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RE: Notice of proposed revision

FR Doc 04-7984

Dr Walter Vogl
Drug Testing Section
Division of Workplace Programs
5600 Fishers Lane
Rockwall II, Suite 815
Rockville, MD 20857

Attn: Dr Vogl,

I would like to offer my comments on the Notice of proposed revisions. As the owner of a drug testing consortium/TPA and a Certified Substance Abuse Program Administrator, C-SAPA, with nearly 15 years of drug testing industry experience I am offering my suggestions and comments on items I feel are flawed and may cause challenges and legal ramifications in the future if these regulations go into effect as they stand.

Hair Testing:

I am not comfortable with the comments made in numerous sections of the document which reflects inconsistencies between hair color and drug metabolite absorption. I feel unless this issue is dealt with and brought to a definite medical explanation and acceptable ranges this leaves an argument open to discrimination between a person with dark hair versus light hair. I am uncomfortable with knowing the document states known flaws but is intending to continue with the use of hair testing after all. I would think the government would want to ensure it was 100% reliable before subjecting donors to its use.

Another point that I am not comfortable with, as with other commentors, is the extensive time period for the usage of the drug to show up in the hair. I do not feel that any employer has a legal right to know if a donor was using a substance up to 90 days ago (but less than 7 -10 days) before they apply for a job. Urine testing shows a smaller window where a chance of "Current" use is logical. I do not feel it is fair

to incriminate someone for using a substance before they even had a desire to take a pre-employment test. Although I wish that the donor would not find the need to take the substance at all I still feel we are violating their rights by utilizing such a large window of detection. On page 28 of the document it states that the drug or drug metabolites takes 7 to 10 days to appear in hair. That is not my definition of "Current" drug use.

Having such a large window of detection would hurt a donor who was trying to quit, had started some re-habilitation and tried to get a job. They would more than likely turn up positive with the hair test even though they were on the right track to starting over. If they were forced to wait the 90 days to clear their hair shafts from drug metabolites that could hamper them financially. I understand that we will miss some drug users by not using hair testing but I also feel we are punishing others who may want to honestly work while being drug-free.

Other points to consider on using head hair:

It may violate some religious rights. Some may not want their hair cut and feel it violates their freedom of religion. If this is the case does the donor have the right to request a different sample and at what time must that be done? At the time of hiring, at the clinic, before they are sent? At which time will it not look like a refusal to test?

If you are taking 1.5 inches to test from an individual with long hair which should amount to a 90 day window of past history but someone with shorter has 1.0 inches of hair cut would that not amount to approximately only a 60 day history? This would mean you are penalizing someone for having longer hair and rewarding the individual who keeps his/her hair cut short. This seems not only unfair but also illegal. This is not guaranteeing fair testing to all donors. If a method cannot be obtained that provides a clear cut even testing method then it should not be used.

I would think the only time you would want a larger window of testing is in the private or parole system where it is necessary to prove drug use over a long period of time. Child custody cases would be a great time to prove no drug use as well as maintaining your probation. If you were to use hair testing in a Federal application then any testing would work for me only if you had been in the program for at least 90 days. This takes out the window of before you were hired so that you are not punished for a substance you took before you were hired.

If this practice were accepted there would need to be a method in place to determine when the 90 days had passed. This would be cumbersome therefore I feel that hair testing should not be instituted in a Federal program.

Oral Fluid Testing

I find numerous problems with this type of testing and have also noticed similar comments on the web site postings.

I find it very cumbersome and unusual to require two tests in order to come up with one result. I don't understand why a POCT device would even be considered if it could not test for all the drugs required. It seems very costly and redundant to take a urine test as well as an oral fluid test.

One of the biggest complaints from donors are the time it takes at the clinic to get seen and perform the tests. If the system adds one more test to the requirements this will back up the tests taken after it and so on and so forth. This may make some clinics take less clients a day or go to appointments only. This would be a burden to the system and cause numerous problems with scheduling. It would also make it difficult for donors who show up for a test without an appointment. If they are turned away because the clinic is too busy and another facility is not close by will this become a possible refusal to test if the test is not completed? In smaller towns it is hard enough to find a clinic much less put more work on them.

Another time addition to this test, in addition to the fact that a urine test is also required, is that if the donor comes in chewing gum or has had anything else in the mouth this makes the collector wait for ten minutes before beginning the test. I understand that paperwork alone will take a few of those minutes up but a good collector should not need all ten of those minutes to get to the point of the collection. This extra delay will now make the collection process take longer, further backing up the waiting room.

The method for collection of the oral fluid I feel is very offensive. The oral fluid devices I had seen in the past used a swab that was placed in the cheek to absorb the saliva. This method was fairly simple and kept the dignity of the donor in place. This method that is mentioned in the regulations involve the donor to spit into a tube, allowing up to 15 minutes to fill this tube to a pre-determined amount. I think there will be many donors which will find it nauseating to drool or try to spit the required amount into a tube and then watch as the saliva slides down to the bottom. They are further subjected to watch the collector as the saliva is "mixed" and separated into two vials in clear view, then to sign the vials.

I cannot imagine that all walks of life would like to have to spit in front of someone for a drug test. I find it demeaning and I feel others do as well. I think that there can be problems with lipsticks interfering with the test - whether intentional or not - as well as cold sore medication or any other product that may be placed on the lips or the outside of the mouth prior to the test. I did not see any indication in the rules which made a woman or a man wipe their lips clean to ensure an accurate test, although in what way can you guarantee a clean sweep of the lips without further irritating the donor by messing up their makeup or giving them a bad taste or even an allergic reaction?

There was a request that comments be made regarding "dry mouth" and I do feel there is a need for a specific procedure where this is concerned. There will be issues of intentional dry mouth as well as real occasions where enough saliva cannot be produced. This needs to be addressed or there will be legal

challenges.

I think the use of oral fluids is flawed in many ways and I would like to see it dealt with differently before I would say that I can agree with its use in the Federal workplace environment.

Sweat patch.

The mandatory guidelines document did not make me feel confident in the choice of the sweat patch when numerous comments of known limitations. Again why would an industry want to incorporate a device with known limitations?

Some of my concerns on the use of the sweat patch are as follows:

In the document it is stated in one place that privacy is not a concern but I feel there will be on a small number of occasions a privacy issue. Females which do not want the patch on the arm and need it to be placed discreetly on the back should be granted a desire to have a same sex collector if the only way to reach the area for the patch to be placed is to remove or lower their shirt. This could leave a woman either left in her bra or with bare breasts if she had come to the clinic without a bra. Concessions need to be made to avoid a lawsuit for invasion of privacy or the refusal of a donor to test because the collector is of the opposite sex and privacy cannot be guaranteed.

I am also concerned with the stigma of wearing patches as well as the allergy issue. For some donors who are allergic to the patch they could end up with marks where the patches had been for weeks if not months. It is not bad enough for someone to have to explain the reason for wearing the patches in the first place it could get very humiliating to explain two marks for months. Having a known allergy to the adhesive devices used in medical testing I can attest to having suffered with round circles from a cardiac test for nine months before they disappeared. At what point does a donor say if they cannot tolerate adhesive tape? Will this be after the failure of the first test or do they need to go through the failure of the first attempt every time? Will they be able to have acceptable documentation from a doctor or a federal agency so they can skip this test in the future with this and other employers as well? Things to think about.

Timing of removal of the patch is also my concern. Will there ever be an occasion to where a holiday weekend or employee out sick or in a remote area that the patch cannot be removed by the 7th day? At whose expense will that be? Will the test be cancelled and this be in the donors favor, or will the test be extended now to the employers favor? If the test comes up positive on an extended test will this be open to legal challenges?

I am also concerned with the instructions to where a donor cleanses the skin first to prepare for the alcohol wipes before placement of the patch. If there is not a clear definition as to what the donor may

use to clean the skin with this leaves a legal loophole. I would think the agency would want a definite wording of which type soap can be used and that the donor cannot bring in soap of their choosing. I think it would be best to always have the collector perform the washing of the skin placement since the area may be placed on the back where a donor cannot be expected to reach. If the collector does not allow the employee to clean the skin first can the donor then come back later if they get a positive test and state it was not cleaned enough? Clear instructions removes any questions as to the procedures.

POCT general comments:

In regards to the requirements for ensuring the integrity of the system I would like to know how the issue of responsibility and payment are going to be determined in sending in the 10th sample for verification. Who will be responsible for paying for the extra fee in the lab confirmation of the testing? Does the clinic randomly choose which client to bill/send in for further testing depending on amount of usage at the clinic or is it going to be the actual 10th test that is done? Or must they incorporate this fee into their own collection fees and the results are given to the clinic? If the results are given to the employers then it would be logical that they would be billed by their own lab accounts. Who is responsible and thus held liable for tracking the number of tests to ensure that one of every ten tests are submitted to the lab for confirmation? Will it be the clinic or the agency using the clinic? Will the clinic be required to keep documentation to prove compliance and if so are the clients utilizing the clinics services expected or allowed to ask for poof?

If a test sent in for validation testing fails to confirm will it negate other tests done at that clinic or in the batch lot for the units? When a breath alcohol device fails to confirm then all tests done since the confirmation are also cancelled, will this also be done with the urine tests since the last confirmation and what will the basis be? The day of the collection, the collector or the batch lot of the collection device?

MRO requirements

I am not in agreement with the requirement that is being imposed on the MROs to track errors from collectors, labs, the transfer of a specimen to another tester or to the IITF facilities. I think this is incredibly burdensome and not very feasible. It would require a way to manage a database for errors that is not currently in place. I would think this needs to be managed by the inspectors whom are out in the field and seeing to inspections at the client locations as is done with the Drug Abatement Division for Federal Aviation Administration clients. Although I do not favor the clients receiving the penalties for the clinics negligence as is done for Federal Aviation Administration inspections I do think the inspectors should be able to take away an ability to utilize a clinic which has repeated infractions against it. If a clinic relies heavily on the usage of federal employee testing then this would be a financial burden to be restricted. This would then cause them to ensure compliance or risk losing income from a loss of client base.

I am in agreement with 11.26, 11.27, 11.28 and 11.29 which allow for a laboratory to report quantitative values for non-negative specimens rather than waiting on the request from the MRO. I think this information is important for the MRO to have and it slows down the review process when the MRO has to request it. This information should be available so an educated determination can be made as quickly as possible, especially in a random situation where the employee is currently working and possibly endangering the public and his/her co-workers.

Subpart D

I think there is contradictory information regarding who may act as collector. It states that the collector cannot be someone who could link the identity of the donor yet further in the document (Section 12.18) it states that the collector can after the donor leaves unseal the bottles and use the urine to check for negative results in POCT test units. This is against the rules of Subpart D. If you collected it you obviously can link the donor.

I also do not feel that in the federal realm of testing one collector should be responsible for determining the results. I think there is too much room for bribery, threatening and intentional misconduct, both positive and negative. For a collector to unseal the bottles to perform the initial screen unsupervised is not advisable. I would be agreeable to urine POCT devices only if the initial screening of the urine was done in a controlled environment. I do not feel that the clinic which collects the urine should be allowed to be the one to determine the result. Or, if the authors of this regulation feel strongly about allowing this right to the clinic there should be changes made as to how the tests are performed. They should never be done with only one collector present and at least one collector should be of management level. Both collectors should have to verify each result and sign off on the results. They both must be willing to stand up in court and defend the result. Having two collectors, one of high management level will discourage most chances of tampering with the specimen. In the event that the collection site has only one employee then instructions would have to be written in for this type of situation. Having the owner of the company being present to sign off on the test along with the collector could be positive or negative in effect. This then brings me back to having a screening or confirmation lab be the one to verify the specimen. This is my preferred method for reporting the result to the MRO.

I think having one collector being responsible for the results brings in too many chances for legal challenges and can cause unwanted threats from a disgruntled donor. Having all tests turned into a faceless lab removes the chance of placing a face to a result.

In Section 12.18 (e) I would hope that if this regulation is passed as it is written now that it would be very clear for the collector to understand which specimens are sent to the lab for confirmation. Since 90% of program errors we see for our clients seem to be collector/collection site errors having the collector having to determine which specimen to send in and how to read the result does not leave me feeling very confident. There is such a high turnover rate at collection sites and training is very sporatic. All rules on interpreting results and which specimens to send in must be very clear and specific so as to

not lose the chance on resulting a positive test. It is bad enough when a test is lost to error and the end result is unknown, but when you lose a known positive screen it would be very disheartening.

In Section 12.19 there is a requirement for testing POCT devices on a daily basis. I wondered if there was a thought put into who would be responsible for payment of these devices as well as the spiked samples and validity testing materials? Since these tests need to be performed on a daily basis how should a clinic incorporate these costs? Do they bill the first test of the day and/or who tests the most? Into the general operating costs for collections? Should a collection site wait until an appointment is made and rush to do the verifications before they take a donor to the back or should they do these types of verifications every day even if no POCT collections are done? Whom also will regulate over if they are done correctly and how should the clinic document and keep logs for such tests? Who has the right to see these logs? For how long should they be kept?

In general I am not comfortable with the proposed changes to the regulations since these guidelines will help shape future changes for 49 CFR Part 40. We have come a long way to gaining legal ground regarding the collection process and it is scary to think of going into uncharted territory with devices that are known to have some drawbacks. If I were to choose one device to be allowed I would go with a urine POCT collection container, however I would ensure that it was read by a screening laboratory off site from where the collection was made so there is no connection to the initial donor.

I hope I may have pointed out some issues that may be helpful in the re-writes to this proposed regulation change and that my comments have been beneficial. You may contact me at the address listed if you have any questions regarding my points.

Sincerely,

Kimberly LeClaire

Kimberly LeClaire C-SAPA
Owner