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June 9, 2004

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 WORKPLACE DRUG TESTING PROGRAMS

To Whom It May Concern:

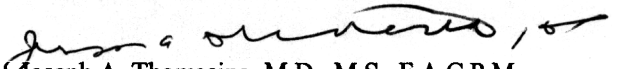
I have reviewed the above captioned guidelines and have the following additional comments:

1) Section 12.22: In considering POCT testing it appears to me that the greatest challenge is preserving the validity and integrity of federal workplace drug testing programs when this form of testing is employed. If POCT testing is to be permitted for federal workplace drug testing the enabling regulations must insure accountability on the part of the collector and the employer or agency participating in POCT testing. Any guidelines or regulations written to allow for POCT testing must insure that the collector is held responsible for accurately reporting the results of every POCT test performed, and that the employer or agency is held responsible for properly acknowledging, recording and taking appropriate action on every test performed. Without proper controls, deliberate misreporting or non-reporting of the results of POCT tests by the collector may occur, and/or employers may ignore results on POCT tests that are not to their liking (e.g., deliberately ignoring or discarding positive POCT test results without sending them forward for further testing until a negative POCT result is finally obtained for a favored employee). In order to obviate this I think that test kits to be used for POCT testing must be uniquely numbered by the manufacturer with that number prominently displayed on the kit container. The kit should include a chain of custody and control form, specimen container seal/labels, and a device showing the outcome of the POCT test, that are all also uniquely numbered with that number matching the number on the kit container. Manufacturers and re-sellers of the kits must be required to keep track of the kits they sell by this unique number and the end user employer, C/TPA or other service provider, and the collector must also maintain a log of all the kits they receive by number and the disposition of each kit, i.e. by the date the kit was opened, the donor for whom the kit was used, the donor's employer or agency, and the outcome of the POCT test (i.e., negative, non-negative sent for further testing, opened but not used for testing and if so why). These logs must be held for a sufficiently long period (e.g., 3 years) to allow auditors to cross check the logs with actual results reported so as to insure the integrity of the federal workplace drug testing program. Federal regulations for POCT kits should detail these requirements in the same manner that the standards for urine collection kits are currently stated in Appendix A to 49 CFR Part 40. The chain of custody and control form for POCT testing should allow for the collector to record the outcome of the POCT test on the CCF. The basis for the collector's determination on a POCT test must be obvious to any other observer and the device showing the outcome of the test must be able to be

preserved and maintained by the collector, once again in conjunction with the log for every test so that on audit the basis of each POCT determination can be examined. The MRO should be permitted to verify the result of a negative POCT test solely on the basis of the MRO copy of the POCT test marked negative by the collector. The MRO's report of POCT tests, once again showing the unique CCF specimen ID number which matches the unique number on the POCT kit container could then also be used in the audit process to insure that every POCT test collected is properly reported, recorded and acted upon. The collector must be required to forward the MRO copy of the CCF showing the outcome of the every POCT test (i.e., negative, non-negative and sent for further testing, other etc.). These forms must be such that if they are faxed the MRO copy is legible when they are faxed (too many CCFs are currently designed with shadings, colorings, high lighting, etc, that render them unreadable when they are faxed to the MRO) and the regulations should require that this be so. These forms should also allow the MRO to record his verification on them so that a copy of these forms could be used to report the verified result back to the agency or employer.

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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