From: Ted Shults [mailto:teds@mindspring.com]
Sent: Wednesday, October 08, 2008 2:35 PM
To: zzMSHA-Standards - Comments to Fed Reg Group
Subject: RIN 1219-AB41

Dear Sirs

Attached are the public comment on the MSHA drug and alcohol rule RIN1219-AB41.

An attempt was made to submit these comments through the electronic portal. It did not appear that the attachment was received.

Thank you.

Theodore F. Shults
Chairman
American Association of Medical Review Officers

AB41-COMM-58

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October 7, 2008

Richard E. Stickler
Acting Assistant Secretary for Mine Safety and Health
MSHA
Office of Standards, Regulations, and Variances
1100 Wilson Blvd, Room 2350
Arlington, VA 22209-3939

RE: Public Comment, RIN 1219-AB41

Dear Mr. Stickler:

I am pleased to submit the following in response to your invitation for public comments on the role of Medical Review Officers as outlined and envisioned in the MSHA Proposed Rule: *Alcohol- and Drug-Free Mines: Policy, Prohibitions, Testing, Training, and Assistance.*

I am the Chairman of the **American Association of Medical Review Officers** (AAMRO), a nationally recognized and respected certification board established in 1991 to train and support physicians acting as Medical Review Officers in workplace drug and alcohol testing programs. AAMRO works to establish and enhance guidelines and standards of practice by means of a national credentialing and registry program. AAMRO has certified over 6,000 physicians as MROs and has sponsored MRO training programs throughout the United States, Canada and Mexico. In 2001 passing the AAMRO written examination became a requirement of the U.S. Department of Transportation under its drug and alcohol testing regulations for physicians reviewing DOT drug test results. MRO certification is also required by the Nuclear Regulatory Commission Fitness-for-Duty Program and the U.S. Coast Guard. Many of the MROs who are involved in the mining industry are also AAMRO-certified.

I am, however, submitting these comments on my own behalf. I do not speak for all of the certified MROs but as someone who has worked in this field for 30 years as a consultant, teacher, toxicologist and attorney. I have authored many texts and papers in the field. I am the editor of MRO*ALERT*, a publication which advises MROs of the technical, medical and legal issues of drug and alcohol testing. I am also a board member of the American Board of Forensic Toxicology, which is involved in the certification of forensic toxicologists and laboratories involved in forensic toxicology.

From my perspective, MSHA's *Alcohol- and Drug-Free Mines: Policy, Prohibitions, Testing, Training, and Assistance* is a groundbreaking federal program in two fundamental ways. First, it requires testing for an expanded panel of drugs; and second, it requires employers to give employees

one opportunity for assessment and return to work. These are good ideas and they are functionally related. It is a pioneering rule—but as such presents some fundamental challenges. Here are some of the concerns the rule presents.

Clearly Defining the Role of the Medical Review Officer

First and foremost, it must be appreciated that the federal model for drug testing was fundamentally designed as a demand-reduction program focused on illegal drug use and not prescription drug abuse. It has been expanded over time by regulators and employers to address safety concerns, but in a reactive rather than systematic manner. When a prescription drug issue presents itself, the Medical Review Officer has a duty to notify the employer of a potential safety risk.

Although there appears to be some confusion on this issue, the MRO plays a critical but discrete and carefully defined role in the drug testing process. First, the MRO provides the important opportunity for the donor to discuss his or her results and where applicable provide an alternative medical explanation for the results. The term *alternative medical explanation* does not mean that anything that is technically possible is allowable. An acceptable alternative medical explanation is defined by regulation or employer policy. It is not defined by the MRO. The MRO does not make policy; the MRO supports policy. For example, the use of medical marijuana in compliance with a state medical marijuana act is not an acceptable alternative medical explanation for THC in a urine specimen under federally required drug tests. However, it may be allowable for an employer who is drug testing under their own authority. Where there is some flexibility in federal regulations (such as the use of a foreign medication), it is ultimately an issue of employer policy as to how the MRO should address the facts presented.

The touchstone for the MRO and the essential question addressed by the existing federal model of workplace drug testing is *"Did the donor obtain the drug legally or illegally?"* This is determined by the MRO in the verification of prescriptions submitted and the medical records of the donor. If it is legal, the results are designated as negative. If legal possession is impossible (such as for PCP) or not established by the donor, the results are deemed as positive.

MRO Verification or Diagnosis?

Although I do not believe it is the intent of the MSHA rule, I am concerned that the process outlined changes the status of the MRO in a legally significant manner. Determining whether a donor has a prescription drug problem is essentially diagnostic in nature and is fundamentally different from verifying whether or not the donor has a prescription. The legal and medical distinction is critical in that forcing a diagnosis would appear to be creating a doctor-patient relationship—a relationship the courts have determined is not created by traditional MRO practice.

Although the MSHA rule does not expressly require the MRO to make a diagnosis, it does so indirectly. The rule does state that *"possession of a valid prescription from a medical professional in and of itself may not constitute sufficient proof of legitimate and appropriate use"* [§66.402]. That is fine, but the only alternative for the MRO is to report the drug test as *positive*. I think this is a

problematic approach. I have little doubt that by following this model many legitimate prescription medication patients will end up with "positive" drug tests, through no fault of theirs, their physician or the MRO. The fundamental nature of the problem is that the determination of abuse is rarely black and white. This problem, however, can be readily fixed.

Currently, under the DOT regulations (49 CFR Part 40) the issue of safety and prescription drug use is addressed on a case-by-case basis when presented to the MRO. The end point is that the MRO must determine whether the drug use and/or the medical condition revealed present a safety problem. This is distinguishable from making a determination of whether the donor has a prescription drug problem. It is certainly distinguishable from designating the results as "positive."

Under no circumstances should "legal" prescription drug use be designated as a "positive" drug test. Instead, the MRO should report the result as an immediate safety concern or medical qualification issue requiring further assessment and diagnosis. At the same time, I think it would be reasonable for the MRO to "hold" the reporting of a negative result in the face of a potential prescription drug or medical problem. (Naturally, donors who are unable to provide valid prescription use or medical records showing administration of the drugs in question would have positive drug test results.)

What I am recommending is that the MRO process be limited to verification of prescriptions and the identification of donors that need further assessment. The MRO can certainly do that assessment, as can a qualified physician or substance abuse expert.

How Is Prescription Drug Abuse Determined?

The MSHA rule defines prescription drug abuse not in the definition section but in the text as *whether the individual is using the medication in accordance with the prescriber's instructions.* That is certainly a good workable definition, but it is not comprehensive.

From a medical perspective the term *prescription drug abuse* is used generically to describe the excessive and harmful usage problems that certain people have with prescription medications. *Prescription drug abuse* covers both the diagnostic criteria of substance abuse and the diagnostic criteria of substance dependence (addiction). Essentially, *prescription drug abuse* means using too much prescription drug, usually of the sedative-hypnotic class (tranquilizers and sleeping pills) and the opiate (narcotic) class. A broadly accepted and somewhat more refined and revealing definition of prescription drug abuse is *"The intentional misuse of a medication outside of the normally accepted standards of its use."* This is very similar to MSHA's definition.

What is revealing in this broadly accepted definition is that it introduces the complexity of determining *"intentionality."* Intentionality is not an issue with illegal use, and it is not something an MRO can definitively determine. Determining whether a person is using *too much* or is *using the medication in accordance with the prescriber's instructions* or whether use is within or outside the normally accepted standards is not much simpler.

I am very concerned that there appears to be the notion in the proposed rule that an MRO can determine whether an individual is abusing a prescription medication or taking it in accordance with the prescriber's directions based upon an enlightened interpretation of the normalized urine concentrations of the drug(s) or drug metabolites in question. This is a pharmacological fiction that is being promoted by some toxicologists who have an economic stake in this process. This type of data may be useful, but it is simply not definitive. The urine of a chronic pain patient who is stabilized on a narcotic analgesic over a long period of time is identical to the urine of an opiate addict who robs the pharmacy for narcotics. The MRO could sort out such a situation based on the legal/illegal use criteria of having or not having a prescription but not according to the urine concentration of drugs or metabolites.

Also implicit in the rule is the fiction that an individual who is taking a medication in accordance with the prescriber's instructions is, to use the non-medical terminology, A-OK. The appropriate bottom line for this rule is assuring mine safety by addressing and managing the adverse consequences of prescription drug use and abuse—not solely abuse. Physicians tend to be in general agreement that a patient who is starting a prescription course of opiates, benzodiazepines and Soma for pain should not be piloting helicopters.

Fitness for Duty

I am encouraged that your rule states that it is not MSHA's intent *"to have the MRO determine whether the use of a given substance is compatible with the performance of safety-sensitive job duties, as this is a determination that is best made by the miner's physician."* I would like to recommend however that employers retain the independent right to a third-party medical assessment to determine whether the miner's medical condition is compatible with the job requirements. The medical directors of the mines are in the best position to make that assessment.

Pre-employment Testing and the ADA

I am pleased that the MSHA rule requires pre-employment alcohol testing and makes the testing compliant with the Americans with Disabilities Act by requiring a conditional offer of employment as a prerequisite to alcohol testing.

On a related note, I have concerns that testing for prescription drugs may also require employers to make a conditional offer of employment to applicants as a prerequisite for testing for prescription drugs. In an abundance of caution I have recommended that practice to private employers. It is clear that the ADA carves out drug testing for illegal drugs as not being a medical test, but there is no case law I am aware of that deals with testing for prescription drugs that, although they can be used illegally, are overwhelmingly used legally.

Prescription Drug Testing and HIPAA

The investigation and verification of prescription drug use by the MRO and any follow-up assessment requires interaction with treating physicians, hospitals and pharmacists. All of these healthcare providers will require HIPAA authorizations to release medical information. Although donors who refuse to release information or rescind authorizations are considered to be refusing to cooperate with the employer's drug testing program, I would recommend requiring the donor to execute HIPAA waivers or authorizations as part of the rule.

MRO Guidelines and Suggestions

AAMRO has been working with the MRO community to develop guidelines for managing prescription drug use. Many states have prescription drug databases which have been very helpful in identifying donors with multiple prescriptions and multiple treating physicians who may not know of each other's existence. Some MROs are looking at these databases to flag potential abuse problems. It appears to be remarkably useful.

The White House Office of National Drug Control Policy has promoted the concept of physicians and healthcare providers screening all patients for substance abuse disorders with a short questionnaire. The unavoidable acronym for this process is SBIRT for Screening, Brief Intervention and Referral to Treatment. This may be more effective for alcohol and tobacco use, but the concept is something that MROs will be looking at as part of their practice. The required testing for prescription drugs called for by your rule and the information obtained by the MRO will provide the opportunity for intervention, treatment and rehabilitation.

My hope is that this rule will provide an effective approach for the assessment and diagnosis of prescription drug abuse, and will allow for miners to be returned to duty. I believe that the final rule will frankly deter all forms of substance abuse. There is no perfect solution, but this is a giant step in the right direction.

I endorse your efforts to address this significant and complex problem and I hope that my comments are useful.

Sincerely,

Theodore F. Shults, JD, MS
Chairman