FR Doc #04-7984
Public Comment 8400031

From: <Richard_E_Hipkins@nbc.gov>
To: <wvogl@samhsa.gov>
Date: 6/18/04 10:47AM
Subject: comments on proposed revisions to the mandatory guidelines for federalworkplace drug testing programs (69 FR 19673, April 13, 2004, FR Doc #04-7984

sir, please:
- see below for comments
thanks

- section 8.6; concerning the proposed requirement to conduct annual inspection of all collection site clinics
- it is always a good idea to try and continually improve the collection process
- however, it would seem to be cost prohibitive and logistically impossible to do an inspection of 100% of all of the collection clinics; as there are thousands
- would hhs provide the money to do the inspections; currently we do not have a funding source to cover this extra work
- rather, a 1-3% inspection of them would make more sense (like for qc's)
- the inspection could consist of a combination of clinic self inspection; inspection by outside entity; collector certification like for dot; an online collector training course that would allow collectors to receive standard training; updated educational and procedures info; requiring a collector (as overseen by the employing clinic) to undergo refresher training for any fatal flaws on the collection; this would more directly address the specific issue of following proper collection procedures
- the overall percentage of errors at collection clinics; approx 1%; should not dictate a 100% inspection for the other 99% of clinics that do the collection properly; we always err on the side of caution; and the mro can always throw the test out if there are significant problems
- is there any info to support the need for 100% inspection of clinics, such as statistics or research

- section 2.4; concerning the proposed requirement for all specimens to be collected as split specimens
- continue to allow the agency to decide whether to collect a single or split specimen
- split specimens seem only to give the false sense of safety and security; is there any valid research or study showing that it is safer and/or better to collect 2 specimens at the same time rather than just one
- 30 mL of urine already provides an adequate amount of urine to allow a portion of the original specimen to be tested by a second laboratory; this has been working well for 15 years in the hhs program
- split collections only provide twice as many opportunities for mistakes, errors and problems during the collection and lab analysis process including: handling; packaging; transporting; accessioning; analyzing; maintaining; and reporting
- if an error happened in the collection or lab process; then wouldnt all of the urine that was collected/processed at the same time be tainted no matter how many bottles you put it in or how many other labs you sent it to
- based on operational experience; people have a difficult enough time

giving 30mL; much less 45mL; which requires the donor to drink more fluids and stay around the testing site longer
- for any problems with the specimen; we have always erred on the side of caution and the donor
- if the overall percentage of non-negatives is less than 1%; then why change 99% of the program for less than 1% of the problem; especially since the challenge rate to the less than 1% of the non-negatives seems to be exponentially low
- maybe require a different lab technician to retrieve and package the aliquot to be sent to a second lab; in order to provide added integrity to the process
- is there any info to support the need for split specimens, such as statistics or research

- section 8.5; concerning the amount of fluids and time the donor may be given in order to collection a specimen
- in order to be more consistent between hhs and dot regulations; recommend using the same amounts of fluids and timeframes as indicated under current dot regulations