American Medical Review Officers, L.L.C.

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Dear Dr. Vogl:

Thank you for the opportunity to respond to the proposal to modify the Mandatory Guidelines by adding alternative specimen testing and point-of-collection testing. While I see a few good things coming out of these proposals, I also have some grave reservations.

Medical Review Officer's need clear, consistent and defensible guidelines in order to do our jobs. Drug testing and the implications it has for the individual worker, requires solid science and solid interpretation of that science. When someone's career and livelihood is on the line we should expect nothing less.

Many of the proposals contain language revealing that the science is incomplete. In light of this how can we even consider such changes?

Clear and defensible science allows everyone in the drug testing industry to make clear and defensible decisions regarding the drug test results. Many of the proposals will leave labs, MROs and employers hanging on the incomplete science. Lawyers will have plenty of opportunity to attack these guidelines—and at what expense in time, money and careers?

Please, let us think this through more clearly and rationally before proceeding.

Training Issues:
My understanding is that one of the major collector training organizations has diverted attention to alternative specimen training and has neglected actually doing the mock collections as part of the urine specimen collection training. Hands-on training is the only way to properly learn and retain this material. It should be required for certification.

Few medical practices are going to spring for the training costs for each particular specimen and I see it as unlikely that they will keep up with the changes. I have already seen places messing up hair and oral fluid collections due to poor training. Multiple alternative specimens should not be allowed. It will only confuse the collection and review process.

Subpart H -- Specimen Collection Procedure
Section 8.2 Head hair:
Is there a Federal CCF for hair collection? Producing and refining forms takes time.

Lice defense: If the donor has lice and the choice is made to use a different specimen (urine, oral fluid) does this create a bias for or against that donor? Hair detects longer-term use and repetitive use. If oral fluids / urine are used they might detect more recent use that would not otherwise have been found in a hair sample or might miss use that would have been detected in the hair.

Is there a breach of confidentiality for "diagnosing" head lice and reporting it to an agency? Who is authorized to make the call? Can a medical technician, lab technician, or nurse make the "diagnosis" or will a doctor, ARNP, or PA do this?

Weight of hair sample:
It is very doubtful that most collectors will have the equipment available to weigh out 100 mg of hair. If the sample arriving at the laboratory does not meet the 100 mg criteria, will it be rejected for testing?

How likely is it for the average collector to make sure the hair is aligned with the root ends to the left in the envelope? We have a hard enough time getting urine into a cup. I doubt the average collector will align the hair properly.

If I were using drugs in the past and did not want a hair test done for that reason, I could shave my hair and thus divert testing to urine or oral fluids with a shorter detection window. What happens later if I have to do a hair test and I come up positive? There would not be a baseline hair test to compare. How would I defend myself that the positive was from use that would have been noted if I had had hair tested as a pre-employment test and not from use while I was employed? Would the hair sample be sectioned? What guidelines would be used?

Oral Fluid Collection --

Is there any requirement to visually inspect the oral cavity for potential agents to adulterate / substitute a sample?

How long does it take for someone to submit a 2 ml oral fluid specimen? It is unlikely that the average collector will be willing or able to tolerate observing this procedure. Watching someone for 15 minutes continuously drooling or spitting into a collection container is undoubtedly difficult to stomach. If you have several donors show up for collections it will also take a long time to accomplish this feat.

Oral fluids detect drugs for "one to 24 hours". This is an extremely short window. Marijuana, the number one drug of choice, can only be detected via oral contamination and for less than 24 hours. Collecting a urine specimen to be used only if the oral fluid is positive (and the donor claims passive exposure) seems to miss the point. If we can't detect THC in the oral fluids very

well, why even use the test or why not use the urine to test for THC and the oral fluid for the rest (unlikely scenario).

In my fulltime MRO position, I speak with many donors with a positive urine drug screen for THC. Invariably they report use days to weeks to months prior. I have followed some donors in rehabilitation who were still positive over 2 months after they were originally detected. Looking at the normalized ratios it did not appear that they had reused during rehabilitation.

Oral fluids would essentially not detect the vast majority of the marijuana users that I currently review. It would make my job easier (far fewer positives) but would miss the point of the entire program.

I have seen the statistics from the oral fluid testing claiming similar detection rates as urine. I just cannot see how a test that we all know can only detect THC for less than 24 hours is as good as one that can pick it up for days, week and even months. Is there a good head to head study out there?

Recently I had a donor who admitted a 20-year marijuana habit. She was shocked when her urine came up positive. She claimed having quit marijuana a month earlier and having passed an oral fluid test approximately 5 days before the urine test. Her quantitative on the urine was 29 ng/mL. I wonder what her recidivism rate is.

Once donors know that all they have to do is wait 24 hours to be able to pass a Federal oral fluid test you will see a lot more marijuana addicts joining the Federal workforce. You could party all you want on Friday & Saturday and still pass the test on Monday.

Another recent case: Donor: "I can't be positive, I quit (marijuana) 3 weeks ago so I could get this job." His quantitative was 100ng/ml. I hear this type of statement all the time from donors. If oral fluids were used (with a detection window of 24 hours or less imagine this scenario..."I can't be positive, I quit (marijuana) the day before yesterday so I could get this job."

While I know some are lying to me, many are likely telling the truth. We have a longer detection window with urine than with oral fluids. Given the incredibly short detection window, I would not choose to use Oral Fluids for THC. Perhaps it could be used for post accident or reasonable suspicion situations, but even then THC detection is problematic (short detection time and environmental contamination).

Pg 19674
The following is a troubling statement for those of us who will have to deal with the daily consequences of this proposal:
"Although performance in the pilot PT program has been encouraging, with individual laboratory and group performance *improving over time*, 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. (italics added)

We need a solid program. Not something that is "improving over time" and has not yet met acceptable accuracy requirements. It sounds like the science and the ability for laboratories to properly run the tests is incomplete. This proposal needs to be withdrawn until the science can support the concept.

Hair concerns:

Pg 19675 "Sweat can be responsible for drug incorporation at distal segments of hair which does not correspond to the time of drug ingestion."

Does this mean that the concept espoused that hair can be used to lengthen the detection window and that by sectioning it can help determine when a drug was used is actually or potentially wrong?

"Factors that influence the amount of drug incorporated into hair

Drug dose
Length of exposure
Drug chemical structure, charge
Of particular concern are environmental contamination and the role of hair color"
"Environmental contamination (marijuana, cocaine) is somewhat controlled by washing the hair and presence of the parent drug but lack of the metabolite suggests environmental exposure." (emphasis added)

The issues of environmental contamination and hair color effect are not adequately resolved to be able to stand up to forensic scrutiny.

Hair color:

Hair color influences drug incorporation.

The proposal talks about the definite difference in drug incorporation and then turns around in the next paragraph and says that the limited population studies do not show a significant association between hair color or race and drug analyte. It then goes on to admit again, "despite these suspected limitations the Department still proposes to go forward with incorporation of this new technology..."

pg 19687 states: "The Department is requesting specific comments on this hair color bias issue....." The data is incomplete, yet we are proceeding??

What guidelines are we to use? Do we wait for litigation to sort out the "facts"?

"Though there continues to be some question about the effect of hair color on the amount of a drug or its metabolite present in hair, there is no question about the fact that the drug or metabolite is present."

I see a bias here. If my hair is black and my co-worker has blond hair and we do the same amount of drug at the same time, I may fail the test and he may pass it—due to our hair color difference. If there is a racial bias that would further supercharge the issue. The public and the courts will take a dim view of this if the bias issues are not conclusively resolved.

ORAL FLUIDS
Pg 19676

Are there cutoffs for IgG levels? What medical conditions could / should we consider if someone has low IgG level in the oral fluid? Have MRO guidelines been developed for this?

"less is known about the pharmacokinetics and disposition of drugs into oral fluid as compared to urine"

When is this going to be sorted out? Is it going to take litigation to accomplish this?

THC—you can only detect the parent drug and for 24 hours or less. This is an incredibly short detection window and may be due to environmental contamination.
The urine specimen is only processed if the THC is positive to rule out environmental exposure. Since the vast majority of oral fluids will be negative anyway (the donor only has to wait 24 hours or so to be "clean" it's a colossal expense to collect and store the urine. If you are going to collect the urine then at least run it for THC and run the oral fluids for the rest.....I know that sounds ridiculous to run two specimens but the oral fluids cannot give us the information we need.

What if the collector fails to collect the urine specimen? Is that a fatal flaw? No guidance is given.

"Unfortunately, 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....."

This leaves it open to litigation since it is proposed to do something that could negatively impact an individual when the science behind the decision is incomplete at best.

"...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. The Department will revise the Guidelines when...

If the guideline is not as solid as possible now, please fix it before using it.

SWEAT PATCH

"The incorporation of drugs into sweat is poorly understood...
"Sweat patch contamination issues continue to be a concern."

How does the MRO handle this then??

Pg 19677
The Dept plans to allow this type of specimen yet, "...the Department encourages researchers to conduct further research in this area."

Again, incomplete science in a litigious situation that can have significant impact on someone's livelihood.

POCT for Drugs pg 19677

"Non instrumented POCTs for oral fluid have been characterized by only one group of independent investigators. Their study was performed on spiked oral fluid at concentrations consistent with the proposed cutoffs. This study found device variability and difficulty in detecting cannabinoids, but suggest the rapid evolution of the technology should overcome current problems relating to targeted analyte and manufacturer's cutoff and provide an assay consistent with proposed HHS cutoffs. The investigators felt that "there is every reason to be optimistic about the future for drug testing using oral fluid matrix" (emphasis added)

Optimism does not translate to practical use in a forensic, legal environment.

Pg 19678
"The use of highly trained laboratory personnel provides no specific or added value to any oversight process, beyond the actual testing of sample POCT devices.

We hear stories of POCT collectors misusing the information all the time. Our State Parole officers do not confirm with GC/MS. I was told by one, "we just let them tell it to the judge". Why even take it to court if its only a presumptive test? Other companies get a presumptive positive and stand there and ask the donor, "Now do you *really* want me to send this to the lab or do you just want to go your way." They don't understand the risk of acting on a presumptive positive. We have had furious donors come to our collection facility after being called positive on a POCT done by local companies(presumptive positive—not sent in for confirmation as it should have been). They then give us a standard urine drug screen (tested at a Federally certified laboratory) and it confirms/verifies negative. Medications tripped a presumptive positive in some. Others have been the victims of a collector misreading the counter-intuitive POCT test strips.

"This is a complex area that will benefit from public comments now, and from lessons learned over time."

This translates into litigation as a means to "learn".

Pg 19678 second column

" Oral fluid is not suited for return to duty, follow up testing and pre-employment."
Pg 19679 third column
"oral fluid is not suited for return to duty, and follow-up testing" (Pre-employment is not listed here but should be.)

Please clarify this issue.

Pg 19679
Bottom of 2nd column
"Drug detection times for the regulated analytes in oral fluid range from less than one to approximately 24 hours."

Which ones can you only detect for one hour? Why even bother? Its highly unlikely anyone would get tested within an hour anyway. The proposal should specify the drug detection times for each substance in each alternative specimen. This would shed more light on the challenges with alternative specimens and would give guidance to MROs and employers.

Pg 19679 last sentence
"It is expected that different results would be obtained for the different types of specimens because the windows of detection are different...If a problem occurs during the collection of one type of specimen (e.g. shy bladder for a urine specimen, insufficient specimen available), permission can be obtained from the Federal agency to collect an alternative specimen"

Where are the guidelines to decide when to divert to a different specimen. DERs will need very clear guidelines. When these situations occur at collection sites decisions must be made quickly.

If I am a savvy donor who has done marijuana in the past few weeks I would quickly learn to play the shy bladder or insufficient specimen game to get to do an oral fluid test. That way I'd be assured a negative test. I'd be taking my chances with the urine test. If a hair test were then used I'd be ok if I had just used in the past 7-10 days but would be taking my chances if I'd used enough and frequently enough beyond 7-10 days prior. If I was blond I'd have a better chance on the hair.

Pg 19680
"Based on the results from the PT testing program, it appears that some industry proposed cutoff concentrations for the alternative specimens are currently set at what appears to be approaching a limit of quantitation that reflect the analytical capabilities of one or two laboratories to detect extremely low drug concentrations.....The Department is specifically requesting comments on the appropriateness of these cutoff concentrations and the ability of laboratories to meet this requirement."

This does not inspire confidence. Can the labs are able to handle the requirements? If not, why are we on the verge of doing this?

Pg 19680 third column

"The Department is specifically interested in obtaining information on the ability of the various immunoassay test kits to detect MDMA.

Again, the science seems incomplete at best.

Pg 19680 last sentence
Lowering the cutoffs for cocaine and amphetamines seems very reasonable. But why are we tightening the regulation here in urine while essentially throwing out our ability to detect THC (the #1 drug of choice) in oral fluids?

Pg 19681 second column

"The Department also recognizes that validity testing proposed for alternative specimens is not as robust as for urine, but is confident that this testing will be refined over time."

Incomplete science, how can we initiate a program that is admittedly not ready scientifically?

Pg 19682 Re not altering CCFs

Practically speaking sometimes companies run out of CCFs and a CCF for another company is used in a pinch, appropriately altered and the testing proceeds. This can be critical in post accident tests especially. Why prevent the testing by adopting this regulation?

Why forbid the collector from annotating in a remarks section items related to a problem collection? Granted the space now is too small but it is often our only alert that a problem occurred.

2nd Column
This is a NPRM but we have not decided on the proper collection containers for the alternative specimens? We need a standard kit for each specimen (similar to the DOT program). Also, CCF forms (or preferably a single form for all specimens) need to be developed.

Inspection of Collection Sites
Great idea but how do we do it. My company alone receives results of collections done at over 3,500 collection sites. We find many who are not certified, or even if they are, don't understand the basic rules. Putting some teeth into the inspection process would be great. Who pays for it? Who holds their feet to the fire to maintain quality? We send out affidavits when we see errors. It's a huge task and often dismissed by the collectors. (We drop sites we find are not complying.)

Pg 19686 Subpart N
Section 14.3 MRO review of 5% of negative results reported by staff is consistent with the DOT rule. However, there is no cap. Reviewing the required 5% is a challenge administratively. I think the % should be lowered. Also, HHS should at least put a cap on the # needed to review such as DOT's cap at 500.

Pg 19686 third column at the top
It states that head hair cannot be substituted. I have seen people getting fake hair glued onto their heads due to pattern baldness. Apparently this process allows the fake hair to stay in place for several weeks. Is there a way to tell this hair apart from the donors real hair (aside from pulling on it!!)? What if someone does this with hair from a hair donor who was positive for drugs? (my call would be that it was the hair the donor submitted for testing so they would have to deal with the consequences). I think head hair could be substituted.

Pg 19687
MROs should NOT be required to track QA issues for collection sites, laboratories, IITFs, collectors etc. Each should have their own QA program in place. I routinely send memorandums to collectors & labs when discrepancies are noted. To do the additional tracking etc this proposal implies would mean having to hire additional staff and raise fees for no real benefit.

Pg 19687 3rd column top

Dry mouth—I think of Sjogren's syndrome, parotid gland disease and possibly some other disorders that reduce salivary function. This would be a pre-existing disorder or a new diagnosis prompted by the "dry mouth" problem collection. Procedures similar to shy bladder could be drafted.

Pg 19720
POCTs
I see it unlikely that most POCT users (individual companies) will do the negative controls required.

What liability is there for MROs accepting / reviewing negative POCTs from collectors not under their control? Most companies do POCTs so as to avoid the extra cost of MRO & laboratory services. MROs would have to charge to oversee the negatives.

Pg 19725
14.7 (b) The MRO requirement to contact every negative dilute will create a HUGE burden on MROs. I receive numerous negative dilutes every day. In fact I would spend most of every day just calling these donors. While we know that the percent of positives increases as the samples become dilute, we also know that many of these are completely innocent.

What criteria would you propose for MROs to decide which are legitimate and which are not? No guidance is given. Is the donor saying that they drank extra water prior to the test or "I always drink a lot of water" a legitimate explanation? How about diuretic use etc etc? Please stick with the DOT protocol allowing the companies to retest once. It works and will not require doubling or tripling the number of tests that would require a MRO's review.

Pg 19726 Subpart O 15.1(b)

This requires the donor to request the Split in writing. Currently DOT allows verbal requests. I have never had any trouble taking verbal requests. Forcing the request to be in writing would cause unnecessary delays in proceeding with split testing.

19729 16.3 c I work with over 3500 collection sites and 4 laboratories. I see no way to track errors by collectors and labs that "occur more than once a month" so as to direct corrective action. I notify them as I see them. They have their own responsibility and QA systems to take corrective action. If we have repeated problems we quit using them.

16.4(b) No donor signature on chain of custody. I agree with Dr Thomasino's proposal to have the MRO cancel these tests. Currently we can obtain affidavits. However, this is time consuming, reveals a lack of attention to detail on the collector's part and could raise some concern regarding the integrity of the test. Canceling the test would result in collector retraining and pressure from the company involved for the collector to do it right the next time. Collectors should then be required to pay for the test. Note that the "no donor signature" will not be caught until the MRO receives the CCF. Many times the specimen will already be in testing or completed at that point.

Summary
I recall that the military had a problem with their drug testing program back in the 1980s or 90s. Something in the testing was inaccurate and a number of individuals were falsely accused. Back tracking and clearing these people was undoubtedly a mess. Do we want to have such a thing happen on an even greater scale and with far more risk of litigation?

On the surface alternative specimens sound like a great idea and, maybe someday, they will be useful. However, there are far too many unanswered questions (including all the serious questions raised by the quite accomplished authors of this NPRM and by the public commenters.) Let's resolve these important issues before subjecting ourselves to the consequences of incomplete science. Hopefully these questions will be a springboard to enable researchers to resolve the issues.

Please withdraw this proposal until the science allows us to step forward with confidence. The American workforce deserves nothing less.

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