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Subject: RIN 1219-AB41

Comments attached

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RE: RIN 1219-AB41 Public Comment

The following comments are provided concerning MSHA's Proposed Rule for drug and alcohol testing in the mining industry. I currently serve as the Regulatory Affairs Officer for FirstLab, Inc. a national Medical Review Officer (MRO) and Third Party Administrator (TPA) company providing Drug Free Workplace Program services to several thousand employers in the US, Canada and Mexico. I have served in various policy analyst positions with the US Departments of Army, Defense and Transportation in developing, implementing and enforcing regulations on drug and alcohol testing. I serve on the faculties of the American Society of Addiction Medicine and the American College of Occupational and Environmental Medicine for their Medical Review Officer training courses. Additionally, I have authored several books, chapters, and technical papers on workplace drug and alcohol testing. Thus, it is in the context of over 20 years of experience in the field of public policy and programs designed to facilitate drug and alcohol-free workplaces, that I submit these comments on the MSHA NPRM.

OVERALL COMMENT:

MSHA is to be commended for addressing the potential impact of drug and alcohol abuse and misuse on safety in the mining industry. A comprehensive policy and program that includes drug and alcohol awareness education, drug and alcohol testing, employee assistance programs and rehabilitation, and standards of conduct related to drug and alcohol use is essential for the mining industry. The framework for policies and programs in the mining industry must come from a MSHA regulation that standardizes the substance abuse deterrence and detection initiatives that foster mine safety and protect employees' rights. In general, the MSHA proposed rule accomplishes that. There are several specific elements of the proposed rule, however, that warrant further consideration and modification to optimize its objectives and effectiveness.

TEN DRUG PANEL: §66.301

While I understand MSHA's rationale for expanding the drug testing panel beyond what is currently used in other Federally-mandated workplace drug testing programs, I am not convinced that the NPRM adequately addresses the issues associated with urine drug testing for classes of drugs that consist primarily of prescription medications as opposed to illicit non-pharmaceutical drugs . Urine drug testing does not lend itself to determining impairment, intoxication or any standardized measurement of dose or amount of drug consumed. While synthetic opiate drugs, including methadone have substantial potential for illicit use and abuse (e.g. use for nonmedical purposes), there is little evidence to support the same for barbiturates, propoxyphene, and benzodiazepines. Based on data from several large

medical review officer practices, close to 90% of all laboratory urine drug test results positive for those three classes of drugs are determined to be legitimate, authorized medical use of a prescription drug.

Recommendations:

1. Consider using SAMHSA 5 drug panel with the inclusion of expanded opiates (oxycodone, oxymorphone, hydromorphone, hydrocodone)

2. Use a 300 ng/mL cut-off for the opiate screening analysis for both morphine and oxycodone. Use a 300 ng/mL confirmation cut-off for morphine, codeine, oxycodone, hydromorphone, etc.

3. If the 10 panel drug test is mandated, MSHA must establish standard cutoffs for both screening and confirmation; as well as the target analytes for confirmation analysis. Leaving the decision of cut-off levels to the laboratories or employers will create inconsistencies and potential unfairness to miners tested under the MSHA rule. A credible source for standard cutoff levels for the non-SAMSHA drug classes is the CAP FUDT proficiency program. For benzodiazepines and barbiturates, in particular, there is a significant range of analytes in each class that can be chosen for the confirmation process.

4. Employers should not be permitted to expand or customize the drug test panel on urine specimens collected and processed under the MSHA rule. If the mining operator/employer wishes to conduct additional testing under its own authority, it should use a separate specimen—not the specimen collected under MSHA authority. Basis for this recommendation is 4th amendment rights of employees concerning a search and seizure conducted under government order or authority.

5. Laboratories conducting the 10 panel drug test must have CAP FUDT certification for all classes of drugs required under the MSHA rule and must participate in proficiency testing programs for all those drug classes.

RANDOM TESTING (§66.305)

Inclusion of random testing as a measure for substance abuse deterrence is appropriate. Both the frequency of random testing and the rate or amount of random testing have been shown to affect its effectiveness in deterring the misuse abuse of prohibited substances. The following recommendations are provided concerning the NPRM's random testing requirements.

1. Consideration should be given to increasing the random testing rate, especially for the initial year or two of program implementation. A 10% annual rate of random testing is generally regarded as "maintenance or low-probability" rate. A 25% or 50% random testing rate at the start of a DFWP provides a much stronger deterrent value, by increasing the "perceived risk" of being tested. MSHA could follow the pattern of random testing annual rate determination used by both the US military and DOT programs, by beginning testing at a higher annual rate and then decreasing the rate once prevalence and incidence data are established by monitoring positive rates on random tests.

2. The NPRM does specify that random test must be conducted/administered throughout each year and the dates when testing is accomplished must be "periodic and irregularly scheduled throughout the calendar year". However, the rule does not specific that random test selections must be made throughout the year. This is important so that employees who are added to the "pool of eligible employees" at various times during the year are included in the random selection process. Again, the DOT regulatory requirements that state that employers must conduct random test selections multiple times during the year as well as actually scheduling or conducting the tests of those individuals selected throughout the year is a good way to prevent an employer for doing its 10% or 25% random pool selections at the beginning of the year and then spacing those tests throughout the year. This "one time selection" permits an employee who has been selected and tested early in the year to know that he/she will not again be randomly tested that year. The deterrent value f random testing is markedly increased if an employee recognizes that he/she could be randomly tested more than once during a calendar year.

SUBSTANTIATING LEGITIMATE USE OF OTHERWISE PROHIBITED SUBSTANCES (§ 66.402)

These comments largely address the role of the Medical Review Officer (MRO) in reviewing, interpreting and making a final test result determination on drug tests administered under the MSHA rule. The NPRM in its preamble and in section 66.101, essentially indicate that the MRO's interpretation of a laboratory positive drug test result should include, in addition to a determination that the individual has a valid, current prescription for the substance found in the urine drug test, a determination of whether the urine drug test results are consistent with the individual using the medication as prescribed. (e.g. at the recommended dosage and intervals) Making a determination of dosage and administration time/interval is based on the urine drug test quantitative levels of drug detected, or even the metabolite(s), parent drug ratios, is not a recommended practice in drug test interpretation. There are so many variables, most of which the MRO cannot accurately determine, that impact dose-response relationships. Likewise any attempt to make a sound judgment about impairment or intoxication at the time of the collection of the urine specimen based on the urine drug test result is also fraught with uncontrolled variables beyond the MRO's purview.

Recommendations:

1. The MSHA rule should mirror the DOT regulation that places the requirement on the MRO consider the medication and medical information provided by the donor at the time of the MRO interview and evaluate the relative safety risk posed by the employee's use of medications and/or underlying medical conditions. If the MRO believes that the employee's use of medication(s) presents a risk to his/her performing safety-sensitive tasks, the MRO, along with verifying the drug test as negative, the MRO reports a safety concern to the employer. The employer then has the responsibility to remove the employee from safety-sensitive duty until the issue is resolved. The recommended course of action for employers in resolving safety concerns is to have the employee undergo a fitness for duty examination by an occupational health physician or to have the employee's treating/prescribing

physician provide a written statement that the employee's use of prescribed medications does not adversely impact the employee's ability to safely perform safety-sensitive duties.

2. Section 66.101 Paragraph (2) should be changed to " . . .unless an MRO has determined that there is a legitimate medical explanation for the use of the prohibited substance."

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