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PROPOSED REVISIONS TO MANDATORY GUIDELINES FOR FEDERAL WORKPLACE DRUG TESTING PROGRAMS

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COMMENTS OF
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July 8, 2004

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To Whom It May Concern:

I am writing to provide comment on the Department of Health and Human Services' (DHHS) proposed rule changes to incorporate new technologies and procedures for federal employee drug testing. WorkSafe is one of the largest Third Party Administrators (TPA) in the industry serving both public and private sector clients throughout the nation. While WorkSafe is totally behind the concept of alternative testing methods, we believe there are significant problems with the new technologies, which include hair, sweat, and saliva testing, as are identified in DHSS' qualifying statements. WorkSafe and many members of the drug testing industry are concerned about the far-reaching consequences of these proposed guidelines in both the federal government program and beyond federal employee testing. The Omnibus Transportation Employee Testing Act of 1991 specifies that the Department of Transportation (DOT) must "incorporate" DHHS guidelines.

WorkSafe is opposed to the proposed changes in the federal drug-testing program for the following reasons:

1. Inferior Technologies

DHHS is proposing to allow the departments of the federal government to choose among different testing technologies. Yet, DHHS concedes in the Supplementary Information section of the proposed regulations that there is a technological inferiority among the alternative testing methods proposed. In many cases, a drug test result affects the career of an individual and we cannot support a testing method that does not

meet or exceed the standard of urine testing – too much is at stake. A representative sample of DHHS' statements follows.

PT Testing

"Based on the information obtained from four rounds of PT samples, it appears that valid PT samples can be prepared, although some further refinement is needed, and that over time some laboratories testing alternative specimens have been able to achieve performance levels *approaching* those levels applied to urine testing laboratories."

"Although performance in the pilot PT program has been encouraging, with individual laboratory and group performance improving over time, there are still three serious concerns. First, the data from the pilot PT program to date show that not all participants have developed the capability to test for all required drug classes, *nor to perform such tests with acceptable accuracy*. Second, some drug classes are more difficult to detect than others, for any given type of specimen. Third, the specific drug classes that are difficult to detect varies by the type of specimen."

Hair Testing:

"There are a number of factors that may influence the amount of drug incorporated into hair (e.g., drug dose, length of exposure, drug chemical structure, charge). *Of particular concern* are environmental contamination and the role of hair color."

"The limited population studies published in peer reviewed literature at this time do not indicate a *significant* association between hair color or race and drug analyte."

"Despite these *suspected limitations*, the Department still proposes to go forward with incorporation of this new technology as an alternative to urine for Federal agencies who may find it useful in certain missions and tasks that only individual Federal agencies can identify."

Saliva Testing:

"Unfortunately, further scientific study is needed to be able to differentiate between whether the parent drug was present in the oral cavity due to drug use or environmental contamination, i.e. the individual was present in a room when others smoked marijuana, for example."

Sweat Testing:

"The incorporation of drugs into sweat is poorly understood but possible mechanisms appear to be passive diffusion of drugs from blood into sweat gland and transdermal migration of drugs to the skin surface, where it is dissolved in sweat."

"Sweat patch contamination issues continue to be a concern."

"Skin sensitivity and rash are factors that can only be known after the patch is applied for the first time."

"Despite these known limitations , the Department proposes to incorporate this new technology as an optional selection for Federal agencies because sweat testing may be useful in certain missions and tasks that only individual Federal agencies can identify."

Oral Fluid Testing:

"This study found device variability and difficulty in detecting cannabinoids , but suggests the rapid evolution of the technology should overcome current problems relating to targeted analyte and manufacturer's cutoff and provide an assay consistent with proposed HHS cutoffs. The investigators felt that "there is every reason to be optimistic about the future for drug testing using oral fluid matrix ."

"The Department also recognizes that validity testing proposed for alternative specimens is not as robust as for urine, but is confident that this testing will be refined over time ."

The DHHS known limitations poses many costly potential legal challenges to the program. The success of the current drug-testing program has been the uniform and consistent approach to both the technology and procedures. During the refinement stage for testing of these alternative technologies, is the government willing to take on the additional liability for employment dismissals from potentially faulty test results rendered by the technological limitations of these products?

2. Testing Inconsistencies

Unlike the consistent testing protocols and standards of the current DHHS urine testing program, other drug detection technologies have different cut-offs for each specimen type and detection timeframes that are not equivalent to each other. Each requires a different technology of confirmation testi ng (LC/MS, GC/MS/MS) for various specimens that may not be as reliable as the "gold standard" of GC/MS used for urine. There are significant inconsistencies in the window of detection of drug use. Urine has a 3-5 day window of detection while hair testing can detect drug use up to 90 days, using 1.5 inch long cut length. Saliva has a one to 24 hour window of detection, and the sweat patch method tests drug use for as long as the patch is worn. Moreover, not all laboratories currently have the ability to test these alter native specimen types or even test some with acceptable accuracy. There will be limited laboratories qualified to re-test samples at the donor's request. Because of the limited re-test options available, there could be situations where the only laboratory qualified to re-confirm a positive sample has the same owners as the original laboratory. Laboratories will have to change their entire testing protocol to incorporate the new technologies that will impact the urine testing program, both in cost per test as well as in sample turnaround time. For those laboratories that can test all specimens, there are serious issues to resolve, such as what are considered fatal flaws verses correctable flaws? What determines an adulterated sample for each new method?

3. Collection Inconsistencies

The proposed rule further complicates the weakest link in the drug testing program – the collection process. There is a huge potential for confusion and resulting errors in collection of alternative specimens. Collectors will have to be trained in collection procedures for alternative samples, and completely retrained in current collection protocols. Under the proposed regulations, collectors are required to collect two samples in certain situations, one saliva point of care (instant) test with a back up urine sample to be sent to the laboratory, for random, post accident, and reasonable cause testing. Important questions remain as to how collectors will collect different samples and what supplies they will use. Will there be one all-incl usive chain-of-custody or separate type of chains of each specimen type? How should oral fluid samples be split.....spit twice, etc.? How will collectors handle different adulteration attempts? How will employers deal with situations in which the wrong sample is collected? Since the proposed rule states the sweat patch should be worn between 3 and 7 days, who will determine how long it should be worn? All these issues and many more will have to be resolved and retraining efforts undertaken on a broad scale to ensure collections are done correctly. This may require a separate DHHS NPRM that addresses just collection procedures.

4. Legal Challenges

Collection and testing inconsistencies will undoubtedly ultimately have legal challenges. Union attorneys will have a heyday using t he DHHS known concerns with the proposed technology to begin to reverse all of the progress made in the advancement of the drug testing industry since 1988. There will be other types of lawsuits due to conflicts with the American Disabilities Act (ADA). As an exam ple, how will the ninety-day window of a hair result affect the ADA's definition of "currently using?" Other challenges will relate to review of results, such as how the Medical Review Officer considers a new prescription dated less than 90 days when the donor has tested positive for the same drug. Further contributing to the potential for legal challenge is the fact that the NPRM allows federal agencies to choose a preferred type of testing. How will a drug test be found valid when one department's method renders an employee positive and another agency's different testing technology delivers a negative result for the same employee?

5. Increased Costs

The DHHS NPRM underestimates the increase cost to administrators of the proposed rule whether that is the federal government or a contracted TPA. Collection of two samples, a point of care (instant) saliva test and a urine sample as a back up tested by a laboratory, would significantly increase the cost of the program to the federal departments and vendors. In addition, since collectors will need stringent cross training in multiple specimens including point of care testing, how much will this additional training cost? How will that affect the cost of the federal drug program when the high rate of collector turnover is taken into consideration? There will undoubtedly be an increased cost for TPAs and other vendors to obtain the necessary Errors and Omissions Liability insurance, if acquiring this insurance is even possible given the liability issues surrounding the new technologies.

In conclusion, the known DHHS problems with the types of technologies and the myriad of uncertainties regarding the implementation of the proposed regulations are evidence that it is premature to undertake such a massive change in drug testing at this time, even on a smaller scale within the federal government. These changes have the dangerous potential of dismantling the integrity of the DOT program outside federal government testing. With all the problem areas, why would DHHS propose regulations that do not make sense for an industry that has built a reputation on reliable and legally defensible results? It seems obvious that political pressures are being exerted to incorporate alternative technologies prematurely befor e development of sound science. As a vendor for government testing, this NPRM will cause WorkSafe to reconsider contracting with the federal government due to the increase cost and labiality of serving this market.

We urge you to reconsider incorporating new technologies in the federal drug-testing program at this time until there is more reliability in testing and there is an orderly, predictable system of incorporating different testing. Thank you for the opportunity to provide comment on these crucial issues affecting the industry and America's workplace and economy.

Sincerely,

Matthew Fagnani, C-SAPA, C-SI
President of WorkSafe, Inc.