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Substance Abuse and Mental Health Services Administration

Mandatory Guidelines for Federal Workplace Drug Testing Programs

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Background

The expansion and revision of the proposed guidelines recommends sweeping changes to the process drug testing procedures for federal employees that will undoubtedly set a new standard for all drug testing performed in the US workplace. Considered the "gold standard" of drug testing in the US, the proposed federal guidelines will begin a chain reaction of program conversion and a paradigm shift in the current model of urine-based laboratory-centric drug testing.

First, and foremost, there is a significant difference in alternative specimens and alternative technologies, and for these comments, please note that we refer to alternative specimens as the added specimens of hair, saliva, and sweat, and alternative technologies as POCT, and more specifically to urine-based POCT. Alternative technologies, specifically, alcohol POCT, has been proven in the DOT drug testing arena since 1992 when alcohol testing performed at the point of collection was first approved. There is an established precedent for POCT, and HHS should consider "unbundling" the alternative specimens from the alternative technologies. Approving alternative technologies (urine POCT, IITF) now could easily be achieved, until the environmental contamination and other controversial issues of alternative specimens are fully explored. Since alternative specimens have never been sanctioned by HHS, there is relatively little experience in the private sector to confidently state that serious issues will not surface in the future with any of the proposed alternative specimens. We continue to discover new issues of toxicological and analytical importance with respect to drug detection in hair and saliva. Undoubtedly, we will discover new findings in the coming years. Will one of these new finding destroy the credibility of all drug testing?

Drug testing works solely because it can be trusted to be accurate. This

commenter is significantly concerned for the credibility of drug testing in the US when the "gold standard" becomes a testing ground for unproven or "partially proven" alternative specimen testing. In 1983 a few years before GC/MS, a faulty reagent produced positive immunoassay results for THC in the presence of ibuprophen. It is still believed that this can happen today. What will we learn about hair, sweat and saliva testing in the future that could introduce a flaw in the program and result in the "overturning" of potentially thousands of positive test results, and cost billions of dollars to litigate? This small but unacceptable risk could cripple all workplace drug testing forever.

One important difference between urine as a matrix for drugs as compared to sweat, saliva, and hair is drugs that circulate in the body and ultimately excreted in the urine, are protected from environmental factors. Urine is maintained in the sterile, protected environment of the urinary bladder until collected for testing. Hair, sweat, and saliva are not. The mouth, hair, and skin are actually collectors of environmental contaminants. They are exposed to the external environment, continuously and without intention, exposed to environmental pollutants, chemicals, foods, drugs and other substances, contributing unknown entities to the matrix.

The manufacturers and private enterprises, which stand to reap huge rewards from the sanctioning of these alternatives, have failed to disclose these potential risks of environmental contamination. There are limited peer-reviewed academic studies on the contamination of these matrices from environmental conditions. Oral fluid manufacturers have known for years that parent THC can reside in the oral cavity from environmental or passive exposure to marijuana. The limited data available, which has been produced by these same oral test fluid manufacturers, is seriously skewed, and fails to address the actual passive exposure conditions which may occur in the real world.

Hair testing studies demonstrating an astonishing increase in the deposition of opiates in certain hair colors and racial types is a serious concern. Tests which are biased against a minority population will surely be challenged. It is difficult to believe that a test which discriminates against certain racial or minority populations could be allowed in the federal workplace. It is also difficult to reconcile that employees tested using one method could test positive, while testing positive using another type of specimen.

Therefore, it is my recommendation that *alternative specimens be withheld* at this time until the scientific and technical issues can be fully resolved. However, the

alternative technologies (POCT and IITF) of urine-based tests could easily be *implemented at this time.*

Subpart B-specimens
Value of Short Window drug tests

Urine based drug testing was the only viable method available 20 years ago, and met the needs of employers to detect drug use from the recent past (3-14 days). Although what employers sought was not a test of past use, but rather a test of impairment. Keep in mind, that the perfect drug test is a test of *impairment* that can be performed frequently without disruption of work. When first offered up, the urine test for the "past use of drugs" was a less than perfect option, since the socio-cultural issues of past use in the absence of impairment had not yet been resolved. It was Nancy Reagan's "Just Say No" movement that pushed the issue of past use into the unacceptable realm and allowed employers to accept positive drug tests as a violation of policy, both public and private. Federal, state, and local laws have been re-written in many cases to accommodate the disparity between current use and past use as indicated by a positive urine drug test.

We are confronted with a unique opportunity to revisit this issue of current use and impairment due to the unique nature of saliva testing. The very short window of detection, and the mirroring of blood drug levels, is an ideal indicator of recent use and highly correlates to being under the influence. An oral fluid test that detects drug use in the *1-12 hour window, used post-employment for post-accident, and reasonable cause* situations, ideally hits the nail on the head, by determining current use as a direct cause of the accident/impairment and findings of correlation between the two.

However, oral fluid device manufacturers know that the lion's share of revenue comes from pre-employment testing. They have therefore lowered their cutoffs and "tuned" their devices to widen the window of detection and raise the positive rate to compete with urine-based tests. A window of detection longer than 18 hours, removes the impairment connection in all cases, and reduces the correlation to past use. In fact, a perfectly tuned oral fluid test, that has window of detection <24 hours, will be used by many more employers for post accident and reasonable cause testing, and finally address the issue that both employers and the States have been desperately seeking. If oral fluids are allowed for pre-employment tests, we will lose this great opportunity.

Insufficient experience in the workplace arena with oral fluid testing projects a distorted and biased view of the benefits of oral fluids. Current industry data suggests

equivalent positive rates in a limited study comparing oral fluid to urine tests. Pre-employment testing protocol dictates that once an offer of employment is made that the applicant present to a collection site to be tested for drugs, usually within 24-48 hours. In reality, the 24-hour window is rarely monitored, since there is no good tracking method for this, and applicants often delay the pre-employment test if they suspect they will be positive. Donors who present the next business day (Friday to Monday is acceptable in most workplace pre-employment drug testing programs) could be tested 36 hours or more after notice. Detection window studies for oral fluid tests usually begin at the time of drug use, not at the time of collection. Adding a 24-hour (or in many cases 48-hour) notice, or lead-time *prior to the collection* of oral fluids for pre-employment tests makes no sense. Current data presented by oral fluid test device manufacturers demonstrate similar positive rates compared to urine-based testing. This data is biased since the oral fluid samples were collected in the workplace at the time of an offer, and is being compared to urine collected the following day(s) in a third party location.

The vast majority of the specimens in these studies were collected in the workplace during the job interview process. This practice surely catches applicants "off-guard" since in most cases they are given 24 hours notice to present to a collection site for a urine drug test. In practice, oral fluid collected in a collection tube and split will rarely be collected in the workplace, but rather in a third party locations, with standard 24-36 hours or more notice to present to the collection site. Real-world use of oral fluid tests will demonstrate that detection rates will be dramatically lower. In cases where oral fluid specimens are collected in the workplace without notice, at least for some period of time, donors will be detected at abnormally higher levels. Recall the early days of urine drug testing, when workers were subject to drug tests for the first time, and positive rate exceeded 20%. Once this practice is known donors will "clean up" or abstain from drug use for 24 hours prior to their job interviews. Our survey suggests that most employers will not collect oral fluids themselves, rather use a third party collection site in the same way that urine is collected. This is especially true of expectorated saliva which requires splitting the sample into 2 separate vials by a collector. The "yuck factor" is way too high for most employers. This additional period between notice and collection (24-36 hours) will shorten the detection window to near zero. In situations where oral fluid testing is done during the job interview process itself, it can be reasonably expected that, as oral fluid testing becomes more prevalent, donors will learn that simply abstaining for 24 hours before the interview is all that is required to achieve a negative test result. This suggests that pre-employment use of oral fluids is completely inappropriate.

Additionally, the effect of passive exposure to marijuana on oral fluid screening has yet to be firmly established. Due to the lack of marijuana metabolite in the oral cavity, oral fluid test manufacturers have resorted to testing for the parent compound. This raises the issue of passive exposure and its effect on oral fluid testing. One manufacturer's (Orasure Technologies) own study, presented at the American Association of Medical Review Officers conference last year, showed that passive exposure leads to positive oral fluid screen results for up to an hour after exposure. Furthermore, that study was conducted in a relatively large room and does not represent other real world circumstances, such as passive exposure in small break rooms and in automobiles. In an attempt to fill in these gaps in the knowledge base around oral fluid testing, I will submit a study of passive exposure in an automobile setting for HHS review by July 26, 2004.

This combination of lack of experience, short window of detection (in many cases shorter than the period of lead-time noticed before a collection, and the contamination of the oral cavity with passively exposed THC, suggests that oral fluids should not be "endorsed as a gold standard" by HHS at this time.

Oral fluid is NOT SUITED for marijuana or pre-employment testing.

(Note: the proposed revisions state on page 22 "Oral fluid is not suited for return to duty, follow-up testing, and pre-employment." On page 27, under Oral Fluid, pre-employment use is inadvertently left out. In section 2.2 pre-employment is listed as an acceptable reason for collecting an oral fluid sample.)

The Added Testing Options and Locations-POCT In the laboratory-centric model of drug testing, all samples are collected, CCF completed, and shipped to the laboratory for screening and confirmation if applicable. 90-92% of samples screen negative and are discarded by the laboratory. The objective of the POCT is identical to the EMIT (lab-based) immunoassay- it is merely to identify which samples are *negative*, and allow them to be discarded without further delay or analysis.

Subpart L- Point of Collection Test (POCT)

Point of collection tests provide for a decentralization of the laboratory screening process, as well as providing a negative result within minutes. Decentralizing the laboratory screening process places additional burdens on the collector to "analyze" an aliquot of the specimen, and handle the unsealed specimen in a fashion that maintains

the forensic chain of custody. This is an area of the testing process that we have studied extensively for the past 10 years.

Point of collection testing devices for drugs of abuse evolved out of the point of care industry manufacturing tests for pregnancy. These OTC rapid pregnancy tests were designed using lateral flow assays which produced a visual endpoint color change. Results are currently easy to distinguish, with high sensitivity and specificity, producing few false negative or false positive results. The problematic legacy associated with the evolution of drugs of abuse tests from the pregnancy test market are as follows: Pregnancy tests are designed to be purchased, and used by the donor. In this case, the donor, the collector, and the customer of the resulting information from the test are all the same person-the donor. In the workplace drugs of abuse testing model, the donor, collector, and employer each have specific, limited roles in the testing process. It is risky to undo many of the safeguards currently put in place in the drug testing process.

Several new burdens will fall on the collector or POCT tester. First, and foremost is the "breaking of the forensic seal" which is required to aliquot the sample. POCT exist in various forms, e.g. dipsticks, cassettes, integrated cups and self-aliquoting collection cups with integrated test strips. Integrated cups come in a variety of designs, with strips integrated into the side of the collection vessel (donor cup), the lid, and in some cases a separate card inserted after collection. SAMHSA-certified POCT tests should be limited to "self-aliquoting" test devices, e.g. those devices which can be aliquoted "under seal", i.e., without breaking the tamper-evident seal. Non-negative samples can then be forwarded to the HHS-certified laboratory in its originally sealed container without the question of specimen integrity and handling concerns by the POCT tester.

Presumptive positive results in the current non-instrumented configuration of drugs of abuse POCT tests, disclose to the collector, presumptively positive test results. This adds a new, previously unknown, liability to the POCT process, presumptive positives which are later reported as negative by the HHS-certified laboratory. Previously, disguised within the confines of the HHS-certified laboratory, screened positive results are now geographically and physically removed from the confines of the protected laboratory environment. This information is now out "in the open" and subject to disclosure, or errors in procedure. Many of these "presumptive positive tests" will be reported as negative by the HHS certified laboratory. This author suggests a built-in positive control, so that a small percentage of true negative samples are triggered as send to lab "control presumptive positives" to bury "true presumptive

positives" which are reported as negative by the HHS lab. In this case, the collector has no idea if the "presumptive positive" result is a true presumptive positive or a positive control intended to mask true positives and reduce the risk of adverse action until a confirmed laboratory result has been reported by the MRO.

Subpart B- Specimens

Section 2.2 Under what circumstances can the different types of specimens be collected?

Oral fluid tests are not suited for pre-employment testing. Limiting oral fluid tests for post accident, reasonable suspicion/cause, and random testing, will drive the oral fluid tests manufactures to tune their tests to more accurately reflect conditions of "under the influence" with detection windows in the 12-18 hour range. This will also limit the defense of passive exposure, since donor claims of passive exposure during the past "few hours" is unlikely to occur in employment settings. Passive exposure claims over the past 20 years have always occurred "outside of the workplace" usually at a party, concert, home or automobile. Nine states have adopted medicinal marijuana laws, and the trend is expanding. As medicinal marijuana becomes more prevalent in the home, claims of passive exposure will likely increase.

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(Note: the proposed revisions state on page 22 "Oral fluid is *not suited* for return to duty, follow-up testing, and pre-employment." On page 27, under Oral Fluid, pre-employment use is inadvertently left out. In section 2.2 pre-employment is listed as an acceptable reason for collecting an oral fluid sample.)

Section 2.3 Can more than one type of specimen be collected at the same time from the same donor?

a) When an oral fluid specimen is collected, a urine specimen must also be collected.

This may appear ludicrous, and may obviate any benefits of oral fluid testing. But in light of the environmental contamination by marijuana, oral fluid tests can not be used to detect the presence of marijuana.

Wake-up and smell the coffee! Oral fluid tests are not ready for prime time.

Federal workplace drug testing programs are the "gold standard" of all workplace drug tests. Non-federal employers are anxiously awaiting HHS "endorsement" of the alternative specimen procedures. Our survey of employers currently using oral fluid tests revealed that they refuse to collect urine samples. Urine specimen collection with oral fluid specimens will not be done in the private sector, and unwitting donors and employers will face-off in litigation because of this premature endorsement by HHS.

Oral fluid test advocates will argue that collecting a urine sample concurrently with the oral fluid sample is unnecessary. It will be suggested, that passive exposure of marijuana is unlikely to produce a positive result more than 45 minutes after exposure. New data suggests otherwise. (see Passive Exposure Study). Passive exposure, and environmental contamination from marijuana is a bigger problem than originally suspected.

Oral fluid test advocates will argue that oral fluid tests should be collected alone, and in the event of a marijuana positive test, a urine or hair sample can then be collected at a later time. This is especially true for oral fluid POCT tests. Since only about 2% of the oral fluid samples will confirm positive for THC, this later collection would eliminate 98% of concurrent urine sample collections. This would set a seriously flawed precedent. It is well known by employers and MROs that the most common donor response to a positive test is "I'll take another test, right now" to disprove the results of their first test. Donor confrontation and collector bias will unleash collection site disputes beyond our wildest imagination.

Collecting a "neat oral fluid" sample will produce poorer THC detection than currently implemented "swabs" since THC sticks to the oral mucosa and is only detectable when scrubbed from the oral cavity. Neat oral fluid tests for marijuana will prove highly unreliable and ineffective within a few hours after use, not 24 hours as claimed by the manufacturers of "swab-based" oral fluid tests.

It is known that urine specimens collected hours apart (in some cases minutes apart) may produce different results. The presence of a drug in one sample should never be confirmed by the collection of another sample-even of the same matrix. Once alternative matrices are offered, apple-to-orange comparisons will occur. This situation was previously "shut-down" when previous positive donors offered up negative results of their own hair tests to disprove their DOT positive urine tests. We have seen this over and over again. This will affect the credibility of the Federal workplace drug testing program, but more importantly, open the door for non-regulated employers to use alternative specimens to "confirm" urine tests, and vice-versa. These apples-to

oranges comparisons will cause harm to the credibility of workplace drug testing programs. Positive donors will offer up any specimen to disprove (discredit) the results of their positive test. Why not, they have nothing to lose, and everything to gain. This option will create havoc in the Federal and private-sector workplace.

DHHS is effectively stating in the proposed revision that oral fluid tests are not suited for marijuana testing. Why not just come out and say it?

b) If a problem occurs during the collection of one type of specimen, permission can be obtained from the Federal agency to collect an alternative specimen.

The situations when this is acceptable, should be clearly defined. Otherwise, we will see an increase in shy bladder claims, etc. by donors seeking to offer alternative specimens more likely to produce a negative result.

Section 3.11 What validity tests must be performed on a urine specimen?

Although not stated here, if POCT test, the specimen should be screened for specimen validity and adulteration prior to reporting a negative result by the POCT tester. Any specimen which fails a SVT or adulteration screen by POCT tester should be sent to an HHS certified laboratory for confirmation.

Subpart F Federal Drug Testing Custody and Control Forms

OMB-approved Federal CCF are multi-part carbonless forms which are pre-printed, usually by the drug testing laboratory and coded with client information embedded in the barcode number of the form. Laboratories report that 1 form is returned with a sample for every 2 that are printed. Additionally, several weeks are required to set-up a new account and pre-print and distribute these forms. It is estimated that the cost associated with managing pre-printed OMB-approved CCF may be as high as $4 per form. These costs are borne by the laboratory, collector, and MRO, but ultimately passed along to the employer as overhead costs.

Allowing the OMB-approved Federal CCF to be available in an electronic format will cut the cost by 80%. Pre-printing forms will no longer be necessary, since they will be printed on demand. Forms will be immediately available to all that have access to the laboratory's web site. New accounts could be set-up on line, without the delays associated with printing and shipping forms. In its preferred mode, donors and

collectors would sign the form using an approved signature capture method or digital signature, allowing the service providers access to the signed CCF on-line.

Section 12.6 What criteria will the Secretary use to place a POCT device on the list of SAMHSA-certified POCTs?

a) Criteria for SAMHSA-certification is to correctly identify 80% of positive drug samples in the + 20% range. This actually holds POCT devices to a higher standard than laboratory-based screening, and is beyond the capability of lab and POCT tests at this time. In today's laboratory-centric model, the screening portion of the lab (using an instrument that costs over $200,000 each) routinely sends 8 to 10 % of specimens on to confirmation for further testing by GCMS, where only 4-5% confirm positive. This is because the focus has always been to allow no false negatives. This is the same approach that should be taken in the POCT area. The standards should be set to focus on eliminating false negatives. Therefore, an evaluation that demands 100% accuracy in samples above the cutoff, but where the evaluation at 20% below the cutoff is eliminated. This would allow POCT manufacturers to increase the sensitivity of their devices to allow no false negatives, with the tradeoff that some specimens slightly below the cutoff are sent to the laboratory for confirmation.

b) Section 12.6b suggests that no false positive adulteration tests will be tolerated. Section 12.12c suggests that a single false negative POCT after confirmation by a laboratory (from the 10% of the negatives sent to the lab) or a single false positive PT sample failure of the POCT, is subject to SAMHSA decertification. (12.13) Comparing POCT test results to GC/MS or even EMIT result will prove misleading. The goal of the POCT is to report zero false negatives. However, to achieve this feat, which even EMIT cannot achieve, the POCT must effectively lower its cutoff level to -25% to -50% below SAMHSA cutoffs. Doing so, will increase the number of samples sent to the laboratory and increase the false "presumptive positive" sample number.

Three percent (3%) of POCT negatives sent to the laboratory is more consistent with current QC for lab-based tests. This will reduce the financial burden on POCT testers.

Section 12.13 What is the responsibility of the Secretary when a failure is

reported.

Based on the current criteria, no POCT device will be used for long before a false negative or false positive (presumptive) is identified. There is no clear definition of what constitutes a problem with a device under Section 12.13a. Is a single false negative or a single false positive sufficient to establish that a problem exists? Is it a number of repeated errors, a percentage of errors, and what role does the POCT tester play in this determination.

Temporarily suspending the use of the device OR removing the device from the SAMSHA certified list may unduly injure the POCT manufacturer prior to any due process of allowing the device manufacturer to reply to HHS concerns.

POCT are not designed to report positive results, merely with a very high degree of certainty, similar to EMIT, identify negative specimens, i.e. specimens which contain no drugs at the cutoff levels. Establishing a near-zero (lab-based immunoassay rates) or zero false negative rate makes more sense for POCT than a zero false negative/zero false positive expectation.

Section 12.16 What are the quality control requirements when conducting POCTs?

Based on the current criteria, conducting a POCT testing will be prohibitively expensive for Federal Agencies. In particular, the requirement for one positive and one negative control to be run each day of testing is not economically practical or consistent with practice with other POCT devices. It is critical to understand that the average volume per day per POCT-equipped clinic is less than four and in at clinics that are new to POCT the average is one. Therefore, adding a daily negative and positive control will add 50 to 200% onto the cost of a collection/test event.

Aside from the clear economic problems, this daily QC requirement is not consistent with current practice with POCTs in clinical settings. These products are designed to be operated with minimal training and operators who read at a fifth grade level. Detailed stability studies performed as part of the FDA submission process will assure that, as long as the product is used within the approved dates, the product performs consistently day-to-day. This is particularly true for Instrumented POCT tests, where variables such as visual acuity, background lighting, and subjective interpretation are eliminated as causes of day-to-day variation. In lieu of daily QC, I

would propose running QC samples on a per-lot basis, consistent with other POCT programs. This would assure that the lot used is a good lot, and would reduce the cost of the QC program substantially.

In summary,

1. Separate alternative specimens from alternative technologies (POCT and IITF)- consider waiting with alternative specimens until further scientific issues are resolved. proceed with urine POCT and IITF.

2. POCT- Consider limiting to tests performed "under seal. Do not certify devices which require the collector to break the tamper-evident seal and introduce a foreign object into the sample for purposes of aliquoting the sample in an uncontrolled environment. This is likely asking too much from the tens of thousands of POCT testers that will appear worldwide.

3. Introduce the concept of a "positive control" on a POCT. Make POCT standards consistent with laboratory EMIT screening, by focusing Proficiency Testing and the Device Evaluation Process on eliminating False Negatives, not on an arbitrary 80% overall accuracy figure.

4. Remove oral fluid tests for marijuana at this time. Reconsider oral fluid specimens at such time as the scientific issues related to environmental contamination and the proper window of detection, and cutoff levels have been established before granting them "gold standard" status.

5. Do not allow oral fluids for pre-employment testing. This will create tendency for oral fluid devices to lower cutoffs and widen the window of detection beyond the "under the influence" window. Maintain a window of detection that is consistent with impairment for post accident and reasonable cause, not the limits of detection for pre-employment.

6. If oral fluids are allowed for any type of testing require the urine sample to be

collected concurrently, not subsequently for marijuana confirmation.

7. Allow the OMB-federal CCF to be available in an electronic version from end-to-end, consistent with the Paperwork Reduction Act, and improve the efficiency of all federally regulated tests, while cutting costs by up to 80%. Include donor and collector signature capture capability.

8. Change the QC program requirements to be on a per-lot basis, eliminating the substantial financial penalty of daily QC and making it consistent with other POCT tests used in the clinical setting. Set the % of negatives sent to lab at 3%.