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Agenda

- Function of an MRO
- Function of an MRO-A
- Responsibilities of an MRO
 - Lab positive results
 - Invalid results
 - Substitutes and adulterated results
 - Shy bladder
 - o Collection site issues
- Strengths of the MRO process
- Weaknesses of the MRO process
- MRO best practices

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The MRO



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Medical Review Officer

- Definition
 - Licensed physician
 - Basic knowledge
 - Knowledgeable about and have clinical experience in controlled substances abuse disorders, including detailed knowledge of alternative medical explanations for laboratory confirmed drug test results
 - Knowledgeable about issues relating to adulterated and substituted specimens as well as the possible medical causes of specimens having an invalid result
 - Knowledgeable about DOT and its agencies' regulations
 - Knowledgeable about state specific regulations
 - Qualification
 - Receive qualification training and pass an examination every 5 years



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Medical Review Officer

- Act as an independent and impartial "gatekeeper" and advocate for the accuracy and integrity of the drug testing process
- Provide quality assurance review of the drug testing process for the all specimens under his/her purview
- The primary reason for the MRO process is to determine whether there is a legitimate medical explanation for confirmed positive, adulterated, substituted, and invalid drug tests results from the laboratory
- The medical review of donors' test results does not establish a doctor-patient relationship with the donors
- Must act to investigate and correct problems where possible
- May not enter into any relationship with an employer's laboratory that creates a conflict of interest or the appearance of a conflict of interest with your responsibilities to that employer



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The MRO-A



What is an MRO-A?

- MRO-A = Medical Review Officer Assistant
- Enhances the efficiency and integrity of the drug testing review process, as well as assists in protecting the rights of the donor during the collection process
- Must understand all aspects of the regulations



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MRO-A Certifications:

- Not a regulated position
- Certification is available (every 3 years)
- MRO-A certification currently conducted by the Medical Review Officer Certification Council (MROCC)

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MRO-A Responsibilities

- Assisting the MRO wherever possible
- Primary responsibility is processing and reporting **laboratory negative** urine drug test reports

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MRO-A Can:

- Review CCFs
- Investigate and correct problems, including requesting affidavits for correctable flaws
- Provide feedback to employers, collectors, and laboratories
- Consult and report to the Office of Drug and Alcohol Policy and Compliance (ODAPC)
- Report laboratory negative drug test results
 - MRO must review 5% of all negative CCFs
 - MRO must review ALL results reported by MRO-A that required corrective action



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MRO-A Can:

- Contact donors to schedule MRO interview for non-negative laboratory drug tests
- Obtain Copy 1 of the CCF from the laboratory for non-negative tests
- Report a negative dilute that does not require re-collection under direct observation
- Ensure the timely flow of test results (including split specimen)
- Transmit results to the DER after MRO has completed donor interview
- MRO-A must protect the confidentiality of drug testing information



MRO-A Cannot:

- Gather medical information
- Determine legitimate medical explanation for laboratory confirmed positive, adulterated, substituted or invalid drug test
- Conduct the donor interview
- Be involved in shy bladder evaluation (except paperwork)
- Cancel a drug test



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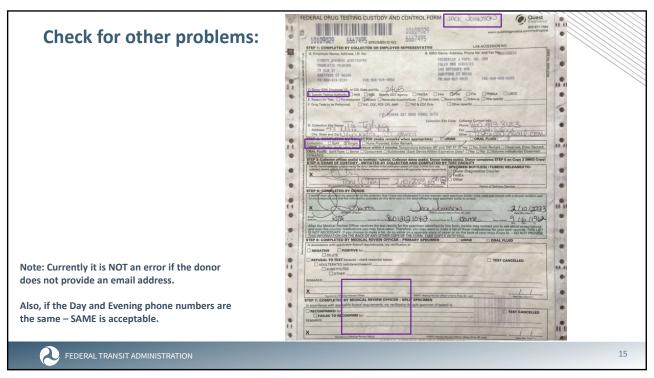
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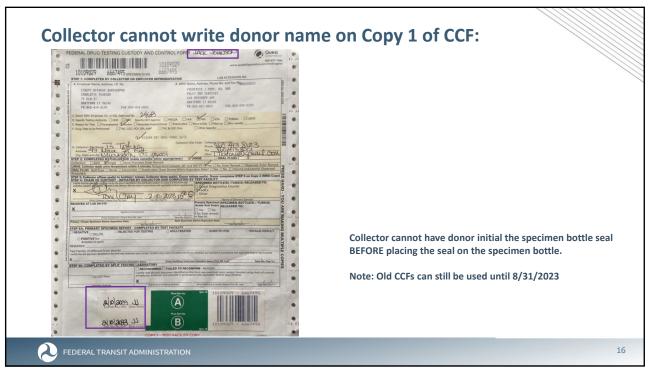
MRO-A Reviews Copy 2 of CCF to Verify:

- Matching specimen ID number on CCF and laboratory report
- Testing authority checked
- Reason for testing checked
- Temperature box checked
- Collector's printed name and signature in Step 4
- Donor's printed name and signature in Step 5
- Observed collection box checked if necessary (return to duty test, F.U., etc.)
- Notations in the "Remarks" section (i.e. dual collection for temperature out of range)

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Correctable Flaws (40.203):

- MRO-A may request affidavits and follow-up for correctable flaws
- If not corrected or affidavit is not received, only the MRO can cancel the test
- Examples of Correctable Flaws:
 - Temperature box not checked
 - Collectors signature missing from Step 4
 - Employee signature is missing in Step 5 and no notation in Remarks section that donor refused to sign
 - A non-DOT CCF was used for a DOT drug test



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Fatal Flaws (40.199):

- Test is reviewed and canceled by the MRO, cannot be corrected
- MRO-A may send documentation to requiring Error Correction Training (ECT)



Fatal Flaws

- Collectors name AND signature both missing
- Specimen IDs on bottle and CCF do not match
- Specimen bottle seal broken or shows evidence of tampering
- Leakage or insufficient quantity in primary specimen and split cannot be re-designated
- No CCF submitted with the urine specimen
- No urine specimen submitted with the CCF
- Two separate collections performed using one CCF



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Non-Contact Procedures:

- MRO or MRO-A must make at least 3 attempts over 24 hours to contact donor at number listed on the CCF
- If no contact within 24 hours, MRO or MRO-A notifies DER to contact donor
- DER must make at least 3 attempts to contact donor over 24 hours (document date and time of all attempts)
- If the DER cannot contact donor within 24 hours, DER may place the donor on "temporary medically unqualified status"







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MRO Verified Results

- Negative
 - May also be qualified as dilute
 - Means:
 - No analyte detected above the laboratory cutoff
 - The donor had a medical explanation for the result
 - » Which may generate a safety concern
- Positive
 - May also be qualified as dilute
 - Means:
 - The lab confirmed an analyte as positive, and the donor did not have a medical explanation for the result
 - » May also result from a non-contact event



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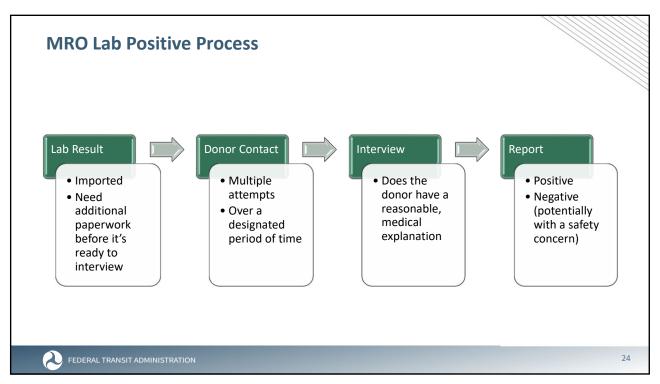
MRO Verified Results

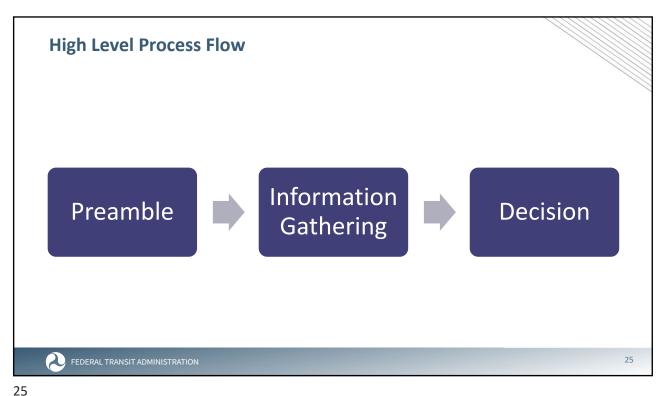
- Refusal to test
 - Means:
 - Laboratory criteria met for substitution or adulteration, and the donor did not have a medical explanation for the result*
 - Also used when donor failed to go to a mandated evaluation or had the evaluation which revealed some derogatory issue
 - » Shy bladder
 - » Opiate evaluation
- Canceled
 - Means:
 - Either a fatal or uncorrected correctable flaw occurred
 - The lab confirmed the specimen did not meet the specimen validity criteria



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Preamble

- State
 - Who you are
 - What you are doing
 - What your relationship is to the requesting company
- My preamble
 - I am Dr. Simo
 - I have to talk to you about your recent drug test result
 - Even though I am a doctor, I am not establishing a doctor patient relationship; I am acting as an agent of the company to discuss your drug test result



Information Gathering

- Three areas of inquiry
 - Prescription medications
 - Recent medical or surgical procedures
 - OTC medications
- Do not open Pandora's Box
 - Inquire about:
 - Parties
 - Passive exposure
 - Unknown exposure



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Stimulants

Amphetamines (Amphetamine, Methamphetamine, MDMA, MDA)

- Amphetamines are central nervous system stimulants
 - Speed up the mind and body
 - The physical sense of energy at lower doses
 - Mental exhilaration at higher doses
- Legal prescription trade names
 - Include: Desoxyn, Dexedrine, Adderall, Vyvanse, etc.

Cocaine

- Cocaine is used medically as a local anesthetic
- It is abused as a powerful physical and mental stimulant
 - The entire central nervous system is energized
 - The brain experiences an exhilaration caused by a large release of neurohormones associated with mood
- Legal prescription trade names
 - Include: Surgical cocaine packing, TAC solution

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Stimulants

- Cocaine
 - Prescription medications
 - Obtain list
 - Recent medical or surgical procedures
 - Procedures within 7 days of the collection of the specimen
 - OTC medications
 - N/A
- Cannot accept:
 - South American Coca Teas

- Amphetamine
 - Prescription medications
 - Obtain list
 - Recent medical or surgical procedures
 - N/A
 - OTC medications
 - N/A
- Cannot accept:
 - Ritalin
 - Adipex

- Methamphetamine
 - Prescription medications
 - Didrex
 - Desoxyn
 - Selegiline*
 - EMSAM*
 - Recent medical or surgical procedures
 - N/A
 - OTC medications
 - Nasal spray allegations*
- Cannot accept:
 - Ritalin
 - Adipex
 - Sudafed

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Opioids

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- Opioids (also called narcotics, opiates) are drugs that alleviate pain, depress body functions and reactions, and, when taken in large doses, cause a strong euphoric feeling
- Legal prescription trade names
 - Include: Morphine IR, MS Contin, Tylenol #3, Lotab,
 Vicodin, OxyContin, Percocet, Multiple cough syrups



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Information Gathering (Opioids)

- Oxycodone, Oxymorphone, Hydrocodone, Hydromorphone
 - Prescription medications
 - Obtain list
 - Recent medical or surgical procedures
 - Procedures within 7 days of the collection of the specimen
 - OTC medications
 - N/A
- Cannot accept:
 - Familial prescriptions
 - Prescriptions that cannot be verified



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Information Gathering (Opiates)

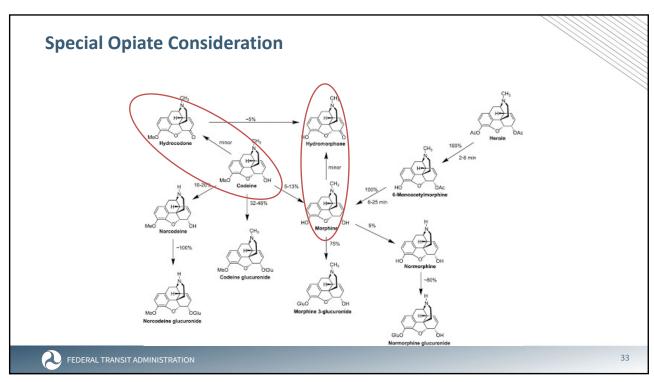
- Codeine, Morphine
 - Prescription medications
 - Obtain list
 - Recent medical or surgical procedures
 - Procedures within 7 days of the collection of the specimen
 - OTC medications
 - Obtain list
- Cannot accept:
 - Familial prescriptions
 - Prescriptions that cannot be verified

- Opiate Nuance
 - Clinical evidence rule
- ->= 15,000 ng/ml
 - Need verifiable proof
- < 15,000 ng/ml</p>
 - If illicit use not admitted to, need clinical evidence

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Information Gathering (No Explanation Instances)

- PCP, Substituted, Adulterated, MDMA, MDA, Heroin metabolite (6 MAM)
 - Prescription medications
 - Obtain list
 - Recent medical or surgical procedures
 - Obtain list
 - OTC medications
 - N/A
- There is no explanation
 - Medical questions are asked to defuse the situation

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Δ 9 THC

- Marijuana is one of the most misunderstood and underestimated drugs of abuse
- People use marijuana for the mildly tranquilizing and mood and perception-altering effects it produces
- Street names
 - Pot, dope, grass, hemp, weed, hooch, herb, hash, joint,
 Acapulco gold, reefer, sinsemilla, Thai sticks
- Legal prescription trade names
 - Include: Dronabinal, Marinol, Sativex



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Information Gathering (THC) Federal Program

- Marijuana (THC)
 - Prescription medications
 - Marinol
 - Recent medical or surgical procedures
 - N/A
 - OTC medications
 - N/A
- Cannot accept:
 - CBD
 - Medical marijuana cards
 - Protonix



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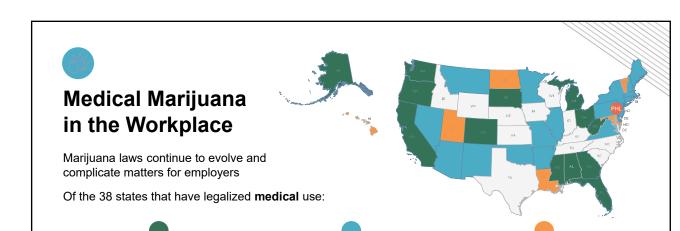
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Information Gathering (THC) NREG

- Marijuana (THC)
 - Prescription medications
 - Marinol
 - Recent medical or surgical procedures
 - N/A
 - OTC medications
 - N/A
- Cannot accept:
 - CBD
 - Protonix

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19 have statute or case law in place

addressing need to accommodate

when possible.

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Banned pre-employment marijuana testing.

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13 have regulations/case law

explicitly stating that employers do

not need to accommodate medical

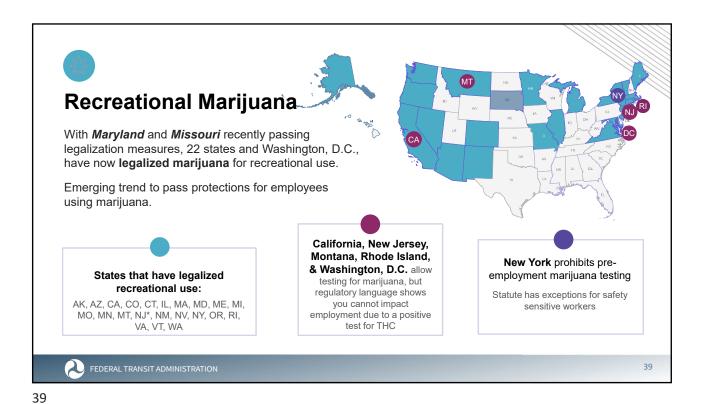
marijuana use.

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6 remain silent regarding need

to accommodate

(no regulation or case law)



Information Gathering (Invalids)

- Invalids
 - Prescription medications
 - Obtain list
 - Recent medical or surgical procedures
 - Procedures within 7 days of the collection of the specimen
 - OTC medications
 - Obtain list
- Invalid: pH 9.0 to 9.5
 - Determine if there was a 3 day or greater delay from specimen collection to arrival at the lab

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Shy Bladder

- Federal Program
 - Donor unable to urinate after being afforded the opportunity to hydrate and given an adequate window of opportunity
 - 3 hours
 - Face to face evaluation to determine if the donor has a medical condition with <u>a</u> <u>high degree of probability</u> to cause that donor not to be able to urinate
 - Remember:
 - Urine production is on the low side ~ 0.5 cc/lbs.
 - Sensation to urinate starts at about 150 cc

- NREG Program
 - Mimic federal program
 - Use an alternate specimen
 - Based on company policy
 - Hair is the ideal specimen in these instances

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Collection Site Issues

- It is not the MRO's responsibility to make decisions about factual disputes between the employee and the collector concerning matters occurring at the collection site that are not reflected on the CCF
 - Example: Allegations that the collector left the area or left open urine containers where other people could access them)
- It is the MRO's responsibility to correct or document flaws
 - Correctable flaws
 - Donor name/signature missing
 - Collector name or signature missing
 - Wrong CCF
 - Documenting flaws
 - No temperature



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MRO Process: What It Does and Doesn't

Does

- Assure the external chain of custody is intact
- Offers the donor an opportunity to present a reasonable medical explanation
 - What is asked for may vary by drug detected
- Can help ascertain <u>potential</u> safety concerns based on the class of analyte identified
- Prompts donors to seek accommodation if they state they use decriminalized marijuana

Doesn't

- Cannot determine impairment*
- Cannot definitively say how much or when a donor "used"
- Does not provide the donor "the answer" to the question
- Does not make an employment decision
- Does not create employer policy
- Does not resolve allegations made by the donor



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Non-MRO Refusal to Test

- The majority of refusal to test determinations are not the MRO's to make
 - Pursuant to § 40.355
 - The employer must make the determination that a driver/employee has refused a drug or alcohol test
 - This is a non-delegable duty of the actual employer
 - Your service agent may provide advice and information regarding refusal-to-test issues

- § 40.191 Refusals
 - Failure to appear for any test (except a pre-employment test) within a reasonable time
 - Failure to remain at the testing site until the testing process is complete
 - In the case of a directly observed or monitored collection in a drug test, fail to permit the observation or monitoring of your provision of a specimen (see § § 40.67(l) and 40.69(g));
 - Failure to cooperate with any part of the testing process



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MRO Best Practices

- Company/TPA Perspective
 - Know your MRO
 - Hours of operation
 - Disaster recovery plans
 - Know how he/she handles:
 - Non-negative review
 - Decriminalized marijuana
 - pH from 9.0 to 9.5
 - Shy bladder
 - Provide your MRO how you want to be notified on troubled results

- MRO Perspective
 - Know your clients
 - Codify how you handle all situations
 - Negative review
 - Non-negative review
 - Decriminalized marijuana
 - » Non-DOT testing ONLY
 - pH from 9.0 to 9.5
 - Shy bladder
 - Create memos
 - Dilute results
 - Invalid results
 - Shy bladder
 - Collector determined refusals

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