

The Family Physician As Medical Review Officer

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Background: The medical review officer is a position established by federal statute in 1988. The role of the medical review officer is to interpret positive urine drug tests in view of the donor's medical history. With more than 4 million workers affected by the Department of Transportation guidelines for workplace drug testing, and many private employers having urine drug screening programs, there is a need for medical review officers.

Methods: Materials for this report were collected while the first author was pursuing certification from the Medical Review Officer Certification Council. Much of the data was published in the Federal Register from 1988 through 1993.

Results and Conclusions: Urine drug testing is divided into three stages: collection, laboratory analysis, and medical review of results. Because the workplace urine drug test is a forensic test, the urine is collected under strict chain of custody. Analysis of specimens is conducted by laboratories that have met stringent technical criteria and are approved by the Substance Abuse and Mental Health Services Administration (formerly the National Institute on Drug Abuse). Family physicians are in a unique position to become medical review officers because of their training and professional roles. Educational programs are available for physicians interested in becoming a medical review officer. (*J Am Board Fam Pract* 1995; 8:29-33.)

The medical review officer is an entity established by federal mandate in 1988 and is defined as "a licensed physician responsible for receiving laboratory results generated by an agency's drug testing program who has knowledge of substance abuse disorders and has appropriate medical training to interpret and evaluate an individual's positive test result together with his or her medical history and any other relevant biomedical information."¹ The role of the medical review officer is to review and interpret urine drug test results. Although interpretation of a positive drug test might appear straightforward, the actual process of following the regulations of the Department of Health and Human Services (DHHS) and Department of Transportation (DOT) can be difficult. The reason for having a physician receive the results of drug tests is that only a physician has the necessary training to determine whether a positive urine drug test is the result of legitimate use. Family physicians are particularly suited to becoming medical review officers because of their training.

History of Workplace Drug Testing

The history of urine drug screening by the federal government started in the military in 1981.² The US Department of Defense initiated periodic and random drug screening because of high rates of drug use in the young adult population. In 1986 President Reagan signed Executive Order 12564, which directed federal agencies to develop programs to achieve drug-free workplaces.³ This order specifically prohibits use of illegal drugs by federal employees. It also requires that employees be educated about drug abuse, supervisors be trained about drug use, and employee assistance programs be provided to help employees who use illicit drugs. An additional part of the order calls for drug testing. This executive order and Congressional Public Law 100-71⁴ charged the DHHS to develop technical procedures regarding drug testing, which resulted in the 1988 publication of the DHHS "Mandatory Guidelines for Federal Workplace Testing Programs."¹

These guidelines were adopted by the DOT and implemented in 1989 and 1990.⁵ More than 4 million employees working under the DOT guidelines were affected by these regulations. The governmental agencies included as part of the DOT are the Federal Aviation Administration, the Federal Highway Administration, the Federal Railway Administration, the Urban Mass

Submitted, revised, 17 August 1994.

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Transportation Administration, the Coast Guard, and the Research and Special Programs Administration (natural gas, liquefied natural gas, and hazardous liquid pipeline operations). In 1988 Congress enacted the Drug-Free Workplace Act,⁶ requiring federal agencies entering into contracts to have contractors guarantee provision of a drug-free workplace, and the Department of Defense issued regulations requiring contractors to institute drug-free workplace programs.⁷ Although the Nuclear Regulatory Commission has been testing employees since the early 1980s, in 1989 the Commission published rules on "fitness for duty" aimed at creating a drug-free workplace.⁸ Many private companies have required urine drug screening as part of their preemployment process since the early 1980s.⁹ Although current federal regulations do not regulate private sector drug testing, pending legislation will require private employers to follow the general rules outlined by the DHHS.^{10,11} State laws might also affect the ability of private companies to perform urine drug testing.¹² Because of the legal and social ramifications, it is imperative that urine drug screening in the private sector be done in an appropriate manner.¹³ There is presently no requirement for private companies to have a medical review officer as part of their urine drug screening programs, but most employers have elected to do so.

Urine Drug Screening Procedures ***Collection Procedures***

The urine drug screening process is divided into the collection, the analysis, and the review. The collection of the urine specimen is performed under a strict chain of custody that is fully described in the *Urine Specimen Collection Procedures Guide* developed by the DOT.¹⁴ At the collection site is "a person who instructs and assists individuals . . . and who receives and makes an initial examination of the urine specimen provided by those individuals."^{1,5} Collection site personnel must be trained in urine collection procedures to ensure that the specimen is securely tracked from the beginning of the collection until the time of shipment and that the confidentiality and the privacy of the donor are protected.¹⁵

The person submitting to the urine test should be identified by photograph or an employer representative and allowed to urinate in privacy un-

less a witnessed specimen is needed (e.g., adulterated specimen, specimen temperature outside acceptable range, previously positive test). The person being tested should sign a consent form agreeing to have their urine tested and for the results to be sent to the company's representative and medical review officer. The specimen volume required is 45 mL to be collected during a single voiding, with 30 mL becoming the primary specimen and 15 mL being used as the split specimen (split specimens are now mandatory for all DOT employees).¹⁶ The specimens should not leave the sight of the donor or the collector until they are prepared for shipping. The collector should measure the temperature of the specimen within 4 minutes (acceptable range 90° to 100°F or within 1.8°F of the donor's body temperature) and should inspect the specimen for color and signs of adulteration. Specimens should be sealed with a tamperproof seal, and the seal or identification label placed on the collection bottle should be initialed by the donor and collector.

The collector is responsible for completing the drug testing custody and control form, which indicates that the donor has released the specimen and the collector has received it. The custody and control form is a seven-part form. Copies 1 and 2 accompany the specimen to the laboratory (with copy 2 later sent to the medical review officer with the analysis result), copy 3 goes directly to the medical review officer, copy 4 is given to the donor, copy 5 is retained by the collector, copy 6 is sent to the employer representative, and copy 7 is sent with the split specimen. Donor information is allowed on copies 3, 4, 5 and 6 only. Each specimen submitted must have documented the form every transfer of possession in the chain of custody with appropriate signatures of the donor, collector, and shipper, who acknowledge transfer and receipt of the specimen. If the specimen is not shipped immediately after collection, the collector is responsible for ensuring the security of the specimen until shipping has occurred. DOT regulations require the collector and donor to sign separate certification statements indicating the specimen was collected, labeled, and sealed appropriately.

Because there is no standardized custody and control form, each laboratory has its own version. For non-DOT drug screening tests, a similar custody and control form is used. This forensic test

J. Am. Board of Forensic Toxicology, Inc. 15152/H/10/11/95
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has serious implications for the donor; therefore, the chain of custody must be defensible in a legal challenge.¹⁷ On every part of the completed control form there should be a preprinted specimen identification number, the donor's social security number or identification number, the medical review officer's name and address, the drugs for which the specimen is to be tested, the type of test to be conducted (i.e., preemployment, random, reasonable cause, biennial, or post-accident), indication that temperature of the specimen has been read, each possession transfer, and the name and signature of the collector. DOT regulations require there be a statement for the medical review officer to verify the specimen as either negative or positive. This statement appears on parts 2 and 3 of the custody and control form.

Laboratory Procedures

The drugs tested in DOT urine drug screening programs are marijuana, cocaine, codeine and morphine, phencyclidine (PCP), and amphetamines (the so-called NIDA 5).^{1,5} All samples are initially screened by immunoassay techniques, and DOT rules specify the concentration thresholds for each of the drugs. The purpose of the immunoassay screening test is to eliminate true negatives from further consideration. Mandated screening threshold concentrations for immunoassay are marijuana metabolites 50 ng/mL, cocaine metabolites 300 ng/mL, opiate metabolites 300 ng/mL, PCP 25 ng/mL, and amphetamines 1000 ng/mL.^{1,5} These thresholds levels were chosen to differentiate false positives and inadvertent exposures (e.g., passive inhalation of marijuana smoke) from users. At concentrations lower than the mandated thresholds, the samples are deemed negative and require no further testing. DOT regulations require urine samples that test positive for any NIDA 5 drug to be confirmed by gas chromatography and mass spectrometry (GC-MS). The GC-MS thresholds are also specified by DOT rules and are 15 ng/mL for the 11-nor- Δ -9-tetrahydrocannabinol-9-carboxylic acid metabolite of marijuana, 150 ng/mL for the benzoylecgonine metabolite of cocaine, 300 ng/mL for codeine or morphine, 25 ng/mL for PCP, and 500 ng/mL for amphetamine and methamphetamine.^{1,5}

For non-DOT urine drug screening programs, many employers screen for additional drugs including barbiturates, benzodiazepines, propoxyphene,

hydrocodone, and other drugs. Private (non-DOT) employers can also use different thresholds. The DOT has consistently refused to allow drugs other than the NIDA 5 to be included in their drug screening program. The Nuclear Regulatory Commission has been allowed to test for an expanded list of drugs for their purposes and has authority to use different concentration thresholds.¹⁸

Laboratories approved to perform DOT urine drug testing undergo a specific, rigorous certification process.^{19,20} There are approximately 85 laboratories in the United States that are certified,²¹ and a list of them is published monthly in the *Federal Register*. Certification of the laboratories is conducted by the Substance Abuse and Mental Health Services Administration and requires three cycles of performance testing. Laboratories must correctly identify and confirm the presence of the specified drugs in 90 percent of test samples submitted with each cycle of testing. Even one falsely positive test result in this cycle of performance testing automatically disqualifies the laboratory from further consideration. During certification a laboratory is required to measure the drug level accurately in 80 percent of the test samples to within 20 percent of the known values for that sample. After certification, the laboratory is challenged every other month with at least 10 test specimens, and failure to achieve accurate determinations will result in suspension. For continued quality assurance, each certified laboratory is inspected by a team of 3 inspectors twice a year. The above requirements are in addition to blinded specimens, which are required to be submitted by employers (3 percent of total), and batch testing, with 10 percent of the samples of each batch being control samples of known content.

Medical Review Officer Procedures

Negative urine drug tests are required to be administratively reviewed, and records of negative tests must be kept for 1 year. Positive urine drug tests are reviewed by the medical review officer to determine whether a legitimate medical explanation exists. DOT regulations require the medical review officer to discuss positive tests with the donor. This discussion might include review of the donor's medical records and confirmation of prescriptions. The employee can request within 72 hours of notification of a positive test that the split specimen be tested. The medical review of-

ficer is then required to notify the laboratory in writing of this request, and the laboratory is required to send the split specimen to a different DHHS-certified laboratory for analysis. Records of positive urine drug tests must be kept for 5 years. Of the NIDA 5 drugs, only codeine and morphine are commonly prescribed drugs. PCP is illegal, amphetamines have limited medical uses, and marijuana and cocaine have very limited medical uses. DOT regulations require clinical signs be present before opiate use can be verified as positive, because normal foodstuffs (e.g., poppy seeds)²² can cause a positive opiate urine drug test. These clinical signs can be needle marks, clinical signs of intoxication, or even admission of illicit usage. In practical terms it is difficult to verify a positive test for opiates in DOT-regulated drug testing programs.

Family Physician as Medical Review Officer

Many family physicians have large occupational and industrial medicine practices and also perform DOT (e.g., truck driver) physicals. Family physicians are, therefore, logical choices to serve as medical review officers. Even if family physicians desire not to serve as medical review officers, their offices could serve as collection sites; thus, familiarity with the rules of collection is essential. Family physicians who serve as occupational medicine physicians need to be aware of the medical review officer's role.

There is presently no mandatory educational or certification requirement for becoming a medical review officer; however, an educational course is advised. The American College of Occupational and Environmental Medicine (ACOEM)²³ created the Medical Review Officer Certification Council (MROCC),²⁴ which developed a certification examination. ACOEM offers a 2-day educational course for physicians interested in becoming a medical review officer. They also offer a 1-day medical review officer update course. One does not have to be a member of ACOEM to take the examination or the medical review officer course, but MROCC requires a medical review officer course be completed before taking the certifying examination.

Future of the Medical Review Officer

Although there has been criticism of the medical review officer process (the medical review officer

adds time and expense to the drug screening process), the DHHS and DOT believe the protection offered to the donor by having a physician determine legitimate usage outweighs any other consideration. There has been the suggestion that someone other than a physician (e.g., nurse) be a medical review officer, but this suggestion has not garnered much support. It is likely the role of the medical review officer will be expanded to include fitness-of-duty determinations. There might eventually be a governmental requirement for medical review officer certification. Other future governmental interventions being considered are standardization of the custody and control form, standardization of regulations by different governmental agencies, lower screening thresholds for certain drugs, and regulation of private sector testing.

Summary

Medical review officer is a position established by federal statute that serves an integral role for the protection of drug screening donors who are under DOT rules. The medical review officer is essentially in a neutral position that stands separate and apart from the physical examination. Family physicians are in an ideal position to serve as medical review officers because of their training and normal professional roles. An initial educational program is advised, with continuing education to keep abreast of this changing field. Certification in this field is desirable.

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