From: Danette Krumel
Sent: Monday, January 11, 2010 10:20 AM
To: LoDico, Charles P. (SAMHSA/CSAP)
Subject: Drug testing changes

Dear Mr. Lodico,

I own a small company in Northwest Florida and have been doing drug testing for almost 20 years.
A few comments on the proposed mandatory guidelines:

1. Regarding standardization and sample integrity, the NPRM proposes that when an IITF cannot report a result for the specimen (i.e. negative, negative dilute, rejected for testing), the IITF is to use tamper evident tape to reseal the sample for shipment to an HHS laboratory. Why not create a third label on the CCF for the sole purpose of forwarding the sample? From an “integrity of the process” approach the idea of leaving the standard as “the remaining specimen will be resealed using tamper evident tape” seems too ambiguous and leaves the door open in the areas of donor protection and litigation potential.

2. Step 1 of the proposed CCF does not include a verification check box of the donor's ID. There should be an active check by the collector showing that he/she verified that the donor is who he or she says they are.

3. Regarding Step 1 of the CCF, will the DER and or TPA be allowed to ask the lab to pre-mark the Agency Box (1D) when printing the forms?

4. While the NPRM states that specimens may not be delayed for testing if Step 1D is not completed, it is not clear if the omission of this step will result in a flaw. Please elaborate on what will happen if this new step is not completed.

5. While the new testing requirements (new drugs to be tested, use of IITFs, etc.) go into effect on

May 1, 2010, the NPRM does not discuss the transition period for use of the new CCF. When will the new CCF be approved and available? Since the current CCF has been approved for use through 2012, will companies that are not using an IITF be able to use the current CCF through that date? If not, what are the ramifications for using the current CCF after the new CCF has been approved.

6. One of the largest problems with the current CCF is that it becomes totally illegible when transmitted to the MRO and employer via fax and/or scanning. What if any considerations are in place to improve the print quality of the CCF?

7. Finally, we strongly urge HHS to consider mechanisms other than pre-printing of the new CCF. There are currently numerous labs, TPAs, and other service providers that are using technology to produce forensically viable carbonless chain of custody forms. HHS and the National Laboratory Certification Program (NLCP) would significantly benefit from the use of the technology behind these applications for the following reasons:

a. The data is input electronically, which eliminates the problems faced by labs, MROs, collectors, and employers trying to read a fax of a copy (which is already very faint and hard to read).

b. Copies 2 and 4 can be sent electronically to the MRO and the employer, which they can then print out.

c. This technology allows users to capture both a wet and digital signature thereby satisfying the HHS requirements.

d. Labs, MROs, TPAs, and collection sites spend A LOT of time "chasing paper" to get the necessary copies of the CCF. This technology would save all service providers time.

e. Many times after expending significant time and resources to get the needed copies of the CCF, one finds out that the copy is illegible. Computer produced and sent PDF copies of these forms would eliminate a tremendous amount of wasted effort and significantly reduce the frustration level with these program requirements.

f. Computer produced forms can be easily stored and saved for retrieval should a form need to be reproduced.

g. Computer generated CCFs with the employer and employee's information set-up electronically can solve several issues including print quality, wrong employer information, eliminate errors by not allowing collector to go to the next steps until all necessary information is completed in each section, etc

I thank HHS for the opportunity to provide comments on the proposed revisions to the Federal Custody and Control Form. I trust that HHS will take our comments into consideration. Please feel free to contact me if you would like to further discuss any of the following comments.

Sincerely,

Danette Krumel
Business Development Manager
Professional Health Examiners

http://prohealthexam.com/