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Subject: Comments to Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs, FR Docket No. 04-7984

The subject mandatory guidelines are a substantive change from the current guidelines and attempt to address complex issues in a readable and understandable format. The Department should be congratulated in its attempt to make this complicated procedure "user friendly" and actually attainable. However, there are a number of issues the Department needs to review and/or correct prior to publishing the final rule.

1. The following statement on pages 19674 and 19675 is very troubling: "Although performance in the pilot PT program has been encouraging ... 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." HHS must address this concern and specifically provide scientifically supportable studies and PT results that would unequivocally show that the science and procedures are in place to fully support use of alternative specimens. Otherwise, employees (donors) will use this type of language for litigation and will attempt to show that even HHS as an agency, has some doubts about the accuracy and viability of the proposed processes.
2. This is further supported by other statements throughout the preamble: "There are a number of factors that may influence the amount of drug incorporated into the hair (e.g., drug dose, length of exposure, drug chemical structure, charge). Of particular concern are environmental contamination and role of hair color." [Page 19675] "In order to protect Federal workers from incorrect test results for marijuana ... a urine specimen will need to be collected under the current Guidelines at the same time the oral fluid specimen is obtained, primarily for the purpose of testing for marijuana when the oral fluid specimen is positive for marijuana." [Page 19676] "The Department knows from direct experience ... that some individuals may not be able to wear the sweat patch for the optimal period of time [3 – 7 days]. Skin sensitivity and rash are factors that can only be known after the

patch is applied for the first time." [Page 19677] "The Department also knows from direct experience that if the patch is applied in a normally visible area of the body, such as the upper arm, that there could be a stigmatizing effect on the wearer." [Page 19677]. These statements will be used to challenge the Department's scientific accuracy related to the testing procedures proposed in the NPRM, unless the Department makes specific and definitive statements in the final rule "correcting" these problems and providing reasonable and scientific solutions.

3. Marijuana is currently the most abused illegal drug, both in society and in the work place. Because of scientific unreliability in detecting the parent drug in oral fluids, HHS is directing that agencies which use oral fluid devices, also collect a urine specimen. This is an additional procedure, adds extra cost to the process, and is redundant. Recommend that HHS provide the possible procedures that would be used for oral fluid collection and testing, but withhold implementation until the science can support the results. It does not make any sense, personnel wise or cost wise, to use a process that is known not to produce a result and require another process to fill that gap.
4. HHS is proposing to lower initial and confirmation cutoffs for cocaine and amphetamines for urine with only a reference to one study that indicates that these cutoffs should not result in claims of passive exposure. Recommend that in the final rule, HHS provide more specificity and examples to provide hard rational for lowering these cutoffs. This will prevent future litigation and possible lost cases, especially if the scientific supporting rationale is included in the rule text.
5. There is a significant gap in the NPRM in that it does not address or provide any rationale or scientific basis related to the different cutoffs for different specimens and how these compare with each other and the cutoff relationship to drug use. First, donors will immediately challenge any result on an alternative specimen stating that if urine had been used, they would not have been positive. Agencies will have no data on which to challenge this assumption, i.e., that a cutoff for cocaine of 500 pg/mg in a hair specimen is comparative to 150 ng/mL for urine specimens. If this type of data is available, recommend that HHS place it in the rule text to ensure that agencies and ALJs have access to this information. Additionally, this would preclude donors, after taking a urine or oral fluid drug test, having a hair test or sweat test done with different quantitative results (possibly even a negative), which they then use to show that the original test was not valid.
6. Subpart C – Drug and Validity Tests. The proposed rule states that if A and B specimen do not have the same physical appearance and if A tests negative, the result should be reported as invalid. Recommend that in this case, HHS direct the laboratories to re-designate the A and B specimens and test the original B. If both A and B are negative, the assumption should be that the difference in appearance is a result of collection error and report a negative result. If the original B specimen (re-designated as A) is positive, adulterated, or substituted, the lab would report that result to the MRO. In the majority of cases, when the MRO reports a non-negative result, the donor does not challenge the result. In some cases, the donor may ask for the split to be tested, and since the split is not available (already tested prior to re-designation), the test would be cancelled and another one collected under direct observation.
7. Subpart D – Collectors. 4.1(c) indicates that an individual who can link the identity of the

donor to the drug test result, should not be a collector. However, the rule permits a collector to conduct a POCT collection where the collector knows the results of the test, and even though these results are preliminary, this knowledge is as sensitive and potentially damaging to the donor as the result of a laboratory test. Recommend this prohibition be deleted. Recommend additional constraints be identified, e.g., collector cannot be another safety-sensitive employee, a relative, ex-spouse, etc.

8. Subpart E – Collection Sites. 5.3 requires that collection sites store records for a minimum of 2 years without providing a rationale for this requirement. Collection site records are copies of the CCF that the employer or agency would have and that the MRO has. All information related to the collection should be on this form or as an attached MFR. Collections sites which are health clinics already have an inordinate amount of records to store and it is questionable as to the benefit to ask them to store collection records for such a long time. The Department of Transportation requires collection sites to keep records for 30 days, in case the original employer or MRO forms are lost in the mail. Once the employer (agency) and MRO receive the CCF, there is no need to require the collection site to maintain it. Recommend that HHS delete this requirement in the final rule.
9. Subpart F – Federal Drug Testing Custody and Control Forms. HHS asked if there should be separate forms for each type of specimen collected. Recommend that only <u>one</u> CCF be developed that can be used for all specimens. Collectors have a hard time now – with only two forms – in using the right form. If each specimen had its own form, a large percentage of collections would be done on the wrong forms.
10. Subpart G – Collection Device. 7.2 (a) and (b) seem to place the employer or agency into a catch-22 situation. Only devices that do not affect the specimen may be used; if cleared by FDA, it is deemed not to affect the specimen, but (b) states the Guidelines no not determine if a device must be cleared by FDA. This is very confusing to the reader and needs to be clarified.
11. Subpart H – Specimen Collection Procedure
    a. 8.1 (c) requires that the collector <u>request</u> the donor read the back of the form. This will be interpreted to mean that all donors must read the back of the form and if they do not read it, they will challenge the validity of the collection. Recommend that the procedure direct the collector to only point out to the donor that collection procedures are spelled out on the back of the form and the donor <u>may</u> read them if he/she desires to do so.
    b. 8.2 Recommend that directions be included for the collector of hair to check for such items as hair extensions, wigs, hairpieces, and provide guidance on what action a collector is to take.
    c. 8.2 Recommend that directions be provided describing what to do if the collector places the hair sample inside the envelope with the root-ends to the right instead of the left. Will this result in an "invalid" collection?
    d. 8.2 In hair collection as in other specimens, HHS needs to specify that the MRO copy of the CCF must be sent (mailed, faxed, scanned) to the MRO.
    e. 8.3 (3) The collector examines contents of donor's pockets and proposed rule text indicates that if an item is found that appears to have been brought to the collection site with the intent to adulterate the specimen – the collector must

secure the item and continue with a normal collection. This is inconsistent with the requirement in urine testing; when an individual brings an item with intent to adulterate, this becomes a serious issue and results in an observed collection. Recommend as a minimum, that if this is the case in an oral fluid or other specimen collection, direct the collector to do another collection using an alternate specimen or as a minimum make a notation on the CCF describing what happened during the collection.

f. 8.3 In all cases, the collector should be directed to have the donor open his or her mouth so that the collector can ensure that the donor does not have any item in his/her mouth that would interfere with or dilute the oral fluid collection (e.g., lozenges, capsules filled with fluid, etc.).
g. 8.3 (8) Recommend that HHS provide more specificity on how the collector will mix and transfer the oral fluid into two tubes.
h. 8.3 (9) Approval to send only one tube of oral fluid should be deleted. Recommend procedures for "dry mouth" be developed and, as a minimum, if this condition exists during a collection, direct the collector to use a different specimen for drug testing, not just send in one tube.
i. 8.3 (17) Recommend that HHS direct collectors (and by that nature manufacturers) to send the oral fluid in tubes or packaging that would resist damage in transit to the laboratory.
j. 8.3 (17) Recommend that HHS provide guidance on how to transfer the specimen to the POCT tester – via an MFR, note on the CCF, etc.
k. 8.3 (b) Recommend that HHS direct the collector to send the MRO copy of the CCF to the MRO.
l. 8.4 (8) Recommend that HHS stress that when the donor returns with the sweat patches to the collection site, he/she must be properly identified, again, to ensure it is the same person returning with the same patch ID number.
m. 8.5 (4) Recommend that HHS also address removal of head gear. This had been an issue with DOT collections, specifically related to "religious" head coverings.
n. 8.5 (9) Recommend that HHS permit a monitored collection in a public restroom be conducted by either gender. This requirement frequently causes additional cost to the employer or agency and slows the collection process. DOT has always permitted a different gender collector in this type of situation and has not had any problems, complaints, or litigation based on this procedure. Additionally, here, as in other collection procedures, consistency with current DOT practices would help standardize the whole collection process.
o. 8.5 (10) Recommend that HHS change the amount of fluid provided to the donor in a shy bladder situation to 40 oz. Based on medical and scientific studies, DOT determined that this amount would better ensure that the donor had sufficient fluids to provide a sample and at the same time be within a safe margin for the amount of intake. At this point, DOT has had no adverse reports related to the amount of fluid permitted in a shy bladder situation. Recommend that HHS be consistent with DOT procedures. This would also prevent collectors from being confused as to how much fluid to administer during different collections.
p. 8.5 (19) Recommend that HHS delete approval to submit only one bottle if there

is insufficient urine specimen. This is inconsistent with 8.5 (10) where the rule text directs that the collector "discard the insufficient specimen and a second specimen must be collected". Additionally, with the capability to use alternative specimens for drug testing, authorizing a single specimen to be sent to the lab is inconsistent with the process. Also, all DOT collections require two bottles. For HHS to permit one bottle will cause additional problems for collectors who will be confused with two different requirements from two Federal agencies.

q. 8.5 (26) Recommend that HHS direct collectors (and by that nature manufacturers) to send the urine specimen in packaging that would resist damage in transit to the laboratory.
r. 8.3 (27) Recommend that HHS provide guidance on how to transfer the specimen to the POCT tester – via an MFR, note on the CCF, etc.
s. 8.5 (b) Recommend that HHS direct the collector to send the MRO copy of the CCF to the MRO.
t. 8.6 (b) Recommend deletion of annual inspection of collection sites. For most large agencies or DOT regulated employers, this would translate into hundreds if not thousands of sites, some being restrooms in train or air terminals. There is no legitimate reason (at least HHS has not provided one) why this inspection should be required. In fact, it is not the site that causes problems, but the training and expertise of the collector.

12. Subpart I - HHS Certification of Laboratories
    a. 9.1 Much of this information should be in the preamble; it is not rule text.
    b. 9.2 A private employer, not regulated by the Federal government, does not test under the Guidelines' jurisdiction, even if the same procedures are used. Not sure why this is in the text?
    c. 9.6 (5) Requiring that a lab detect and quantify 50% of an individual drug on PT tests seems like a very low requirement. Is HHS actually telling the public that a lab that has a 50-50 chance of properly identifying a drug on a PT sample meets HHS scientific and technical requirements to conduct drug testing? The same is true for the other alternative and urine specimens.
13. Subpart K – Laboratory
    a. For all test results, HHS is permitting faxing and electronic transmission of reports to the MRO. Recommend that HHS provide specific guidance on the content of the "computer generated electronic report" and specify minimum security requirements for transmission of electronic data.
    b. 11.10 Recommend that HHS specify what a laboratory must do if the result of the laboratory testing is different from the result of the POCT. For example, the POCT was a negative result submitted per regulatory requirement and subsequently tested positive at the lab; or the POCT test was positive for one drug and the laboratory discovered either a different drug or an additional drug.
    c. 11.15 Recommend that HHS provide rationale and scientific background as to why now they permit use of other technologies (LC/MS, GC/MS/MS, LC/MS/MS).
    d. 11.18-11.21 HHS uses the term "appropriate calibrators and controls" without specifying what they are. Recommend specificity so that each laboratory uses the

same procedures.

e. 11.25 The proposed rule goes into excruciating detail for conducting validity testing on urine specimens, but only briefly mentions a few requirements for alternative specimens. One term use frequently is "measurable concentration" – what does this really mean? Will measurable concentrations vary from laboratory to laboratory? Recommend HHS provide more specificity as to various measures, cutoffs, and other quantitative requirements.

f. 11.32 (d) HSS is directing that laboratories must make qualified personnel available to testify in proceedings based on test results reported by that laboratory. Recommend that HHS consider this requirement only for the newer alternative specimens, since the urine testing program has a supportable legal history and is now rarely challenged.

14. Subpart L – Point of Collection Test

a. 12.1 This part is more appropriate for the preamble as opposed to rule text.

b. 12.2 See comment related to 7.2.

c. 12.12 Recommend HHS also include failure in PT if the result is a false positive.

d. 12.18 The process of sealing a POCT container and then breaking the seal to obtain an aliquot seems cumbersome. Why not remove an aliquot in front of the donor, seal the POCT container and then test the aliquot either in front of the donor or right after the donor departs the collection site. The whole purpose of having a security seal on a container initialed and signed is to ensure the integrity of the specimen. To have a process that permits breaking the seal raises the question of why have the seal at all.

e. 12.21 HHS needs to comment on the whole issue of "stand down" when the initial POCT test is a presumptive positive. Does the agency remove the individual from safety-sensitive function, is there possibility of stigma, etc. DOT has in place a policy that HHS could adopt.

f. 12.24(b)(3) To require a copy of the collector's resume or curriculum vitae seems like overkill in this process. First, what the collector did in previous jobs has nothing to do with the current skills. Only requirement should be documentation that the collector received proper collector training.

g. 12.27 HHS should place some parameters on what appears to be an open and potentially questionable conflict of interest between a POCT manufacturer and a laboratory.

15. Subpart M – Instrumented Initial Test Facility

a. 13.1 It is unclear why HHS now wants to permit a separate "screening" facility when in the current Guidelines it is prohibited for a laboratory to only conduct screening and not confirmation testing. HSS must provide some rationale to the public for this change. Additionally, if would seem that very few laboratories would want to set up these facilities if they can already accomplish this "in-house" at the laboratory.

16. Subpart N – Medical Review Officer

a. 14.1 Recommend that HHS limit MRO functions to those physicians licensed in the U.S., Canada, and Mexico, similar to the DOT requirement. This would prevent physicians from different countries, with different training and cultural

attitudes toward drug use, from functioning as MROs for Federal agencies and would be consistent with current DOT regulations.

b. 14.1(b) For over 10 years there have been three national organizations conducting training for MROs. Recommend that HHS "grandfather" these and only try to approve or certify those organizations which come into being after the date of the rule implementation. Additionally, HHS does not spell out what objective measure will be used to determine qualification. These are necessary if entities want to provide this training and want to meet HHS criteria. However, HHS needs to provide the public with rationale for this requirement. Currently, there are probably no more than 15 or 20 MROs providing services to Federal agencies; there are thousands of MROs who do not come under HHS regulations, providing services to DOT regulated and non-regulated employers . Does HHS have the resources to require this type of certification and review for the small amount of MROs which would be affected by this requirement? Additionally, the public will perceive this as the usual governmental over-reaching to try and foist a requirement on the whol MRO training industry based on such a small number of MROs who support Federal programs. If HHS is concerned about the quality of these physicians, recommend that with such a small number, HHS develop and initiate a training program for Federal MROs. This would certainly ensure that these physicians meet HHS requirements and at the same time would not impose additional burdens on the public.

c. 14.2 Recommend that HHS include ongoing continuing education requirements for MROs similar to those in the DOT rules. This is the only way that many MROs will be motivated to stay abreast of new technologies and requirements in the drug testing field.

d. 14.3(b) Recommend that HHS insert the same requirement that DOT has for the MRO to review 5 percent of the negative results performed by the MRO staff. Quality control is crucial in this process and this will ensure that the MRO provides this oversight to the staff. This requirement is stated in the preamble, but not in the rule text.

e. 14.4 (d) If both tests are invalid and the employer or agency needs a negative result to hire the individual, what is the procedure? This may happen more often than we think and HHS should address this in the rule text. (See h. below.)

f. 14.7(b) Historically, HHS has provided data that indicate dilute specimens are common, especially with the current trend in physical fitness and hydration, and have no relationship to real life attempts at dilution. On what basis is HHS now requiring the MRO to contact all dilute specimen donors to obtain a medical history? When a donor with a negative result that is dilute has no explanation for the dilute specimen other that he/she drinks a lot of water, there does not seem to be a legitimate nexus to require another test under direct observation. Even if the result was positive and the donor had a medical explanation for the positive result, it still does not provide legitimate rationale to conduct another collection under direct observation. This requirement will create a large and added expense to agencies and employers since they will be charged for the extra collection and testing, plus the for the extra work MROs will have to perform. Recommend HHS

return to the current DOT policy that a negative result which is dilute, gives the agency the option of conducting another one time collection with minimum notice.

g. 14.7(d) HHS provides guidance on verification of opiate positives in urine test results, but no such guidance exists for the alternative specimens. Recommend these be included for alternative specimens.

h. 14.9 14.7 (f) If the second test is also invalid, the proposed rule requires the MRO to cancel the test and recommend that no further action is required on the part of the agency. Recommend that HHS change this requirement and direct that in this scenario, the MRO direct the agency to conduct a third test using one of the alternative specimen methodologies. In many cases, a negative result must be obtained if a donor is to be hired. With no negative result, the agency may not be able to hire the donor and may face legal action.

i. 14.9 As written, this paragraph prohibits the use of U.S. mail to send MRO reports. Additionally, it directs that a "hard copy" must subsequently be sent even though a fax or scanned image has already been sent. Recommend that HHS use the same process for reporting as is currently used under the DOT rule and similar to the proposed requirement for laboratory reporting. Because of the added complexity of electronic records, there is a need for HHS to define the various terms used (e.g., hard copy, faxed copy, scanned copy, data file, etc.). Additionally, HHS does not provide sufficient guidance on electronic reports (both from the laboratory and the MRO), in spite of the fact that most laboratories and MROs are using this process to report results. DOT supported a Federal Advisory Committee which met over a two year time period to discuss just these issues. Recommend that HHS review the findings of this committee and adopt some of their recommendations.

17. Subpart O – Split Specimen Tests

a. 15.2 (c) Why is the second laboratory directed to conduct validity testing if it fails to reconfirm the presence of the drug in urine only, and not in alternative specimens? If there is a scientific rationale for this, HHS should provide it to the public.

18. Subpart P – Criteria for Rejecting a Specimen for Testing

a. 16.3 (c) It will be very difficult for the MRO to track "insignificant" omissions or discrepancies, especially when they are reported for different agencies, and from multiple laboratories and collection sites. If it is insignificant, it will be hard to convince someone to make attempts to correct it. Recommend that HHS use the same criteria that apply to DOT tests, i.e., if a test is cancelled because of a mistake or omission, then the MRO must direct the laboratory or collection site to re-train the individual responsible for the mistake. This makes more sense and provides a nexus to the corrective action and the actual problem.

b. 16.4 (b) Recommend that HHS expand on this requirement. As written, it limits the corrective action only if the donor refused to sign the CCF. In fact, many times, the collector forgets to tell the donor to sign the form. The rule text should provide for the collector to be able to state that the reason there is no signature is because the donor was not asked to sign it. The end result – no signature – in

either case is the same and the testing can be conducted and reported.

19. Issues of Special Interest
    a. Collection of a urine specimen when oral fluid is used as a test. Recommend that HHS postpone implementation of oral fluid testing until such time as this technical issue can be resolved and supported with scientific studies. It does not make any sense, management wise, procedurally, or cost wise, to conduct two tests because one is not adequate.
    b. HHS should specifically address "dry mouth" issues for oral fluid testing. This is no different than a shy bladder concept and will occur. Dry mouth may be the result of medications or other physiological conditions. One option may be that if a dry mouth collection occurs, the collector may use a different specimen to conduct the drug test.
    c. HHS is requesting comments on the appropriateness of the proposed cutoff concentrations for each type of specimen. Unfortunately, the general public does not have the technical resources or sources which could provide scientific comparisons to the various cutoff values proposed. However, HHS must seriously consider the fact that urine testing (and the various cutoffs) is the gold standard and has been accepted widely by the public and legal professionals. Any cutoff recommended for alternative specimens must have equivalency and comparison with urine cutoff values. For example, the initial test cutoff for marijuana is 50 ng/mL. Any initial cutoff used for alternative specimens must be comparable to the urine cutoff and supportable by scientific studies, so that there can be no challenge, i.e., the hair or oral fluid cutoff represents a higher level of drug in the system than the cutoff for urine.
    d. The requirement to use collection devices that do not affect the specimen is appropriate. However, how will agencies know which devices meet this requirement? If HHS wants these devices to be approved by the FDA, then that should be clearly spelled out in the rule. Conversely, HHS may want to depend on manufacturers to develop proper devices, but that would require HHS to provide some standards to which the manufacturers would be held. Recommend that the decision related to a device affecting or not affecting the specimen not be directed at the agency or employer.
    e. HHS is proposing that laboratories report quantitative values for non-negative results. Although this information is available at the laboratory and easily reportable, especially with electronic reporting, the value of this requirement is questionable. Historically, policy decisions have been that the actual quantitative result has no impact on the fact that a particular specimen was positive. This policy posture also precluded donors from trying to convince agencies, unions, and others, that they were not "impaired" or that the level of drugs was such that it had to be the result of passive inhalation or environmental contamination. Recommend that HHS determine for which specimens and in what situations the MRO must have a quantitative result to make a verification decision, e.g., such as in the case of a cocaine positive – as opposed to marijuana. These should then be the only quantitative results that the laboratory should send automatically to the MRO.

f. If an invalid result is reported, the MRO, in consultation with the laboratory, should determine if another test using the same specimen or an alternative specimen should be required. If the process is established where the second test is the same specimen and it comes back as invalid again, recommend that a 3rd collection be directed using an alternative specimen.
g. HHS is requesting comments on any other errors that must be corrected before the MRO can report a test. Recommend that HHS specifically direct the MRO to have in his/her possession a copy of the CCF with the donor's signature – otherwise, the result may not be reported. This will prevent MROs reporting results before they receive any of the documentation that they need for the verification process.

Thank you for the opportunity to comment on this proposed regulation. As mentioned earlier, this is a very complex and complicated issue. The comments and recommendations are sincerely meant to help HHS develop a rule that will meet the needs of Federal agencies and other employers in their need to have drug-free employees while at the same time protecting the privacy and rights of the individual employee.

If you have any questions on the above, please do not hesitate to call or email.

Sincerely,

Don Shatinsky, MS
Chief Executive Officer
Drug Testing Policy Consultants