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Robert L. Stephenson II, MPH
Division of Workplace Programs, CSAP
1Choke Cherry Road
Room 2- 1035
Rockville, MD 20857

VIA USPS Mail: Mr. Stephenson

VIA EMAIL: <mailto:charles.lodico@samhsa.hhs.gov>

RE: EMSI Comments on Proposed Revisions to the Federal Drug Testing Custody and Control Form

Dear Mr. Stephenson,

Examination Management Services, Inc. (EMSI) is the largest provider of mobile and fixed site specimen collections in the drug-testing industry, employing more than 6,000 collectors and breath alcohol technicians (BATs) within our network of 230 offices nationwide. This affords EMSI the capability of providing quality services at any of these fixed sites or at any customer location throughout the country. We currently provide collection services to over 60% of the Federal civilian workforce, over 3,000 regulated clients and over 5,000 non-regulated clients. Such collections amount to 3,000+ collections completed per day or 750,000+ collections annually of which 540,000+ are urine specimen collections with the remaining 212,000+ representing breath alcohol collections.

EMSI respectfully submits the following comments on the Proposed Revisions to the Federal Drug Testing Custody and Control Form (CCF).

1. EMSI supports the desired outcome of the proposed Federal CCF revision process wherein the same form size (8.5 inch by 11 inch) as the current Federal CCF, will be maintained. This helps maintain the overall familiarity to which collectors are accustomed to using as noted in the NPRM.

2. EMSI supports the proposal in the NPRM "to increase the space for collector comments in the "Remarks" section to allow additional explanation and to improve legibility of handwritten remarks.
3. EMSI supports the proposed "format changes to improve legibility of handwritten entries and facilitate form completion, while allowing all required information to be included". This includes the proposal "to enlarge the block for the collector's signature" in the collector's chain of custody section.
4. While EMSI supports numbers 2 and 3 above, EMSI discourages the proposal to reduce the current label/seal size from 3/4-inch to 1/2 inch wide labels/seals. The NPRM states that "the reduced size is sufficient for the required specimen identification number and should not affect the legibility of information printed on the labels/seals". However, practical experience regularly results in torn labels/seals while the collector simply attempts to remove the 1.-inch labels/seals from the current CCF. Reducing the size to 1/2-inch would presumably lead to greater difficulty.
5. Regarding Step 1D of the CCF, will Laboratories be permitted to pre-mark the Testing Authority and/or DOT Agency box when printing the forms?
6. While the NPRM states that specimens may not be delayed for testing if Step ID is not completed, it is not clear if the omission of this step will result in a flaw. Request that HHS elaborate on what will happen if this new step is not completed.
7. 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 consequences for using the current CCF after the new CCF has been approved?
8. Perhaps one of the most significant issues 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?
9. Lastly, EMSI encourages 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:
 - 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).
 - Copies 2 and 4 can be sent electronically to the MRO and the employer, which they can then print out.
 - This technology allows users to capture both a wet and digital signature thereby satisfying the HHS requirements.

- Labs, MROs, TPAs, and collection sites spend a significant amount of time "chasing paper" to get the necessary copies of the CCF. This technology would save all service providers time.
- 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.
- Computer produced forms can be easily stored and saved for retrieval should a form need to be reproduced.
- 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.

EMSI thanks HHS for the opportunity to provide comments on the proposed revisions to the Federal Custody and Control Form. We are confident that HHS will take our comments into consideration. Please know that EMSI is open to dialogue with appropriate parties in an ongoing effort to be part of the solution. Thank you again for the opportunity to provide the comments within.

Respectfully,

Michael J. Pedevilla
EMSI / Health Services Division
Program Manager