

Prescription Drugs and the MRO

Dr. Nicholas Lomangino

DTAB

January 2012

This presentation was modified from its original format for 508 compliancy.

Experience

- Board Certified Internal Medicine
- Deputy Manager – FAA Medical Specialties Division
- DOT Departmental MRO since 2000 – oversee FAA Field MROs
- Regional Flight Surgeon – FAA Eastern Region
- Medical Director CMC Occupational Health Services, PC – JFK Airport
- USAF Flight Surgeon
- MRO in private industry since the beginning of workplace drug testing
- Disclaimer: This presentation represents my personal opinions and not those of the US DOT or FAA

Scope of Discussion

- Limited to Opiate Use - I do not differentiate between Opiates and Opioids
- Comments primarily focus on federal employment and regulatory requirements of medical certification and; some issues regarding private employer based programs
 - expanded panels
 - will not discuss testing under State or military regulations
 - are result of my personal experiences and conversations with MROs in private and federal sectors
- Recommendations incorporate strategic concepts and near term practical considerations with a guiding principle to balance the rights of the individual with responsibility of system caretakers

Goals

- I support the expanded opiate testing –clear safety hazard
- To give a clinicians perspective
- To give an MRO perspective
- To raise questions and provoke thought so that we may understand unintended consequences regarding the testing for prescription medication
- To promote clarity of objectives and procedures that do not unjustly identify persons who need medical care as illicit drug users

Societal Realities

Specific Drug Used When Initiating Illicit Drug Use
Age 12 or Older: 2008

- <http://www.oas.samhsa.gov/nsduh/2k8nsduh/2k8results.cfm#5.1>

The Beginning

E.O. 12564 -Sept. 15, 1986

Seeks to restrain use of illegal drugs by federal workers especially those who perform sensitive duties.

The Omnibus Transportation Employee Testing Act of 1991 requires drug and alcohol testing of safety-sensitive transportation employees in aviation, trucking, railroads, mass transit, pipelines, and other transportation industries.

Safety - Security

Migration of Societal Expectations

- Illicit drug use
 - Safety
 - Workplace
 - System
 - Prescription medication
 - Safety
 - Workplace
 - System
 - Substance abuse disorders (addiction)
 - Safety
 - » Workplace
 - » System
 - Rehabilitation standards
 - Illicit drug use
- Alcohol
 - Substance abuse disorders (addiction)

MRO issues surrounding prescription drug testing of opiates

- What is the role of MROs
- MRO Verification process
- MRO practice behaviors
- Employer Behaviors
- Donor Behaviors
- Privacy
- The End Game
- Recommendations to consider

What is the role of an MRO?

- Is the MRO a forensic examiner, safety advocate, employee advocate, employer advocate, or all of the above?
- Protect employee medical privacy from employers
 - a barrier to discriminatory personnel practices
 - avoid interference with the treatment of human suffering
 - thwart Criminal Activity
 - collaborate with diversion program enforcement
 - threat to national security
- Determine
 - illicit use
 - legal use or reasonable medical explanation

What is the role of an MRO?

- Safety – whose responsibility employer or MRO?
 - Workplace duty to worker and co-worker
 - System duty to public
 - Assessment – (verified negative)
 - MRO realistically assess drug tolerance and effect on performance
 - Objective vs. subjective standards?
 - Does the MRO understand the job requirements?
- Identify Addiction – treatment – DSM vs Occupational Standards
 - Determine (SAP or MRO/Physician)
 - adequacy of rehabilitation and
 - fitness to resume covered duties

What is the role of an MRO

- Donor Category (Privacy, regulatory applicability, MRO education)
 - Federal employment
 - Government regulated employment
 - Non government employment
 - School athletic programs

What does the E.O mean to Opiate testing?

- Heroin – illegal substance – schedule I?
- Opiates like hydrocodone and oxycodone?
(illegal acquisition / illegal use / valid medical use)
- Opiates prescribed for another person?
Diversion or
Used by a spouse – same illness or other?
- Unused medication used by the prescribed individual but for a different condition at a different time?
- Recurring chronic condition?
(no, r/o iatrogenic *addiction* and impact to safety)
- Legally prescribed for an active condition but not used by the prescribed route of administration?

MRO Verification process

- Interview
 - Most likely telephone (no ability to clinically observe or to conduct an examination)
- Fax copy of pharmacy receipt/bottle label
- Dr.'s note
- MRO/Pharmacist or MRO/Dr phone call
 - What are the privacy rights and responsibilities
- Label info from donor required
 - Donor name as it appears on the label
 - Prescription number/med
 - Pharmacy name/number/phone
 - Prescribing physician name
 - Date prescription filled

MRO Verification process

- To be reported positive:
 - There must be verifiable illegal use, or
 - The MRO must be unable to verify that the medications have been legally obtained
- MRO's may be unable to verify or obtain documentation of all prescriptions:
 - Polypharmacy
 - Different drug stores
 - Doctor shopping

MRO Verification process

Acceptability issues -Evidence of use

- Documentation of existing medical condition
 - Post drug collection visit
 - Existence of condition – after the fact, physical findings or report of history
 - Age of prescription
 - Quantity prescribed and dispensed
 - Prescribing provider unavailability
- Privacy – Rights and responsibilities

MRO Verification process

The Downgraded Test (verified negative)

- Loss of Privacy
(when a particular result is reported after all the others, employee is unreachable and employer is contacted, stand down policy)
- Requirements to divulge medical information that represents a safety hazard (safety provision)
 - Treating physician is a patient advocate or unavailable
 - Post test diagnosis
 - Documented family use/prescription
 - Opportunity for enabling behaviors
 - Opportunity for transference
 - Dual diagnosis of SUD and Pain Syndrome
(impairment of safety related duties- underlying condition and drug)

MRO Verification process

What MROs cannot do

- MROs are unable to verify abusive use of legal prescriptions
- MROs are unable to verify impairment
- MROs are unable to verify whether or not someone is fit for duty simply on the basis of the drug test result
- Most MROs do not have a clear understanding of the job task requirements, job environment, or a clear understanding of the physical and mental (executive functioning) requirements of a position;
AND no method of objective assessing of impairment;
neither does the individual

MRO Practice Behaviors

- Illicit use – binary process
- Legal Use – binary process
 - Medical encounter at time of illness
 - Date of prescription within days before the drug test
- Medical Judgment – or not
 - Morphing history, facts changing?
 - Foreign Acquisition – importation?
 - Rx and condition valid – Rx is old, medical f/u inconsistent
- MROs need to understand the job to make a reasoned judgment or is the use of the medication sufficient
- What value do we place on consistent and uniform MRO practices?
- When test outcome is a judgment and doubt is present MROs tend to cancel or downgrade to negative

MRO Practice Behaviors

Privacy – Rights and Responsibilities

Privacy Act – the two edge sword made from an alloy of Federal and State steel

(Harmonization - Federal Workplace Testing and Private Sector / regulated industry)

- Can the MRO contact the pharmacy (with or without a release)?
- Can the MRO require the donor to sign a release?
- Should the MRO contact the treating physician?

MRO Practice Behaviors

By the way -What do these phrases mean?

- Likely to pose a significant safety risk
- Reasonable medical judgment
- MRO must attempt to release as little specific information
- Significant safety hazard
- Diagnoses or other specific details of medical information do not need to be provided
- Essential Government Functions
- If, as an MRO, you receive such information from the prescribing physician, you must transmit this information to any third party to whom you previously provided information about the safety risks of the employee's other medication.

Employer Behaviors

- When an MRO calls for employee contact information
 - Raises doubt about the employee who has used medication as a drug user or unfit for duty
 - Employers must document the nexus of drug testing to employment duties
 - Is the practice of a simple declaration of adverse impact to safety sufficient? (res ipsa vs particularized assessment)
 - Must be able to provide the documentation for a fitness for duty evaluation
 - Clear guidance on reasonable suspicion testing
 - Observable behavior
 - Reliable information

Donor Behaviors

Explanation	Example
Borrowed	Spouse / Friend / Man's best friend
Self-prescribed	Old med but used for different problem
Foreign RX or OTC Codeine Amphetamine	Common in transportation or border operations *riot act
Taken in excess - Used other than as prescribed	Old bottle – new drug supply
Obtained by Internet Amphetamine	No rx / proof of purchase
Off-label use	Buphenorphene
Doctor Shopping	Multiple prescribing providers Doctor Feelgood* *The addict is resourceful and motivated

Privacy Laws

- **Privacy Act of 1974**,
5 U.S.C. § 552a,
[Public Law No. 93-579](#)
- (i)(1) Criminal Penalties. - Any officer or employee of an agency, who by virtue of his employment or official position, has possession of, or access to, agency records which contain individually identifiable information the disclosure of which is prohibited by this section or by rules or regulations established thereunder, and who knowing that disclosure of the specific material is so prohibited, **willfully discloses the material in any manner to any person or agency not entitled to receive it**, shall be guilty of a misdemeanor and fined not more than \$5,000.
(2) Any officer or employee of any agency who willfully maintains a system of records without meeting the notice requirements of subsection (e)(4) of this section shall be guilty of a misdemeanor and fined not more than \$5,000.
(3) Any person who knowingly and willfully **requests or obtains any record concerning an individual from an agency under false pretenses** shall be guilty of a misdemeanor and fined not more than \$5,000.

http://workplace.samhsa.gov/DrugTesting/pdf/MRO_Manual_2010_100908.pdf

- The MRO must send the report using one of the following methods, in a manner designed to ensure confidentiality of the information:
- Information provided by the donor (especially at the donor's request) to the report (Note: *this must not include specific confidential medical information*),

MRO Manual 2010 Confidentiality

2. Maintain the confidentiality of the information received during the review process, including:
 - a. information related to the donor's medical condition,
 - b. medications,
 - c. medical diagnosis, and
 - d. medical history.

BUT

MRO Manual 2010 - Confidentiality

- Despite this general requirement to maintain the confidentiality of medical information, there are certain circumstances in which the MRO may provide such information to other parties. In these instances, prior to the donor interview, the **MRO must inform** the donor that disclosure of information learned as part of the medical review process may occur **if**:
 - There is a **significant safety hazard** associated with donor performing assigned duties,
 - Medical disqualification of the donor exists under applicable regulations, or
 - The Federal agency's regulations specify requirements for disclosure of such information under other circumstances.
- When the MRO releases otherwise confidential information due to such concerns, the **MRO must attempt to release as little specific information** as possible and release such information only to parties that clearly “need-to-know.”

AND

MRO Manual 2010 Confidentiality

- Diagnoses or other specific details of medical information do not need to be provided to non-medical personnel. For example, Federal agency representatives may only need to be informed that a safety hazard may exist and that the MRO will provide specific information to the physician responsible for making medical qualification decisions regarding the donor.

In general, unless required by regulation or law, the MRO must only discuss specific medical information with other physicians or qualified health professionals.

Privacy

The Health Insurance Portability and Accountability Act of 1996

Authorization. A covered entity must obtain the individual's written authorization for any use or disclosure of protected health information that is not for treatment, payment or health care operations or otherwise permitted or required by the Privacy Rule.⁴⁴

Summary of the HIPAA Privacy Rule

<http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html>

- **Permitted Uses and Disclosures.** A covered entity is permitted, but not required, to use and disclose protected health information, without an individual's authorization, for the following purposes or situations:
 - (1) To the Individual (unless required for access or accounting of disclosures);
 - (2) Treatment, Payment, and Health Care Operations;
 - (3) Opportunity to Agree or Object;
 - (4) Incident to an otherwise permitted use and disclosure;
 - (5) **Public Interest** and Benefit Activities; and
 - (6) Limited Data Set for the purposes of research, public health or health care operations.¹⁸
- Covered entities may rely on professional ethics and best judgments in deciding which of these permissive uses and disclosures to make.

HIPPA

- **(5) Public Interest and Benefit Activities.** The Privacy Rule permits use and disclosure of protected health information, without an individual's authorization or permission, for 12 national priority purposes.²⁸ These disclosures are permitted, although not required, by the Rule in recognition of the important uses made of health information outside of the health care context. Specific conditions or limitations apply to each **public interest purpose**, striking the balance between the individual privacy interest and the public interest need for this information.
- ***Required by Law.*** Covered entities may use and disclose protected health information without individual authorization as required by law (including by statute, regulation, or court orders).²⁹

HIPPA

- ***Essential Government Functions.*** An authorization is not required to use or disclose protected health information for certain essential government functions. Such functions include: assuring proper execution of a military mission, conducting intelligence and national security activities that are authorized by law, providing protective services to the President, making medical suitability determinations for **U.S. State Department employees**, protecting the health and safety of inmates or employees in a correctional institution, and determining eligibility for or conducting enrollment in certain government benefit programs.⁴¹

Bottom Line on Privacy

- Can be convoluted –
 - Practically never understood or accepted
 - Consents generally required
 - Initially contemplated for use of illicit drugs, but are the same conclusions still valid for prescription medication?
- We need to arm MROs with clear regulatory support
 - Specific references, citations and FR legal interpretations to close off the debate

The Safety End Game

- Eliminate the negative affect of drug use on society
- Must be a process of inclusion not disenfranchisement
- Mandated Rehabilitation
 - condition of performance
 - define level of care
 - effective monitoring – compliance vs. recovery
 - for how long – chronic relapsing condition
- Fitness for Duty
 - Physician and treatment provider should have knowledge of duties, and performance indicators
 - Consider inter-current illnesses – must consider the person as a whole
 - Consider the disease as well as the medication

Recommendations

- Restatement of program objectives:
 - Identification of illicit drug use
 - Deterrence of illicit drug use
 - System Safety – transportation, etc.
 - Workplace safety – employee safety
- Specific Workplace Definitions:
 - Substance use disorders in the workplace
 - Recognize weakness of clinical foundation of DSM-IV which relies on accuracy of clinical history versus the adversarial nature in an occupational setting that relies on observed conduct
- Rehabilitation Standards: occupational regulatory mandate
- Monitoring Standards and Practice
 - Consistency of MRO practice for the downgraded test
 - Clarity of privacy concerns

Recommendations

Recommendation	Issue
Access to State Prescription Databases	Privacy vs. program objectives
Encourage development of company policy's and fitness for duty standards	Employers must be able to provide the documentation for a fitness for duty evaluation
Monitoring Effectiveness	Corporate turnstile
Standards for MRO Determination Drug prescribed (dose/ route) Maximum time Consider condition	Qty Dispensed/ Daily min dose PRN – max time Acute and Chronic Use
Expanded MRO training	Without clear guidelines = variability and arbitrary implementation
MRO Subcommittee	

Recommendations

Education of work force by employers

- Illegal use - definitions
- Medication misuse and abuse
- Employee responsibilities when performing in a covered position
 - Not just simply notification of drug testing and the process
 - List prohibited activities, in particular using someone else's medication

Recommendations

MRO, Safety and Fitness for Duty

- MRO review and Fitness for Duty evaluation are not the same
 - Need specific language to separate these duties
 - Lack of general awareness of job demands by MRO
 - MRO should not have to make a qualitative judgment to determine if use could represent a safety hazard as part of the MRO review
- Partner with Medical Education Institutions
 - Medical Schools
 - Physician Assistant and Nurse Practitioner programs
 - CME providers
 - Pharmaceutical Labeling

END