#04-7984
P.C. 8400159

From: "Mary McPhee, RN" <mmcphee@wholehealthnet.com>
To: <wvogl@samhsa.gov>
Date: 7/12/04 4:48PM
Subject: docket #04-7984

We respectfully submit comments to be considered ib regards to the Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs.

Thank you for this opportunity to be heard and have our concerns hopefully answered.

Mary McPhee

Evelyn Jackson

Mariana Cardosa

Whole Health Management Inc.

Department of Health and Human Services
5600 Fishers Lane
Rockwall, II Suite 815
Rockville, MD 20857

RE Docket # 04-7984

While it is evident that much work and collaboration were involved in the drafting of the new, proposed guidelines, Whole Health Management Inc. respectfully submits the following comments regarding the Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs. WHM supports and appreciates the Department of Health and Human Services commitment to maintaining the integrity of the entire Drug-Free Federal Workplace Program.

WHM serves as a TPA and as such, provides numerous urine drug screen collectors for private companies as well as DOT covered companies including Federal Workplace employees. We would like to express some concerns and request clarification regarding several points concerning the new proposed changes to the rules.

As collectors, we primarily focused on Subpart D-Collectors and subsequent parts as it relates to our organization and role in performing collections with the various testing modes. WHM will certainly be forced to incur increased costs in obtaining certified collectors and testers due to increased donor privacy not to mention the additional costs associated with the increased training necessary to perform additional alternative specimen collections. We are concerned with the increased costs as related to purchasing and storage of additional supplies as well as the increase costs for each collector to perform the volume of quality controls tests (as written, 3 for each mode of collection) that would be incurred. In addition, there would be substantial costs to maintain urine collection when saliva testing is done.

We have need for clarification of what is "donor privacy that is appropriate for the specimen being collected" in section 5.2 of Subpart E, is it only the need for oral and visual privacy or for physical privacy?

In section 5.6 Subpart E

Clarification: What is an appropriate container for collecting spit?. To "expectorate" is to bring forth phlegm from the bronchial passages and is certainly not considered saliva. There needs to be clarification as to what is required for collection: saliva or expectorant.

We believe that a standardized list for the containers and devices used for testing will greatly enhance the program and reduce the liability for collector errors as well as increase the accuracy of the collection and test.

In Subpart H

Specimen Collection Procedures: we believe a switch should occur in the order of procedures allowing Section 8.2 to be before Section 8.1.

Clarification: Is there scientific documentation to support Section 8.2 (5)? Does cleaning scissors with alcohol actually kill lice? What is the probability of adulteration from a previous donor? Is there any possible adulteration to a test where alcohol has been used on the scissors prior to obtaining the specimen?? Do we now need to train the collectors in identifying lice on a head?

In Section 8.2 (7)

Clarification: Will we need a scale that measures 100 mg of hair or are there other guide lines for determining how much is 100 mg?

In Section 8.3 (2)

Will agency and authority be the same personage?

In Section 8.3 (4)

Point of Concern: There will be an increase in testing time to allow for the collector to actually observe the donor for 10 minutes to confirm that the donor has not had anything in his/her mouth for the past 10 minutes prior to obtaining an oral fluid specimen. This will significantly reduce the number of collections that can be done in an 8 hour work shift and impose a major burden to the collection process.

In Section 8.3 (5)

Clarification: the clean specimen tube, will this be specified as an appropriate container and be federally regulated? This tube is not sealed prior to use?

In Section 8.3 (6)

Clarification: Spit/saliva (not expectorate) collection---- if this takes more than 15 minutes, how long should you give the donor, an hour, all day?

In Section 8.3 (8)

Clarification: Mixes what with what? We are unclear as to the focus of this.

In Section 8.3 (9)

If there is not an enough for a split specimen, will there be provisions to accommodate the donor if he requests a split later?

In Section 8.4 – (3)

Clarification: Is it necessary for the donor to empty his/her pockets for a "sweat test"? If the donor refuses to empty his/her pockets and it is a refusal to test, should the employee than be terminated?

In Section 8.4 (5)

Clarification: To wash an area to prepare it for the application of a sweat patch, will it be determined which soap to use as to not interfere with the collection or testing of the patch after removal and what if the donor is allergic to soap, what shall be used then to cleanse the skin? Does the growth of hair over that body part and the use of adhesive for the patch cause any harm to the donor that may be of concern later?

In Section 8.4 (6)

Clarification: Should the collector placing the patch be of the same gender as the donor? What if in placing the patch, the donor would have to remove a shirt or blouse? There is a real possibility that donors will have privately exposed areas for cleansing and patch placement.

In Section 8.4 (7)

Clarification: Define 3 days. Is it based on 24 hours after patch placement or is it considered day to day? Who decides on which of the 3-7 days the patch should be removed? Does the patch need to be removed at the location/facility of placement (for traveling employees that may be difficult)? Does the patch need to be removed only by the patch placer in order to determine if there are signs of tampering? We believe that the MRO should be the one to cancel tests and not the collector.

In Section 8.4 (8 & 9)

Clarification: What are the signs of tampering to a sweat patch?

In section 8.4 (11)

Clarification: Will the date of placement as well as the date of removal be recorded somewhere on the form?

In Section 8.5 (4)

Point of Concern: We believe the written procedures should be shared with the donor prior to collection just as in the DOT guidelines.

In Section 8.5 (9)

Point of Concern: We feel strongly that thee donor should not be the one flushing the toilet before the collector has a chance to inspect the bathroom for signs of specimen substitution or adulteration.

In Section 8.5 (11)

Point of Concern: We feel strongly that the donor should not be turning their back on the collector or their specimen to wash their hands until after the specimen is sealed in the transport containers.

In Section 8.5 (24)

Point of Concern: We question stipulating who can be a direct observer if a same gender observer is not available. Can the agency then acquire an opposite gender observer thus inviting sexual harassment claims and possibly raising privacy concerns? Should the observer be documented on the CCF?

In Subpart L – Point of Collection Test:

We agree, establishing a list of approved devices and requirements for using these devices is paramount.

In Section 12.8 (b)

Point of Concern: A standardized set of operational procedures from DHHS to maintain uniformity and consistency using the testing devices should exist. Each testing agency may develop its own manual would lead to possible misinterpretations and legal loopholes.

In Section 12.8 (g)

Point of Concern: There will certainly be an increased cost for record keeping incurred. How do we document the training of collectors? Who trains the trainers? Will a model course for training be developed?

In Section 12.18

Clarification: Does this section say that a POCT tester can be the same as the collector as long as the donor has left the building?

Point of Concern: We strongly believe that developing a CCF that will contain all the necessary steps for documentation is paramount. An OMB form that will contain the internal COC as well as additional seals for resealing specimens so tracking can exist is also paramount. Would it be a fatal flaw if seals are not numerically matched?

In Section12.19 (a & b)

Point of Concern: There will be the increased cost associated with the Quality Control aspect of testing in that the collector must perform one negative, one positive and one valid normal test on each testing device that that collector will be using during their day. With more than one collector on any given day, the cost of testing devices will be exorbitant. Will the testing devices contain a quality control to determine whether or not it is accurate? If a device is approaching its expiration date, is there scientific data that test is still reliable?

In Section 12.19 (2)(c)

Clarification: How will collectors count the one out of the every 10 specimens collected? Will it be the actual tenth specimen collected, then the twentieth and so on? Or can it be any one of the specimens as long as more than two are performed in that day? As a TPA, we would like clarification on the reasoning for this process in addition to performing blind specimens processing. Would a separate QC lab need to be utilized for processing these specimens in addition to the lab used for confirmation testing and blind specimen testing?

In Section 12.20

Clarification: How many devices should be QC tested and failed before the collector gets a new lot numbered box? With no number established, it is left wide open to anyone's interpretation.

In Section 12.22 (a)

Point of Concern: A three day delay in reporting results to an agency with POCT testing seems to defeat the purpose of POCT.

In Section 12.24 (b)

Point of Concern: With regard to giving the donor a copy of the collectors resume (with the personal address, phone number & other personal information) of the collector would seemingly violate the collectors' right to privacy. Why would the donors right to know supercede & therefore violate the collectors' right to privacy?

In Section 12.26 (a)

Clarification: Will there be a Federal List of Free Lance MRO's that can be used by testing facilities to review drug test results if, as now proposed, the MRO cannot be an employee of the company doing the collections?

WHM strongly feels the new proposed guidelines (as currently written) significantly increase time utilized in performing collections thereby significantly decreasing the quantity of tests that can be performed. Impacting the quantity of tests performed directly impacts agents' volume/numbers of employees that can be tested as required. Additionally, the increased cost for the quality controls for each testing device and the increased audit responsibility place an undue burden on the agencies. As collectors, we are always looking to improve our processes so as not to earn the "weakest link" reputation, the new proposed guide lines will certainly limit our ability to achieve this.

We support any recommendations that have the ability to scientifically improve the drug free workplace for the employees and employers as well as promote the imperative state of "public safety". Respectfully, we request clarification of many of the proposed guidelines and we ask that our points of concern be given serious consideration. We look forward to a collaborative future with meaningful guideline revisions.

Whole Health Management Inc.
20600 Chagrin BLVD, Suite 1000
Cleveland, Ohio 44122
216-921-8601 X18
Mary McPhee
Evelyn Jackson
Mariana Cardosa