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From: "Rick Anderson" <RnLA@pacbell.net>
To: "Walter Vogl" <wvogl@samhsa.gov>
Date: 7/12/04 5:46PM
Subject: Doc. 04-7984 Proposed Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs

Dear Dr. Vogl,

Attached please find comments regarding the Proposed Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs published Tuesday, April 13, 2004 in Vol. 69 No. 71 FR pp. 19673 – 19732 as Doc. 04 7984 Filed 4-6-04; 12:39 pm.

Should you require clarification of the comments or need further information regarding this commentary, please do not hesitate to contact me.

Respectfully yours,
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July 12, 2004

Dr. Walter Vogl
Substance Abuse and Mental Health Services Administration
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Dear Dr. Vogl,

Attached please find comments regarding the Proposed Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs published Tuesday, April 13, 2004 in Vol. 69 No. 71 FR pp. 19673 – 19732 as **Doc. 04-7984** Filed 4-6-04; 12:39 pm.

The comments are divided into four primary areas of concern summarized below with more a more extensive commentary on each of the specific topics within the attached document.

I. Issue of oral fluid sample collection device
The limitation of collection of oral fluid to the use of a single plastic vial is unnecessarily restrictive and should be broadened to include additional collection devices specifically the oral swab class of device.

II. Issue of testing venue
The scale of testing involving oral fluid should be expanded in order to provide a longer drug detection window. This follows from the closer correlation of detection of oral fluid with the time of drug consumption than with urine specimens.

III. Issue of requirement for urine with oral fluid
SAMHSA has expressed concern over the possibility of oral fluid presumptive/confirmed positives for THC as resulting from simple environmental exposure. Public comment regarding this issue was solicited by the Department. Based upon a study performed by LabOne it seems that there is little practical basis for the Department's concern regarding significant numbers of positive specimens resulting from environmental exposure.

IV. Issue of detection window for oral fluid vs. urine
The Department has indicated a concern that the practical time detection windows for oral fluid and urine based testing are significantly different necessitating a differential in the "*reason for test*" allowed for each of these samples. The LabOne oral fluid data taken in conjunction with urine

testing data from Quest Laboratories do not support this differentiation and therefore the "*reason for test*" should be same for oral fluid and urine based testing.

V. Issue of the 10% negative retest rule
The proposed revisions to the Guidelines specify that 10% of all negative oral fluid POCT screens be forwarded to an HHS-Certified Laboratory for quality assurance purposes. This number is unjustifiably large for continuing POCT operations and it is recommended that a two tier system be followed which mirrors the sending of blind specimens by collection sites to HHS-Certified Laboratories, i.e. 20% for the first three months of a program followed by a reduction to 3% of all initially screened oral fluid negatives.

Should you require clarification of the comments or need further information regarding this commentary, please do not hesitate to contact me.

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Proposed Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs

Comments to be sent to:

Agency:	Substance Abuse and Mental Health Services Administration Department of Health and Human Services
Docket Number:	Doc. 04-7984 Filed 4-6-04; 12:39 pm, published Tuesday, April 13, 2004 in Vol. 69 No. 71 FR pp. 19673 - 19732
Title:	Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs
Contact Information:	wvogl@samhsa.gov

From the Guidelines – Specific Sections For Comment:

I. *Issue of oral fluid sample collection device*

The department acknowledges that the use of both alternative specimens and technologies may justify the use of novel and previously unused specimen collection devices. (**p. 19682 "***Since the Department is proposing drug testing using alternative specimens and technologies, it is reasonable to believe that new and different specimen collection devices will be used to collect Federal employee drug test specimens.***")** As a consequence of this expectation, the proposed restriction on oral fluid sample collectors delineated in **Subpart G Sec. 7.1(c)** that requires the use of a "*single-use plastic specimen container*" is unnecessarily restrictive. It would be sufficient to limit the range of acceptable collection devices to the types outlined in **Subpart G Sec. 7.2(a)** whose central theme is to allow, "*Only a collection device that does not affect the specimen collected may be used.*" The use of device(s) that meet the criteria of **Sec. 7.2(a)** is a sufficient condition for acceptability and therefore negates the need for **Sec. 7.1(c)** in its entirety and for this reason it is suggested that **Sec. 7.1(c)** be stricken from the proposals.

The suggestion to broaden the allowed oral fluid collection devices is in keeping with the theme outlined in **Subpart A Sec.1.5** *Split Specimen* that states that for "*oral fluid, one specimen collected that is subdivided or two specimens collected almost simultaneously*" which clearly includes the concept of collection devices (plural) that are not limited to a simple single plastic vial. Flexibility on allowed collection devices is consistent with the mandate that POCT devices suitable for use under the Guidelines be FDA cleared (**Subpart L Sec. 12.2 (a)(1)**). It is both common practice and FDA guidance for submission that for POCT systems, a specific collection device be recommended and has been tested with the specific POCT device for maximum system utility and to ensure system analytical

performance. It is therefore appropriate that the proposed collection device limitation of **Subpart G Sec. 7.1(c)** be deleted from the final Guidelines and such additional alterations be made to the remainder of the Guidelines to implement such deletion (e.g. **Subpart H Sec. 8.3(a)(6)** "*Under direct observation, the collector will instruct the donor to expectorate (to spit) 2 mL of oral fluid into the specimen tube".* This could be reworded for example as - *Under direct observation, the collector will instruct the donor to provide a suitable volume of oral fluid into the oral fluid collection device(s).*

II. *Issue of testing venue*

The department is rightfully concerned with the appropriateness of various sample types to provide detection windows suitable to ensure a drug-free workforce and to be subsequently appropriately linked to rationales for testing. THC for example is widely reported to linger in adipose tissue a consequence of which is that individuals who may not be current abusers but have been chronic abusers in the past may test positive for THC-COOH in urine well after the last ingestion/impairment period. Oral fluid as noted in the preamble to the proposed Guidelines is for instance noted to be "*useful in detecting very recent drug use. Based on the detection window, oral fluid is most suited for reasonable suspicion/cause and post-accident.*" (**p. 19679**)

Clearly a goal of the Guidelines is to provide the maximum ability to detect substance abuse as evidenced by the proposed alterations to the initial cutoff concentrations in urine (**Subpart C Sec. 3.7**). This goal is clearly explained in the preamble to the proposed Guidelines in which the changes to the urine cutoff concentrations are justified by the statement "*Additionally, the revised cutoff concentrations will increase the windows of detection for these drugs, thereby, increasing the number of specimens that may be reported positive*". (**p. 19681**) This is a clear indication that maximization of the abuse detection window is a fundamental goal of the testing program. For this reason it is imperative that the overall sample collection program be expanded to include an oral fluid specimen to be co-collected with each urine specimen and that by analogy to the proposed testing of a complementary urine specimen for oral fluid THC positives, that the co-collected oral fluid specimen be tested for all urine negatives with the expectation of increasing the available detection window and increasing the number of specimens that may be reported as positive. Failure to include such additional oral fluid testing would call into question the rationale for other alterations to the Guidelines such as changes to the urine screening cutoff concentrations intended to maximize the ability to detect recent substance abuse for venues such as pre-employment, random, reasonable suspicion/cause or post-accident.

III. *Issue of requirement for urine with oral fluid*

The proposed Guidelines include a requirement that for oral fluid specimens a urine specimen be collected whose primary purpose is to be tested for marijuana when the oral fluid specimen is screened as positive for marijuana (**Subpart B Sec. 2.3(a)**). The justification offered for this requirement is the assertion that "*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.*" (**p. 19676**) This assertion while understandable from the perspective of protection of the rights of those individuals being tested would seem to be challenged from data presented in a primary study referenced within the preamble to the Guideline proposals (**ref 21**. *Cone E.J., Presley L., Lehrer M., Seiter W., Smith M., Kardos K.W., Fritch D., Salamone S., Niedbala R.S. (2002). Oral fluid testing for drugs of abuse: positive prevalence rates by Intercept ™ immunoassay screening and GC–MS–MS confirmation and suggested cutoff concentrations. J Anal Toxicol, 26:541*). In the cited report the authors comment upon the detected positive prevalence rates in oral fluid in a significantly sized testing population (77,218 oral specimens of which 3,908 are drug positive, of which 2,486 are THC positive, yielding a THC positivity rate of 3.22% taken from the general private workplace). The overall detected drug positivity rate in the author's study is stated to be 5.06% compared with the comparable annual data from Quest for urine testing for the general US workforce population in 2001 of 4.9% (~3.4 million samples), which is quite close agreement (http://www.questdiagnostics.com/employersolutions/dti_10_2003/dti_index.html). The positivity rate for THC cited by Quest for urine testing within the general US workforce is given as 3.17% for 2001, compared to the author's cited oral fluid THC positivity rate of 3.22%, also in good agreement. The justification for including a urine specimen with an oral fluid specimen is that the possibility of environmental contamination will yield oral fluid THC positives, which are not correlated with urine THC positives. Given the marked similarities for both the overall and THC drug specific positivity rates between urine based testing which is unlikely to be environmentally influenced and oral fluid based testing for statistically significant populations; it would seem that while this concern about significant disagreement between the positivity rate of oral fluid and urine may be historically justified, the compiled data does not support this hypothesis and for this reason the co-collection of a urine specimen with a oral fluid be stricken from the proposals for the Guidelines (**Subpart B Sec. 2.3(a)**).

IV. *Issue of detection window for oral fluid vs. urine*

It is also stated in the preamble to the revisions that "*Drug detection times for the regulated analytes in oral fluid range from less than one to approximately 24 hours. Drugs may be detected in urine longer after drug use than in oral fluid.*

This makes oral fluid useful in detecting very recent drug use. Based on the detection window, oral fluid is most suited for reasonable suspicion/cause and postaccident. It may be least suited for random testing if prior notice (greater than 24 hours) is given. Because of the short detection window, oral fluid is not suited for return to duty, and follow-up testing."(**p. 19679**) In **Ref 21** *Cone, et al. (2002) J Anal Toxicol. 26:541* cited above, the overall positivity rate for oral fluid presented by the authors is in good agreement with the comparable data for urine available from the annual compilation from Quest Laboratories. It would seem unlikely that the entirety of the LabOne oral fluid data (77,218 oral specimens) were restricted to samples that had been collected within 24 hours of drug use. So given the concordance of the overall oral fluid drug positivity rates with the urine positivity rates presented by Quest Laboratory, it must be concluded that the practical windows of detection must either be quite similar or that the advancement of the detection window to shorter times by oral fluid improves the overall detection rate to exactly balance the detection loss incurred by a presumed inability of oral fluid to detect positive sample at times greater than 24 hours and thereby result in a rate essentially matching that provided by drug detection in urine. Of the two possible explanations, it is by far more straightforward to accept that the detection rates for oral fluid and urine are generally the same as a consequence of the detection windows being approximately equivalent in length. Given this conclusion, the restrictions on oral fluid for reasons to test given in **Subpart B Sec. 2.2** must be rejected and therefore the reasons to test oral fluid should be expanded to include return to duty and follow-up.

V. *Issue of the 10% negative retest rule*

The proposed revisions to the Guidelines mandate that "*A POCT tester must send one of every 10 negative specimens together with its split to an HHS-certified laboratory to be tested for quality control purposes*". (**Subpart L Sec. 12.19(c)** and **12.21(b)**). The scale of the retesting of negatives is without foundation. Clearly the implementation of quality assurance processes is a vital element in the development of a viable drug testing program. The likely utility of a quality assurance process can be judged by the magnitude of the problem to be controlled. For guidance we can look to information provided in the preamble to the proposed revisions to the Guidelines.

From the preamble, "*Non-instrumented POCT for urine testing have been subjected to evaluations by investigators independent of the manufacturers and found to perform similar to that of the instrumented immunoassay tests in certified laboratories.*[55-58] *These tests were conducted on both spiked and donor specimens with and without drug analytes. Little difference in the performance of these devices was observed between tests conducted by laboratory technicians and laymen who had been trained in the proper procedures for conducting and reading the tests.*[55, 56]" (**p. 19677**) This comment does not justify the expectation

that the false negative rate from POCT devices or testers is likely to be significantly different than seen within HHS-certified laboratories and therefore the number of POCT screened negative samples should not be large, especially given that in oral testimony, within the preamble to the proposed revisions to the Guidelines and within the proposed revisions to the Guidelines, it is delineated that both the POCT devices and the POCT testers will have been previously qualified for the task. "*In order to provide an equivalent program of on-going quality assurance for POCT devices, the Department proposes a certification process under which POCT device manufacturers would provide tests for evaluation to be placed on the list of SAMHSA-certified devices published by the Secretary. This would be followed by periodic additional testing as new lots of manufactured tests become available as well as PT sample requirements, training of POCT testers, and on-going quality assurance requirements*". (**p. 19678**)

It is a stated goal that the outcome of testing should not be dependent upon the venue within which the sample is tested, a POCT screening result should confer the same degree of confidence inspired by a HHS certified laboratory screening result. This concept is embodied within the strictures of **Subpart K Sec. 11.12 What Are the Requirements for an Initial Drug Test?** and paralleled within **Subpart L Sec. 12.2 What POCT Devices May Be Used in a Federal Workplace Drug Testing Program?** Given the equivalency of quality of screening tests within these two testing venues and the Department's historical experience with blind samples that are a close analogue of the proposed POCT negatives to be rescreened, the preamble provides historical context for the scale of such testing. "*In section 10.2, the Department is proposing to reduce the 20 percent requirement for blind samples, for each type of specimen to be tested (i.e., urine, head hair, oral fluid, or sweat) to 3 percent during the initial 90-day period of a new Federal agency program because the 20 percent requirement is excessive and redundant. Since the beginning of the urine testing program, there has never been any evidence to suggest that each Federal agency needs to challenge each laboratory with 20 percent blind samples to determine if a laboratory is making either administrative or technical errors in the testing of specimens*". (**p. 19683**) After a relatively short period of instituting a POCT testing program the number of urine specimens to be provided for rescreening should be no more than 3%, a number which is justified by Quest Laboratories data that indicates that within the Federally-Mandated, Safety-Sensitive Workforce testing population the average annual overall drug positivity rate is approximately 2.8%. (http://www.questdiagnostics.com/employersolutions/dti_10_2003/dti_index.html). Thus the number of negatives to be rescreened will be approximately equal to the number of positive specimens detected, which is a more reasonable balance between the number of samples forwarded for analysis and the number forwarded for quality assurance purposes.

It is also proposed that the Guidelines require the testing of all presumptive

positives and negatives originating from POCT sites to be tested as though no prior testing had transpired (**Subpart K Sec.11.10**). This stands in stark contrast to the testing mandated for presumptive positives originating from HHS-certified IITF facilities (**Subpart K Sec. 11.11** and **Subpart M Sec. 13.15**). Given the written and oral testimony that there should be equivalence between testing outcomes without respect to the originating testing venue for example, results originating from POCT testing versus those of HHS-Certified IITFs, there does not appear to be any justification for differentially dealing with samples forwarded to HHS-Certified Laboratories from POCT sites as opposed to those originating from HHS-Certified IITFs. Therefore it is suggested that **Subpart K Sec.11.10** be revised to mirror the text contained within **Subpart K Sec. 11.10** and **Subpart M Sec. 13.15**, such that samples screened as either negative or positive and forwarded to an HHS-Certified Laboratory from a POCT site are tested as though the screening test had occurred at either an HHS-Certified IITF or HHS-Certified Laboratory.