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MEDICAL REVIEW OFFICER SERVICE

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TO: DEPARTMENT OF HEALTH & HUMAN SERVICES
5600 FISHERS LANE
ROCKWALL II, SUITE 815
ROCKVILLE, MD 20857

RE: FR DOCKET 04-7984, PROPOSED REVISIONS TO MANDATORY GUIDELINES FOR FEDERAL WOTRKPLACE DRUG TESTING PROGRAMS

To Whom it May Concern:

I have reviewed the above captioned guidelines and have the following comments:

1) Sections 3.1-3.7: I am gratified that MDMA will be added to the tests performed for Federal Workplace Drug Testing Programs. This addition is long overdue, and will greatly enhance the value and impact of these drug testing programs. I must once again point out that in the interest of expeditiously and properly completing Medical Review Officer (MRO) reviews of methamphetamine positive results the analytical laboratory should be required to automatically perform and report the D, L methamphetamine isomerization assay (chiral assay) for any methamphetamine positive result. In the absence of this requirement the MRO is often compelled to request and wait for the chiral assay before making a final determination which adds at least one and usually several working days before a final determination can be appropriately and defensibly made and reported to the responsible organization.
2) Section 8.5(a)(10)(ii): This section recommends encouraging donors with shy bladders to consume 24 ounces of fluids in 90 minutes before additional guidance is sought from the appropriate authority. This would appear to be a departure from the 40 ounces, 3 hour rule currently extant in U.S. Department of Transportation (DOT) drug testing rules. I realize that these are guidelines and that different federal agencies may implement slightly different procedures so long as they are generally consistent with the guidelines. However, the length of time collection agencies are required to retain shy bladder donors on site before the testing process is terminated and the shy bladder evaluation is required has always been a major bone of contention. Collection agencies would typically prefer a shorter period, despite the fact that his may result in a higher incidence of donors being referred for shy bladder evaluations, with the attendant sanctions if the evaluation fails to provide a legitimate medical explanation for the shy bladder. In the interest of limiting donors referred for shy bladder evaluation to those given a truly fair period of time to produce sufficient volume for testing, I would argue that the 40 ounce, 3 hour rule be retained as standard guidance.
3) Sections 11.26, 11.27, 11.28, 11.29: The requirements in these sections that quantitative results for all non-negative results be automatically reported to the MRO are entirely appropriate, would be extremely helpful and should most definitely be retained in these guidelines.
4) Section 12.22: I am gratified that these guidelines require POCT negative results to be reported directly to the MRO within 3 working days after the POCT is conducted. This would imply that

federal agencies using POCT tests may not act on a negative result until it has been reported to them by the MRO. Yet Section 12.1(a) states that POCT tests play an important role where testing is conducted in remote locations or where it is critical to receive an immediate test result. Unless the MRO is located at the same location where the POCT test is conducted there can be no immediate MRO verified result as the POCT tester must report the result directly to the MRO. I think these rules should clearly state whether or not a federal agency may take action on any POCT test results prior to MRO review and reporting of the result to the federal agency, and if so under what circumstances. Requiring MRO review of all POCT tests results before action may be taken is very sound and will do much to obviate precipitate action on the part of local supervisors based on POCT test results that are inaccurate due to POCT tester error or chicanery. However, unless this point is clarified it may lead to agency policies that would permit inappropriate action based on POCT test results that have not been properly vetted.

5) Section 14.3(a)(5): This section requires the MRO to maintain records for two (2) years. It does not distinquish between records for negative and non-negative test results. Most MROs are used to maintaining records of negative results and cancelled results for one (1) year and for positive and refusal to test results for five (5) years. These periods are derived from US DOT drug testing regulations but have become a fairly well accepted standard for record retention for all types of testing. In the interest of uniformity of practice, and recognizing that storage of records has its own not insubstantial costs, it is recommended that this section be changed to require maintenance of records for one (1) year for negative and cancelled results and five (5) years for positive and refusal to test results.
6) Sections 14.4(c) and (d), 14.5(c) and (d), 14.6(c) and (d), 14.7(e) and (f): In each of these sections the proposed rule states what is to be done if there is not a valid medical explanation for the finding, but the rule does not state what is to be done if there is in fact a valid medical explanation for the finding. I am sure that these omissions do not imply that there are not nor will there ever be valid medical explanations for the various finding addressed in these sections. If so why do the interview at all? It would seem to me that the action to be taken by the MRO when there are valid medical explanations for the findings addressed in these sections should also be specified. I would think that for these findings if there is a valid medical explanation the result should be cancelled with retesting required if a negative result is required.
7) Section 14.7(b): I think that requiring the MRO to conduct an interview to establish whether or not there is a legitimate medical explanation for a negative dilute specimen is foolish, unduly burdensome, and a waste of time. All any donor has to say is that he or she drank a lot of fluids just before the test, maybe at the urging of a collector! There is no way that the MRO would be able to say that this was not a legitimate medical explanation, especially when we now know that some individuals can produce urine with creatinine and specific gravity levels even lower that what would be considered as dilute, simply by drinking fluids. This section should be changed to reflect the current US DOT rule for this circumstance giving the Federal agency the ability to write a policy that would permit them to do an immediate re-collection following a negative dilute result with the result of the second test being the result of record even if it is negative and dilute again with no third test permitted, and no MRO interview required.
8) Section 16.3(c): Requiring the MRO to keep track of how often a particular omission or discrepancy occurs due to a particular collector, IITF, or laboratory is also unduly burdensome. If these are truly insignificant, do not impair the ability of the donor to have a fair test, and do not require correction or cancellation, I think making the MRO keep track of these is unnecessary and a waste of time. This section should be deleted.
9) Section 16.4(b): I am strongly in favor of this requirement. I agree that it is appropriate that if the donor refused to sign the donor certification section of the CCF, and this can be established, that the review should proceed. I also strongly agree that if this can not be established and it is a matter of the donor forgetting to sign the CCF, and the collector not checking to be sure it is signed before permitting the donor to leave the collection site, that the test should be cancelled, this event should be treated as a fatal flaw, and the responsible collector be made to undergo re-training and re-certification. I think that the current US DOT rule in this regard that permits the review to proceed simply based on a statement from the collector that he or she forgot to have the donor sign the CCF before leaving the collection site should be amended to reflect the requirements of this section.

I appreciate the opportunity to review and comment upon these proposed guidelines. If there are any questions concerning my comments or if further clarification is required please do not hesitate to contact me.

Sincerely,

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