WHAT'S NEW WITH HHS & DOT?

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3/23/24

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DISCLOSURE

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OBJECTIVES

- Understand how changes are made to existing HHS/DOT drug testing Guidelines and Regulations
- Understand what changes are in process and what changes are already required of MROs
- Be able to compare and contrast forensic testing and clinical testing for substance misuse

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ALL DRUG TESTS ARE NOT CREATED EQUAL

- **Detection/Deterrence**
  - Detect every use vs prevent most use
  - False negatives vs false positives
  - High user populations vs low user populations
  - Compare participant protections of each program
  - Medical review helpful vs required
- **Clinical/Forensic**
  - Therapeutic vs disciplinary
  - Point of Collection vs lab
  - Screen vs confirm
  - Medical review helpful vs required

- **What we do with the result is more important than the result itself!**

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2 DIFFERENT EXECUTIVE LEVEL CABINETS

- The Department of Health and Human Services (HHS) through its Substance Abuse and Mental Health Services Administration (SAMHSA) covers the testing of federal employees through its Division of Workplace Programs (DWP)
- The Department of Transportation (DOT) through its Office of Drug and Alcohol Program Compliance (ODAPC) establishes regulations for the testing of covered non federal employees in various regulated sectors of transportation.

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HHS/DOT WHAT'S THE DIFFERENCE????

- HHS/SAMHSA
  - Funds research, establishes standards and certifies laboratories through the National Laboratory Certification Program (NLCP).
  - Issues Mandatory Guidelines for the testing of federal employees
- DOT/ODAPC
  - DOT is required to conform with HHS drug testing panels and must test in HHS/NLCP certified laboratories
  - DOT must issue proposed rules and obtain public comment before it issues those Conforming Regulations
  - DOT may differ from HHS Guidelines in some testing protocols

Omnibus Transportation Employee Testing Act (OTETA) 1991

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"RECENT" CHANGES

- SAMHSA Mandatory Guidelines issued 1/23/17 effective 10/1/17
  - Inclusion of hydrocodone/hydromorphone and oxycodone/oxymorphone in HHS testing panel
  - MDMA, MDA initial and confirmatory analytes
  - Adulterated pH changed to <4
  - Agencies were authorized not mandated to begin new program 10/1/17
- DOT issued Final Rule conforming with HHS on 11/13/17 effective 1/1/2018
  - New analytes conforming with HHS
  - 5 day "pause" for medication related safety concerns

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"RECENT" CHANGES II

- DOT (continued)
  - Employers/TPA's no longer must submit blind specimens
  - Urine is the only authorized specimen for DOT testing
  - DNA testing is prohibited
  - MROs and other service agents must subscribe to the ODAPC List Serve
  - Prescriptions must conform to the requirements of the CSA
  - MROs are now authorized to test for THC-V
  - Service agents must not use DOT logos or other official branding

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ORAL FLUID

- SAMHSA Issued Mandatory Guidelines 10/25/19, effective 1/1/2020
- DOT Issued Final Rule 5/2/23 effective 6/1/23
- BUT implementation of both still in process because devices and reagents are not FDA cleared
  - Laboratories can not be certified until this happens
- MRO Process essentially unchanged
  - Confirmation is for parent THC not metabolite THCA
  - Secondary exposure, CBD will not cause positives
  - Confirmation for both parent cocaine and BE
  - Split specimens required in all federal testing

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SAMHSA PROPOSED HAIR MANDATORY GUIDELINES

- Federal Register dated 9/10/20
- Comment period ended 11/9/20
- https://link.zixcentral.com/u/e2b6e311/SniULGrz6hGtBczR0C6LPw?u=https%3A%2F%2Fwww.federalregister.gov%2Fdocuments%2F2020%2F09%2F10%2F2020-16432%2Fmandatory-guidelines-for-federal-workplace-drug-testing-programs

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SAMHSA PROPOSED HAIR MANDATORY GUIDELINES-II

- Urine or oral fluid specimens must be collected either simultaneously or when ordered by MRO
- If hair specimen confirms positive, MRO reports a cancelled result to the agency and directs testing of the alternate specimen.
- MRO verifies alternate specimen result in the usual manner

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DOT MRO Certification COVID-19 Enforcement Discretion allowed multiple extensions of MRO recertification but timelines have now expired

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SAMHSA DTAB 3/5/24

- Proposal to add fentanyl and metabolite nor-fentanyl to HHS testing panel
  - EIA screens do not cross react between parent and metabolite
  - Discussion about appropriate focus for screening reagents
- Remove MDMA and MDA from HHS testing panel

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THE TESTING PROCESS

- Collection
- Laboratory Analysis
- **MEDICAL REVIEW**

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MAJOR CHANGE FOR USE OF MRO STAFF

- MRO staff may now to call the pharmacy and gather prescription verification from the pharmacy.
- If you use staff for this function, you must ensure operational control over the hiring, firing, evaluation of the staff
- you must oversee the performance of the function of staff contacting a pharmacy:
  - outline or script what the staff will ask the pharmacy;
  - occasionally monitor calls to assure quality control;
  - or other methods to ensure the staff are properly conducting the calls with the pharmacies
- 40.141

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MRO MAY NOT DELEGATE

- Donor interview and discussion of legitimate medical explanation
- Cancellation of test
- Verification of test
- Verification of donor medical or prescription information
  - MRO Team may now collect, but MRO must verify
- Review of at least 5% of negatives
- 40.127, 131

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MRO INTERVIEW

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THE MRO SHOULD THINK

- Is this the right specimen?
- Is the Chain of Custody intact?
- Is the laboratory report accurate and complete?
- Is there a legitimate medical explanation for this non negative result?

Other than the 24-36 hour detection window for all analytes, very few changes to the MRO interview for oral fluid

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2018: DOT SAFETY NOTIFICATION CHANGES - 1

- Timing of safety notifications to employer
  - During the interview:
    - MRO **must** notify donor of safety concerns about prescriptions
    - MRO **must** give donor the option to have the prescribing physician contact MRO within 5 business days to discuss alternative treatment that would alleviate concerns
  - MRO **must** give employer a negative report as soon as the RX is verified.
  - If the safety concern is about a medical diagnosis or condition and not about a prescription, it must be reported to the DER with the verified negative result

40.135

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2018: DOT SAFETY NOTIFICATION CHANGES - 2

- 5 Day Pause:
  - Even though the verified negative is reported, if the concern is about medication, MRO must allow up to 5 business days for the prescribing physician to contact the MRO to see if the medication of concern can be changed. The donor may elect to accept this option or not. If not, the safety concern can be reported to the DER immediately.
  - If donor accepts this option, MRO should help donors facilitate the discussion with the prescribing physician to expedite this process.

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2018: DOT SAFETY NOTIFICATION CHANGES - 3

- If the prescribing physician does not contact the MRO within 5 days after your donor interview, then the MRO **must** notify the employer of the safety concern.
- If the prescribing physician does contact the MRO and changes the drug, the MRO may elect not to notify the employer of a safety concern.
- If the prescribing physician contacts the MRO after the 5 day period and changes the drug, the MRO **must** contact the employer and remove the safety concern.

40.135

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2018: DOT SAFETY NOTIFICATION CHANGES - 4

- MROs should use "reasonable medical judgment" about the safety concern if the prescribing physician refuses to change the drug, even if the prescribing physician insists the drug is safe
- MROs should collaborate with their client employers about protocols for following this new regulation
- MROs are not allowed to question whether or not the prescribing physician should have prescribed that medication

40.135

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CONCERNS ABOUT DOT 5-DAY WAIT*

- MROs may be less inclined to flag and report safety concerns
- Potential for MRO to forget to report after 5 days
- Challenge to employer of hiring an applicant or returning an employee to work with a negative, later to receive a safety warning
- Liability for accidents occurring when MRO knows of but has not reported safety concern

R. Swotinsky: MRO Update, Vol. 23, No. 9, Nov. 2017

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OPIATE CUTOFFS

(LABORATORIES MUST QUANTIFY AND REPORT LEVELS)

- Urine: (Before 2/1/24 for HHS and DOT)
  - Codeine and morphine: 2000 ng/mL
  - 6-AM 10 ng/mL
  - Oxycodone and oxymorphone 100 ng/mL screen; and confirm
  - Hydrocodone and hydromorphone 300 ng/mL screen; 100 ng/mL confirm
- Oral Fluid:
  - Codeine, morphine, oxycodone/morphone and hydrocodone/morphone **all** 30 ng/mL screen; 15 ng/mL confirm
  - 6-AM 4 ng/mL screen; 2 ng/mL confirm

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POPPY SEED BURDEN OF PROOF
GOES AWAY 2/1 FOR HHS NOT DOT

- ~~Since poppy seed ingestion may cause both morphine and codeine confirmed positives, for both HHS/DOT:~~
- ~~Burden of proof is on the MRO except when:~~
  - ~~6-acetylmorphine (6-AM) reported OR~~
  - ~~Codeine or morphine:~~
    - ~~≥ 15,000 ng/mL (urine);~~
    - ~~≥150 ng/mL (oral fluid); OR~~
  - ~~There is clinical evidence of unauthorized use~~
- ~~40.97, 139~~

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CLINICAL EVIDENCE OF UNAUTHORIZED OPIATE USE GOES AWAY 2/1 FOR HHS NOT DOT

- ~~Physical signs:~~
  - ~~MRO may conduct or cause to be conducted a face to face evaluation:~~
    - ~~Miosis, needle tracks, piloerection, diaphoresis, etc.~~
    - ~~Signs of withdrawal, piloerection, midriasis, dysphoria, myalgias, etc.~~
  - ~~Unauthorized use must be recent enough to explain result~~
- ~~Admission of unauthorized use of foreign medication~~
- ~~Admission of unauthorized use of another's medication~~
- ~~40.139~~

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HHS GUIDELINE CHANGES I

- For urine, effective 2/1/24
- For oral fluid effective 10/12/23
- Urine cutoffs:
  - Morphine, codeine screening cutoff remains 2000 ng/mL
  - Morphine confirmation cutoff raised to 4000 ng/mL
  - Codeine confirmation cutoff remains 2000 ng/mL
- **MROs may no longer accept poppy seeds as a valid explanation for a urine morphine or codeine positive**

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HHS GUIDELINE CHANGES II

- The requirement for clinical evidence of illegal use in addition to drug test result for MRO to verify both urine and oral fluid codeine/morphine reviews has been removed.
- MROs report codeine/morphine oral fluid confirmed positives <150 ng/mL as negative
- HHS will now publish annually a Federal Register notice regarding drug/biomarker testing panels, allowing possible annual panel updates.
- DOT required to conform but must publish a rule change before any of these changes are to be used for DOT testing

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GENERALLY SPEAKING…

- Most oral fluid collection devices available today collect oral fluid on a "swab"
  - The swab is left in the buccal cavity for a defined period of time, or
  - Some devices have an indicator for completion of collection
  - Swab collects ≤ 1 mL
- The swab containing the oral fluid is then inserted into a tube of buffer/preservative solution then the sealed collection tube is shipped to the laboratory for testing
- Specimen collection
  - ***HHS***: "Split" → Bilateral/simultaneous collection or Sequential
  - ***DOT***: Specimen must be "subdivided"
    - "Buffered" – Two different swabs that are adjacent to one another in mouth
    - "Neat" (i.e., not diluted) – oral fluid is collected and split

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WHAT ABOUT LABORATORY PROCESSES?

- Drug panel components essentially same as for URINE
  - Except Marijuana target analyte is THC (parent) vs. THCA (carboxy-THC) for urine
  - Cocaine includes parent as well as benzoylecgonine
- Cut-off levels are lower for OF as compared to urine
  - Not designed to be equivalent to urine testing cut-offs
    - Like urine, established by HHS to ensure only use – not exposure – is detected
  - Windows of detection may be different based on the drug(s) and pattern of use
  - OF positive test does not establish or correlate to impairment or being under the influence

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MORE ABOUT LABORATORY PROCESSES

- No specimen validity testing required—authorized only if the specimen is suspect
  - May test for a biomarker such as albumin or immunoglobulin G (IgG) or a test for a specific adulterant
  - Must follow the applicable HHS requirements for any additional validity testing (requires NLCP approval)
- While there is likely one FDA-cleared, buffered collection system that meets DOT requirements, it is being resubmitted to FDA to enable usage with current and (potential future) analytes
  - Not all HHS analytes have FDA-clearance for the paired immunoassay test system

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EVEN MORE ABOUT LABORATORY PROCESSES

- Some labs may opt for neat/unbuffered systems which still require extensive validation
- HHS/DOT require two HHS certified labs prior to implementation of OF testing
  - Must they be with the same device?
  - How will employers know how labs are certified?

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ORAL FLUID ANALYTES / CUTOFFS

Drug/Class	Initial Test (ng/mL)	Confirmatory Test (ng/mL)
Amphetamine / Methamphetamine	50	25
MDMA / MDA	50	25
Cocaine / Benzoylecgonine	15	8
Opioids (Codeine / Morphine)	30	15
Opioids (Hydrocodone / Hydromorphone)	30	15
Opioids (Oxycodone / Oxymorphone)	30	15
6-AM	4	2
Marijuana (THC)	4	2
Phencyclidine (PCP)	10	10

Differences from Urine Guidelines:

- ***No SVT required***
- No 'Amphetamine Rule'
- Codeine/Morphine ≥150 ng/mL w/o medical explanation → verified positive
- Both parent cocaine and metabolite BE confirmed

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MARIJUANA: *MRO ISSUES*

- CBD
  - Laboratory analysis does ***not*** confuse CBD and THC
    - Two distinct compounds with different chromatographic-mass spectrometric characteristics
  - THC ***may be*** a contaminant in CBD products
  - More in the MRO course
- THC analogs (e.g., delta-8-THC)

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THC TESTING IN ORAL FLUID

- In oral fluid confirmation is for parent THC, not metabolite THCA
- THC and metabolites do not diffuse from plasma to oral fluid
- Dronabinol/Marinol®, or Epidiolex®
  - will not cause oral fluid positives for parent THC unless the medications are dissolved in the mouth, but
  - Both medications are available as oral solutions
- Studies show confirmed THC in oral fluid is consistent with ingestion unless specimen collected in smoky atmosphere or within 3 hours of exposure to heavy smoky atmosphere. (*Cone, et al. Journal of Analytical Toxicology, 39(1), 1–12)*

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THC-V (TETRAHYDROCANNABIVARIN)

- Naturally occurring cannabinoid found in various strains of THC not present in Marinol (dronabinol) or in CBD
- Used to differentiate smoked THC from CBD and dronabinol
- Presence is consistent with THC ingestion,
- But THC-V is not always present, so absence does not disprove that THC came from smoking
- Only tested in two DHHS certified urine labs

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PRESCRIPTION AGE

- **FMCSA Q&A #91: Can a driver be certified who tests positive for a controlled substance on the urine test, but claims that the prescription was legally prescribed 5 years before?**

YES!

THE FORMER FMCSA 1 YEAR REQUIREMENT HAS BEEN REMOVED

- **The DOT Rule is silent about acceptable age of prescriptions and it is not likely that there will be any forthcoming DOT Guidance on the subject.**

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Insufficient Specimen Volume

"Shy Bladder"

"Dry Mouth"

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SHY BLADDER

- Protocol begins when the donor is unable to void
  - Donor may be given up to 40 ounces of fluid over a period of time of up to 3 hours.
  - If the donor provides an adequate specimen within 3 hours:
    - Initial attempted specimen is sealed and sent to the laboratory along with the adequate specimen
    - Each specimen must have its own CCF
  - If the donor cannot provide an adequate specimen within 3 hours
    - Initial attempted specimen is discarded.
    - DER is contacted

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DRY MOUTH

- Protocol begins when volume indicator on device does not indicate collection of a sufficient specimen after 15 minutes
- Donor is offered up to 8 oz of water and 1 hour to successfully complete the collection process
- 10 minute observed deprivation period for each collection attempt
- Collection discontinued if donor is unsuccessful at the end of 1 hour, and the DER is contacted

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BUT!!

- The simplest thing to do in either case is to switch specimen matrices:
  - If the bladder is shy, collect oral fluid
  - If the mouth is dry, collect urine
- Employer permission is required
- These are issues between collectors and DERs
- Refusal to test is a DER decision at this point, do NOT issue an MRO report
- The MRO is not involved until…..

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MAKING A LIVING

- Resources:
  - http://www.occ-doc.net/forum/
  - https://www.acoem.org/mro_section.aspx
  - http://www.ndasa.org/
  - http://www.sapaa.com/
  - https://www.mrocc.org/
- Do outreach to local employers
  - Education & Training
  - Quality control (QC) program
  - Random selection and compliance monitoring
  - SAP and compliance monitoring
- Become a certified medical examiner (NRCME)

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SETTING-UP AN ACCOUNT

- Have a contract
- Review policy
- Establish ground rules (non-DOT)
  - DER(s)
  - Status update frequency
  - Reporting method
  - Familial, foreign, old Rx policy
  - Who pays for split/SAP?
  - And more

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CONCLUSION

- There is a lot to know.
- Your comfort level will increase as time goes on
- All questions are relevant

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