they should expect that the fifth day of silence will trigger a report of a safety concern. This will be a formal safety concern letter being issued by the MRO to the employer and a call to the DER for good measure. An MRO may have an equivocal concern about a particular donor and safety, but when the treating physician is contacted and does not engage with an MRO, an equivocal judgment call becomes unequivocal.
- It also appears now more than ever that MROs are practicing medicine, regardless of an absence of a traditional doctor-patient relationship.
- MROs are on a slippery slope here. Historically a "safety concern" was just that, not a fitness-for-duty assessment. The "fitness" evaluation is supposed to be done by someone other than the MRO in the verification. It is supposed to be an independent medical evaluation performed by a physician who has a professional relationship with the donor and the employer. (This may involve the MRO, but not automatically). The MRO is merely raising a warning flag for employers that someone needs to follow up on a driver.
- DOT/FMCSA regulates employers, not the MROs. I do not think the Public Interest Exclusion (PIE) will be a sufficient deterrent for the MRO's intentional non-compliance with this 5-day hold on their safety concerns.
- The immediate concern of MROs is the liability risk of the DOT/MRO who follows the rule and there is a significant accident in the five-day quiet period and there is evidence that prescription drug use may have contributed to the accident. It may be that there is little or no liability for the DOT/MRO because of the pretty solid defense that the MRO was legally prohibited from reporting the concern for 5 business days. On the other hand, MROs in private practice who follow the DOT procedures cannot raise that defense. Further, states that follow "DOT" regulations under drug-free workplace type acts present a difficult legal/liability question to answer.
- Furthermore, the DOT and the drug testing program has a great deal of exposure for negative PR for prohibiting the MRO to raise any concern during the "silent period".
- How much risk does the 5-day hold really present? Opioids have been endemic throughout industry, and in the case of CDL drivers, opioid users are on the road now and a five-day holding period should not fundamentally change the risk profile. The ethical problem is that now the MRO will know of, or suspect, a problem. Imagine the laboratories being told to hold up reporting results for five days!
- The opioid-dependent driver who is called by the MRO and knows that his or her treating physician may not agree that the driver is qualified presents an additional concern to management. It is the problem of having an employee who is still on the job but knows the end may be near. Not smart.

- There is also a general consensus that there was no meaningful opportunity to express any public comment on this significant change in practice. This compounded with a truncated implementation time line makes it feel like the process is driving too fast toward a cliff.
- The new rule also talks about the treating physician changing the prescriptions for the driver despite language in the rule that the MRO should not "second guess" the treating physician. Besides the question of cognitive dissidence of this conflicting language, what could a treating physician change to? For pain methadone, tramadol, buprenorphine and fentanyl come to mind. For amphetamine, well, methylphenidate is attractive. No positive results, everyone is happy and we have licked the problem!
- More than one FMCSA medical examiner and MRO has told me that they get this question from drivers: "What is the best way to beat the drug test?"

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