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Subject: Response to Department of Health and Human Services proposed rule changes FR Doc. 04-7984

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Response to FR Doc. 04-7984 pertaining to proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs.

In the preamble to the proposed changes several concerns are raised by HHS, these discrepancies should be addressed/corrected first before considering implementing these alternative specimens. Lets begin with hair;
As stated, the proposed length of hair being tested will be 1.5 inches, which would give a history of 90 days, how do you treat current (random) and prospective (applicants) employees fairly? Take into account one of the popular hair styles for men, bald, what type of specimen would you then collect? Urine? If you allow an alternate specimen to be collected you have unknowingly established a double standard for employment based solely on the vast differences in detection periods between the specimens being considered. With that, what are the initial screening levels for hair as compared to urine and what are the confirmation levels? Are they equitable? How much hair do you collect for a split? MRO verification for a prescription that expired 89 days ago?

Oral fluids should not be used until you can come up with a method that allows for split specimen testing and eliminating the distinct possibility of environmental contamination. Currently you propose collecting a urine specimen for the split, two different specimens, two different detection times. Again, where are the equitable factors pertaining to screening levels and detection time?

Sweat patches should not be used based on the same reasons, inconsistent with other methodologies and as stated stigmatism resulting from patch being visible while being worn especially if they are required to wear two in order to obtain a split. Having someone conduct a collection on themselves for a week should go against reasonable search and seizure laws as well as forcing one to produce evidence against themselves for actions taken during personal time.

Subpart C: Cutoff Levels, is 1 pg/mg in hair equal to 50 ng/ml in urine and 4 ng/ml in oral fluid and 4 ng/patch for sweat when testing for Marijuana? Have the same studies gone into the alternate specimens to reduce the possibility of environment contamination (being in same location) as have been done for urine.

Subpart H: Section 8, Urine collection procedures. (9) a certified professional should be allowed to conduct a monitored collection (public restroom/stall) should not require same gender. Insufficient quantity (shy bladder) should allow up to 3 hours from start to finish and for the donor to be provided up to 40 ounces of fluids. If test is to be a POCT, have collector collect 60 ml, 15 to test on site, 45 ml in the event the onsite test is presumptive positive, the collector would then process the specimen for confirmation testing at the lab. The following procedures could be followed for POCTs;

1) DER follows company policy as to employee notification (which should include type of test to be conducted and reason).
2) Employee reports to the collection site within time frame allotted per company policy.
3) Employee is given donor instructions at time of check in to read before being taken back to collection site.

4) Collector will come out and escort donor (employee) to collection site.
5) Donor will be asked if they have any questions pertaining to the instructions.
6) Donor will be asked to provide photo identification (must be employer or government issued).
7) Donor will be asked to remove unnecessary outer garments (hats, jackets, etc).
8) Donor will be asked to show contents of pockets. If donor has a known adulterant the collector will immediately conduct a direct observed collection. If donor refuses to provide specimen under observed conditions, it is a refusal to test and must be treated the same as a positive.
9) Collector will initiate testing form and have donor read and sign authorization statement.
10) Donor will be asked to wash hands with water only.
11) Donor will be asked to select own collection cup and testing kit.
12) Collector will verify testing kit is sealed and show donor Lot# and expiration date.
13) Collector will annotate this information on testing form
14) Collector will break seal on collection cup in front of donor.
15) Collector will brief donor as to how much specimen to provide (60ml).
16) Collector will instruct donor not to flush or wash hands until entire process is completed (hand sanitizer provided as interim).
17) Donor will then be given the specimen collection cup and go into collection location and provide specimen.
18) Donor will give specimen to collector. If donor does not provide any or cannot provide enough (60ml), shy bladder procedures are started. Donor is not permitted to leave collection site until specimen is provided or after three hours which ever comes first. Collection personnel can give up to 40 oz of water within the three hours. If donor departs before the three hours are up without providing a specimen, the collector calls the employer and notifies them of the refusal to test. If donor provides enough specimen the collector continues the process.
19) Collector will check temperature of specimen within four minutes and look for signs of adulteration. If temperature is out of range (90 to 100 degrees) or if the specimen appears to have been adulterated, the collector will immediately contact the employer and follow their policy. If every thing is normal the process continues.
20) Collector will then break seals in front of donor and transfer at least 15 ml into testing cup. The remainder of the specimen is set aside and not contaminated in case of confirmation testing.
21) Collector will then place testing device in testing specimen in front of donor and brief them as to what three types of results we could possibly get, negative, presumptive positive, invalid (faulty device).
22) If the results are negative or inconclusive, the collector then conducts an integrity check of the specimen and briefs the donor on the possible results we may see (normal, dilute, adulterated, substituted)
23) If results for both are negative and normal, MRO/MRO staff is notified results are negative and donor given copy and allowed to leave.
24) If test results are invalid (faulty device), donor selects another testing device and specimen is retested followed by integrity check.
25) If the results of the test were inconclusive (positive on the device) and or the integrity checks were not normal the uncontaminated specimen is processed for confirmation testing at a certified lab.
26) Collector will initiate a lab based Custody and Control Form (COC)
27) Collector will have the donor select a lab-based kit.
28) Collector will break seal on kit in front of donor.
29) Collector will break seal on specimen vials in front of donor.
30) Collector will transfer 30 ml from uncontaminated specimen into vial A and 15 ml into vial B in front of donor.
31) Collector will place tamper evident seals on vials in front of donor.
32) Collector will have donor verify that seal numbers match specimen number on COC and have them initial seals.
33) Collector will then have donor read certification statement on COC and sign and fill in day time and night time contact phone numbers in case medical review officer (MRO) contact is required.
34) Collector reviews COC for completeness and then signs the form.

35) Collector then separates form and places copy 1 in the specimen-shipping bag along with specimen and seals the bag in front of the donor and secures specimen.
36) Collector then gives donor their copy (#5) of COC and rapid form.
37) Extra specimen is discarded, collector performs after collection inspection of collection site, and donor washes hands.
38) Donor is allowed to leave the facility.
39) Collector forwards copy 2 of COC to MRO, copy 4 to employer and retains copy 3 for the collection facility as well as copy 1 and 2 of the rapid form (employer does not receive copy of inconclusive/positive rapid forms).
Specimen is transported to the lab either by lab courier or by shipper (FedEx, Airborne Express etc.).
***NOTE: Collectors do not report out positive POCT test results based on several reasons:
1) The collector is not an MRO and therefore is not qualified to make that determination.
2) The results from the lab are what trigger the MRO review if the results from the lab come back as anything other than negative.
3) The donor could be on a legitimate prescription and based on an MRO review would be determined as negative. (Then the collector would have breached confidentiality)

Subpart L- Requiring a daily test of POCTs should be changed to requiring one negative, one positive and one validity control be tested for each batch number received. Requiring one in ten negatives be forwarded to a lab for testing should be more in line with blind specimen requirements currently in place.

Requiring a donor to have their specimen sealed in their presence, then, after they depart the seal broken for point of collection testing and then resealed if presumptive positive goes against the integrity of the current collection process. Have the collector pour off from the specimen and test in front of donor, if results are presumptive positive, the collector would then process the specimen for confirmation testing in front of the donor and have them initial seals and sign form. The worry about the donor being confrontational should not be a consideration, look at the Breath Alcohol Technician. If the donor refuses to cooperate it's a refusal to test.

Not allowing a POCT site to have a relationship with an MRO is preposterous. The majority of your MROs work in an occupational health clinic setting and conduct pre-employment physicals IAW federally mandated programs such as the DOT. The staff of these same clinics collect the majority of your specimens; disallowing these relationships would have a major impact on the occupational health industry as a whole. This would also not permit an MRO to be affiliated with any hospital that conducts these types of tests through the hospital lab for things like pre-employment or through the emergency room for post accident testing. I feel by making confirmation testing mandatory at a certified lab using GC/MS and the MRO procedures for nonnegative results only be initiated based from their confirmed results, this would eliminate any possible improprieties.

Respectfully,

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