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Sent: Monday, January 11, 2010 4:12 PM
To: LoDico, Charles P. (SAMHSA/CSAP)
Subject: CCF revision

Regarding the CCF revision as an MRO and Medical Director of a collection site, I have some concerns and questions.

1. 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.
2. 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. This should be clarified.
3. 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. As an MRO and manager of a collection site these questions need to be clearly resolved prior to implementation.
4. As an MRO, one of the largest problems with the current CCF is that it becomes totally illegible when transmitted to the MRO via fax and/or scanning. What if any considerations are in place to improve the print quality of the CCF?
5. Are there considerations for forensically viable carbonless chain of custody forms? Potential benefits would include:
 - 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.
 - 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. 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.
 - e. Computer produced forms can be easily stored and saved for retrieval should a form need to be reproduced.
 - f. 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.

Thank you for your consideration of these issues.

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