Alcohol & Drug Abuse Testing Centers, Inc.

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Via Email wvogl@samhsa.gov

RE: Comments on the Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs (Federal Register / Vol. 69, No. 71/ Tuesday, April 13, 2004) (FR Doc# 04-7984)

Thank you for the opportunity to comment on the above referenced mandatory guidelines. First and foremost I would like to acknowledge the significant about of time and effort that those within the Department have spent in trying to move these testing guidelines into the use of newer alternative technologies and specimens. There is nothing simple about change, except that is VERY time consuming and difficult for most. Having worked in the substance abuse field for some 30+ years, fifteen of which were in public service I am well aware of the many pressures that come from competing interest on the same issue. I commend all those involved for your efforts regardless of others agreement or disagreement with your outcome.

Although these Mandatory Guidelines for Federal Workplace Drug Testing Programs are intended for federal employees, and the Department of Transportation Procedures for Transportation Workplace Drug and Alcohol Testing Procedures are for transportation regulated employers, they end up becoming the standards that all employers, public and private, eventually have to contend with in the implementation of their own workplace programs. Just a cursory browse through the newsletters and journals covering workplace testing and safety issues will demonstrate the reach of the federal regulations regarding testing. Case law, administrative hearings and labor settlements often hinge on the "process or procedure" touted in the federal programs as the basis of or proper "collector procedure," "chain of custody," "laboratory testing process" or "medical review." In short did the employee get treated fair and equitably, was "due process" afforded?

As a previous Third Party Administrator (TPA) who has worked with employers from a variety of public and private workplaces I have had the unique opportunity to see the outcome of public policy in action. Both public and private employers alike, pattern their programs after the federal regulatory standards. It is precisely this process of "establishing a published standard" that gives me most concern with these proposed revisions.

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It is very difficult to imagine that the "standard" could be a set of regulations that open in the preamble with phrases such as "suspected limitations," "conflicting studies," "known limitations," and "serious concerns." As much as I can understand the frustration of those who do not understand why procedures for the use of alternative specimens has not already been published and enacted as regulation, one only has to thoroughly read these mandatory guidelines to understand we aren't there yet.

In 1988 testing really went mainstream, through implementation of the DOT rules which extended coverage from thousands of federal employees to **millions** of private employees in regulated transportation industries. But not only were the DOT regulated employees affected, those rules changed testing in every workplace that had both regulated and non-regulated employees. Non-regulated employees were affected as employers tried to maintain "balance" and "equity" among their DOT and non-DOT employees in the same workplace. A standard was set. Since then, even those employers who had no regulated employees patterned their testing programs after the safeguards and testing standards found in the DHHS and DOT programs. This reliance on these procedures is so obvious that in the introduction of the DOT Urine Specimen Collection Guidelines DOT wrote *"These procedures, including use of the Federal Drug Testing Custody and Control Form (CCF), apply only to DOT-required testing. While employers may use these collection and testing procedures for testing under employer or state authority, they must not use a Federal CCF nor can they imply that company tests are conducted using DOT authority."*

Since so many employers attempt to maintain equity by following the federal standard, it is imperative that the solidness of the science, technology and procedures of new test methods and specimens be unquestionable. It is the lack of solid science and unquestionable procedure in these proposed guidelines that gives rise to my concerns for the negative impact that "rushing" these technologies to center stage will have on testing as a whole. Make no mistake, WE NEED THE NEW TECHNOLOGIES AND SPECIMENS if we are to be effective in countering all the energy spent in continuing drug use that negatively affects our workplaces. We just can't move forward with technologies that have so many questions, without expecting we will negatively impact all testing.

Even with the current single specimen, urine, we have spent years and significant time, energy and money to overcome the issues of employer misunderstaning in when to conduct required testing, collector error in completing chain-of-custody collections and inconsistency in the medical review and reporting process. 16 years later, even with a single specimen, because of the complexity of testing, consitent application of the rules, correct procedure, and quality review and reporting are more the norm than the exception. Through all of this we were applying one standard to all covered individuals. North, South, East, or West the same rule, same specimen, same procedure, same consequences applied to everyone being tested. Even those who disagreed with the need or right to test recognized the equity in everyone facing the same standard. If implemented these rules will undermine that very standard of equity and consistency that has established the DHHS and DOT programs as the "gold standard" they have become.

Looking at the specific issues of the alternative specimens there are very serious questions and/or

flaws with the specimens that appears to be minimized or glossed over in an effort to implement the technology in the guidelines. Hair testing raises some very distinct and troubling questions for me in workplace testing. Are we willing to implement an alternative specimen we can not say to those we will apply it to "we don't have all the answers yet?" With all that has been touted over the years on the use of hair as a "more reliable specimen," why have there not been more serious, independent, side by side studies with urine, the one specimen we know, on direct correlation of levels of detection? Why if we are even remotely questioning the science on the issue of hair color has serious, independent research not been completed to either acknowledge or refute the issue. I expect we will see many more challenges on the basis of racial bias when the test is not conducted by a private employer for whom the employee chooses to work for, but rather, the federal government where a testing process that may have racial bias is mandated.

Why are we testing 1.5 inches of hair anyway? It always amazes me in the scenarios that employers or others recount of 10+% positives with hair vs. 3-4% with urine testing that we never recognize if urine test for ~30 days and hair tests for ~90 days wouldn't we expect the positive rate for hair to be three (3) times that of urine? Does that mean hair testing is more accurate or just covers a larger window of detection? If we really just want to avoid the mass adulterating we think is going on shouldn't we be testing just 0.5 of an inch of hair to cover approximately the same time period? Is the desire we really want to stop donors passing off invalid specimens, or do we just want to test a larger window of drug use?

Keeping equity of the process in mind. How do we tell federal employee testing is equitable when we tell the FBI agent in Washington State who's been told to give a hair sample that his counterpart in Texas is only going to have to give a urine specimen and his other counterpart in Virgina is only going to have to provide an oral sample. The hair test will cover ~90 days detection, the urine sample ~3-30 days and the oral sample ~an hour – 3 days. More likely will be when, for pre-employment testing, the State Department chooses oral tests and the Commerce Department chooses hair testing. These types of real issues is what we will be facing more than the intended result which was to focus on reducing drug use and alcohol abuse showing up in the workplace.

Oral fluid testing has its own issues the regulation doesn't address, not the least of which is the question of whether the single largest reported positive substance, THC (marijuana) if it shows up in the oral fluid is the result of use or external contamination. Most current urine THC positive donors already claim "passive inhalation" to MRO's during the interview process. No one ever claims to have smoked the substance "it just got in my system". Now imagine the oral test you took WAS from external contamination. Not only will oral testing be questioned but all types of testing will come into question. On top of all these questions if as an employer or agency you pursue oral fluid specimens then the collector MUST collect another biological sample (generally urine) at the time of the oral fluid collection. This urine sample is to be able to confirm whether the THC positive was from the blood stream or from external contamination. I can not imagine any agency, who will be willing to pay for two collections one for oral fluid and one for urine just to get a complete answer.

To further complicate oral fluid testing the regulation chooses the least tolerable of the collection

methods and expects the donor to stand, under direct observation and "spit into the collection tube" 2mL of oral fluid. Then from this the collector is to pour off 0.5mL into the split collection tube? It we thought there was difficulty getting collectors to put 30 mL and 15mL of urine in separate containers, I can not imagine the training to demonstrate that collection routine.

Lastly, there is sweat patches. Sweat patches make the least sense of all the alternative specimens due to the length of time the patch is worn, the need for multiple site visits (one to install the patch and one to remove it) just to get a test answer. Sweat patches have their most practical use in treatment settings and although the preamble considers them to be viable for return-to-duty and follow-up testing, it would not seem to be practical to hold off on a return to duty for an employee while he/she wears a patch for 3-7 days after authorization by the SAP to return-to-duty.

Overall, even though the alternative technologies are advancing, to become part of the standard of testing these questions or inconsistencies must be resolved and eliminated before the alternative specimens should be required of an employee.

I do believe that in specific medical situations such as documented and verified paruresis the rule should allow for an appropriate alternative to be used in every subsequent collection. The arrangements for such collection would be the responsibility of the employer to "accommodate" the MRO's determination that another alternative specimen is necessary.

On the specifc sections of the regulation.
Subpart D: Collectors.
Having trained hundreds of collectors since the beginning of 2001 it has become abundantly clear that expecting ANY employee to conduct collections without very specific training on the rule, the specimen collected and handling the donor in the process is unacceptable. I have found collectors and even Medical Review Officers who have attended collector training that have very distorted understandings of what the federal testing regulation actually requires. Many have difficulty understanding the difference between federal employees and DOT regulated private employees. Understanding urine collections has not been a piece of cake and many of them do 10+ a day at their respective clinics. Because of changes in the two sets of federal regulations over the years we still have collectors who don't know there is a specific collection time period and consequences if the collection is not completed within the time limits. Routinely I find collectors today who let donors "drink all they want" to produce a sample or even more simply don't understand the differnce between a regulated and non-regulated test. In all these cases these collectors only test for one specimen over and over and still have difficulty.

Now we are talking about increasing the number of specimens that the donor will have to be trained to collect and on top of the training the collector now will have to understand when to use each specimen. Training will have to be much more structured and require specific testing and proficiencies as spelled out in section 4. Having conducted this training it should be required that the collector can not leave the collector training until the cognitive part is complete and the collector performs his 5 mock collections accurately FOR EACH SPECIMEN the collector wishes to collect. Training should be by professionals with extensive backgrounds in collections, regulations and training techniques.

The drug testing form, even though it will include different specimens should stay consistent and hopefully use ONE single form for all specimens of regulated testing. Multiple copies means greater chances for error.

Lastly, I can only reiterate my comments in the beginning, DHHS has to set the standard tightly. Each agency or company or collection site cannot be allowed to write their own procedures and standards for testing. There are many very capable professionals who would be willing to work with the Department on separate aspects of this regulation to get a final version that is procedurally correct and legally defensible.

Please don't hesitate to call if I can be of any assistance.

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