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Robert L. Stephenson II, M.P.H.
Director, Division of Workplace Programs (DWP)
Center for Substance Abuse Prevention (CSAP)
Room 2-1035
1 Choke Cherry Road
Rockville, MD 20857

RE: Proposed Revisions to the Federal Custody and Control Form (OMB NO. 0930-0158)

Dear Mr. Stephenson,

Compliance Information Systems (CIS) appreciates this opportunity to submit comments regarding the proposed changes to the Federal Custody and Control Form (CCF). CIS has been a leading provider of data management solutions for the workplace drug testing industry since 1993. Specifically, we provide:

- 1) software that facilitates process, procedure, and workflow;
- 2) secure data transport and exchange between industry participants;
- 3) secure data storage and retrieval.

Our clients include employers, laboratories, MROs, TPAs, and collection sites.

Because we have been asked to build data management tools for all of the key participants in the process, our perspective on drug testing events is very comprehensive. All of our clients are impacted by the CCF and its associated requirements. Our comments are directed at specific characteristics of the revised CCF. We have also offered some suggestions for minor modifications to the CCF that would reduce the public burden and improve the integrity of the overall testing process. The primary objective of our comments and suggestions is to allow collectors the option, where possible, of producing an HHS-compliant paper CCF "on-demand", rather than forcing the continued use of pre-printed, carbon less technology. Finally, we have provided background information that supports our comments and suggestions.

Comments and Suggestions

- 1) New requirement in Step 1, D. Specify Testing Authority. The NPRM states that "The collector or employer should not find it difficult or impossible to complete this new step." We believe collection sites will have a very difficult time completing this new step. For regulated testing, collectors rely on information provided by the donor, in either verbal or written form, to complete the CCF. This exchange of data is notoriously unreliable.

Donors are frequently unable to indicate to the collector the reason for test, whether or not it's a "DOT" test, or even the proper employer name. Also unreliable is the process of giving an authorization form with this information, or a CCF that has been partially completed by the employer, to the donor to carry into the collection site. Both are frequently lost or the security seals damaged while in the care of the donor.

The NPRM implies that employers will be responsible for recording this new information. Employers (or the C/TPAs they hire) are already required to record the testing authority and employee category to satisfy DOT MIS requirements. As a result, employers have already developed methods of tracking this information without using the CCF, and the overwhelming majority of employers use electronic record keeping systems, so adding the information to the CCF offers little help.

If HHS and DOT anticipate laboratories or MROs to modify their electronic systems to capture this information, then the additional burden of doing so should be properly measured and disclosed in the NPRM. Adding any new data element to the CCF will impact the time required to process the form by all participants, as well as the cost and resources associated with modifying their existing systems. Both will be significant and impact the OMB public burden estimates.

Non-regulated testing, which currently comprises approximately 80% of the workplace testing volume, has addressed these types of data capture issues by implementing electronic "ordering" systems that deliver accurate donor and employer information directly into the software systems being used by collectors. The CCF is produced "on-demand" using the most current information for the donor, employer, collection site, laboratory and MRO. HHS and DOT would have much more success gathering the required information if the format of the federal CCF was compatible with such systems, which are already being used by thousands of collection sites.

2) New IITF Block. Echoing many of the other comments already received, we believe that providing dedicated space for the IITF on all federal CCFs will add confusion and increase mistakes. We are not aware of a single IITF at this time, and it is unlikely that the volume of tests that may ultimately be processed by an IITF justifies the inclusion of a dedicated block on the CCF.

Again, HHS should consider making the federal CCF compatible with the existing software systems being deployed at collection sites for non-regulated testing in order to achieve its goals pertaining to the IITF, while reducing the public burden. Software systems that produce a compliant paper and wet-ink CCF "on-demand" can incorporate the IITF information when needed on Copy 1, as well as provide an indicator on the other copies of the CCF to indicate that an IITF is involved. This would mean less confusion for collectors, greater reliability in completing the IITF section properly when required, in addition to making more information available to the MRO.

3) Requirement for Information printed on the back of Copies 1-5. As with prior versions of the federal CCF, the NPRM indicates the Instructions for Completing the Federal

Custody and Control Form, the Public Burden Statement, and the Privacy Act Statement must be printed on the back of specific copies. This requirement significantly increases the public burden by requiring expensive, carbon less multi-part forms as the only technology suitable to meet the HHS requirements. Thousands of collections sites have implemented software and hardware systems that are capable of producing a compliant 5-part federal CCF using plain paper for 4 of the 5 copies, provided HHS allows for alternate locations and presentation methods for these statements.

The NPRM allows entities that produce the CCF some flexibility in font size and spacing. CIS has produced prototype federal CCFs using plain paper that accommodate the Public Burden Statement on all copies without changing the format of the form in a significant way (Attachments include examples of COPY 1 and COPY 2).

The Privacy Act Statement requirement applies to approximately 200,000 federal employee tests conducted each year. Allowing the Privacy Act Statement to be printed or provided to the donor on a separate sheet of paper (or better yet, an on-screen display) not only makes the federal CCF more compatible with the hardware and software systems being used by collection sites, but also provides a better method of meeting the requirement of presenting the information to the donor. With its current placement on the back of Copy S, few donors are ever presented with an opportunity to review the statement when it should be required, namely, at the beginning of the collection process.

The same holds true for the collector instructions. The NPRM states "The purpose of these instructions is to provide the donor with an overview of the specimen collection process." Yet, as with the Privacy Act Statement, donors are rarely, if ever, provided with an opportunity to read the back of Copy 5 before the collection occurs. And, rarely, if ever, are donors directed to read the back of Copy 5 at the completion of the process.

These two provisions to benefit the donor are highly ineffective in their current location on the back of Copy 5. If a collection site has the ability to do so, the rule should provide an option for the Privacy Act Statement and Instructions for Completing the Federal Custody and Control Form to be presented on either a separate piece of paper or an on-screen display that requires the donor to "click and accept". Either of these approaches would provide the donor with the required information in a far more effective manner than the current, and proposed, approach.

4) Instructions for Completing the Federal Drug Testing Custody and Control Form. We would like to suggest that the wording of these instructions be specific for the use of carbon less, multipart forms. HHS should consider adding language to the final rule that allows HHS to approve minor changes in the wording of this section in order to accommodate hardware and software systems that can satisfy the requirements of HHS for producing a federal CCF "on-demand" at the collection site. This would allow an opportunity for HHS to take some initial steps towards utilization of electronic systems

without endorsing a specific technology (as is currently the case with carbonless, multi-part forms) or having to change the requirements of the federal CCF in a significant way.

Background and Supporting Information.

CIS has been involved in several projects during the past decade that provide important case-study information about the feasibility of the suggestions we've made. They are listed below.

Software for collectors and "on-demand" CCFs. The first was a software/hardware project that started in 1999. CIS was contracted by Laboratory Corporation of America (LabCorp) to place a CIS software application called SAFcollect at LabCorp-owned collection sites, along with the hardware required to support the application. SAFcollect was a PC-based software program that guided the collector through specific collection procedures, printed the CCF (using an impact printer and "blank" carbonless forms), and upload the test data to LabCorp's computer system. Over a two year period of time, more than 250 locations implemented the software. The project ultimately failed to gain traction for the following reasons:

1. PC-based software requires a cumbersome data synchronization process, which made it very difficult to keep all the locations up-to-date with LabCorp's client database. However, CCFs printed with the application were still far more accurate than those that had been pre-printed with account data at the lab.
2. Affordable impact printers (aka dot matrix) cannot reliably print through more than 3-part carbonless forms day after day without serious maintenance problems. The 5-part forms used for drug testing require far more expensive printers than could be provided and serviced at hundreds, and ultimately thousands, of locations. In addition, impact printers are far more difficult to use than laser and inkjet printers.
3. Use of the internet had not developed enough to provide cheap and reliable connectivity when this project was started. This impacted the reliability of data synchronization, software updates, and data uploads to the laboratory.

This first foray into "on-demand" CCF production quickly indentified the key ingredients that would be needed for a truly successful deployment to large numbers of collection sites. Fortunately, the proliferation of internet technology has broken through all of the barriers but one- regulatory language. CIS and Quest Diagnostics funded a DATIA study of collection sites in June, 2007. From a sample of 4200 facilities, interviews were conducted with 1,833 separate collection sites. This research project made it clear that the industry was clearly ready for wide-scale deployment of "on-demand" CCF technology. The study verified that the key ingredients for success were present:

1. Connectivity to the internet. This allows deployment of web-based, rather than PC-based, software. Web applications are far easier to administer, update, and keep

secure. In addition, data synchronization can occur in real time, and data transport is far more reliable and secure.

2. Existing computer infrastructure. Not only do most collection sites have computers, but most collection personnel are accustomed to using computers and the internet on a daily basis. This makes training and implementation far easier.

3. Desire to have electronic tools for managing the collection process. Most survey participants welcomed the concept of a software-driven collection procedure, knowing that it would reduce mistakes and improve billing processes.

CIS and Quest Diagnostics initiated a pilot program with 10 collection sites in Denver, Colorado in June of 2007 using a CIS' new web-based collection site application- FormFox.com. The development of FormFox relied heavily on the experience gained from both SAFcollect, and its first web-based successor, WebCollect. FormFox, however, was the first application to use laser printers rather than impact printers with carbon less forms. After six months in pilot and further software refinements, CIS and Quest Diagnostics started deployment of FormFox at an additional 500 locations in 2008.

Currently, there are more than 1400 Quest Diagnostics patient service centers and third party collection locations using the FormFox applications. FormFox is being used by several smaller laboratories as well. In 2009, more than 500,000 lab-based tests were collected using FormFox. It is expected that FormFox will facilitate more than 3,000,000 collection events in 2010.

FormFox Pilot with DOI, DOD, Quest Diagnostics, Pembroke. In July of 2009, CIS organized a pilot program with the Department of Interior (DOI), the DOD Ft. Meade testing laboratory, Quest Diagnostics, and Pembroke Occupational Health (DOI's MRO and collection site management provider).

The purpose of the pilot was to demonstrate the feasibility of producing a compliant federal CCF using FormFox and a laser printer. The pilot has progressed through several phases, including the submission of dozens of "blind" samples, both negative and positive, to the two testing laboratories.

Feedback from the pilot has been very positive and indicates that applications like FormFox can easily produce federal CCF that meets or exceeds all of the current forensic guidelines required of the testing process. The collection sites are able to meet the federal requirements with the same software and hardware recommended for non-federal testing:

1. Computer with a reliable internet connection and web browser
2. Bar-code scanner
3. Wet-ink signature pad
4. Laser or inkjet printer

Both participating laboratories and the MRO have indicated that the CCFs produced during the initial phases of the pilot meet or exceed all requirements. The CCFs produced in the pilot are much easier to read and the software forces all required data to be included. In addition, the MRO immediately receives COPY 2 without having to wait for the collection site to manually fax the document.

The pilot program also tested the concept of having the employer "order" the test electronically. This provides the collector with all the required information to perform the test and eliminates data entry errors at the collection site. In addition, the pilot allowed the testing laboratories, MRO, and employer to receive status updates throughout the entire event, from ordering to the final disposition of the result. The ability to do this provides HHS with an opportunity to greatly reduce the burden associated with the CCF and federal drug testing programs for all participants.

The marketplace has demonstrated its willingness to acquire the equipment needed to implement these types of applications (FormFox, eScreen, and EBTs are examples). While not all collection sites will participate in these types of initiatives, the industry has already shown that most will.

CCF Imaging and Distribution. Another relevant project that supports the need to allow "on-demand" production of the CCF is CIS' imaging and distribution service for certified laboratories. These software and hardware systems, which are specific to each laboratory, process a combined volume of more than 50,000 CCF images each day. The primary objectives are to ensure that Copy 2 of the CCF is transmitted in a timely and reliable manner by the collection site and that it is subsequently made available to the appropriate MRO. Another objective is to provide an efficient and secure method to meet recordkeeping requirements. These systems, which rely on fax transmissions of Copy 2 from the collection site, demonstrate how difficult it is to receive a legible Copy 2 from a handwritten, carbon less document via fax, even when the receiving equipment is the most expensive and technically advanced available. So while the systems we've developed have been very effective at stopping "misdirected" CCFs and improving the timeliness of delivery to the MRO, the usability of the document is impaired due to the inability to read the employer, donor, and collector information. The problems are inherent to the media being used, namely, a carbon less, multi-part form, and exacerbated by the transmittal technology, namely, standard fax machines. In a scenario that is repeated virtually hundreds of times each day, the MRO is forced to contact the collection site and arrange for an "enhanced" copy of the CCF to be produced and retransmitted, which adds a significant burden to the collector and MRO, in addition to slowing down the release of results to the employer. CIS can provide HHS with thousands of examples, on a daily basis, that illustrate this very pervasive and expensive problem.

It is also important to note that almost all federal tests rely on the electronic transmission of the Copy 2 image between the collection site and MRO today. The original Copy 2 stays at the collection site and is rarely, if ever, physically transported to the MRO. In similar fashion, most certified laboratories make Copy 1 available through

the internet, which allows MROs and other authorized parties to access, and print when required, Copy 1 of the CCF. In other words, Copy 1 and Copy 2 are already being transmitted electronically in the vast majority of drug testing transactions today, and Copy 1 is the only copy that is routinely transported in a physical fashion.

Summary

CIS believes that this NPRM provides an opportunity for HHS to make a very small, but very significant move towards complying with OMB's mandate for the CCF to become more compatible with electronic document technology. The first step is to establish very minor format changes that allow a paper CCF to be produced "on-demand". It simply requires HHS to remove the requirement of having information, none of which is pertinent to the forensic nature of the test, to be pre-printed on the back of the form. This will allow thousands of collection sites that already have the required infrastructure to help reduce the public burden of the CCF. It will allow the industry to continue using a paper-based CCF while simultaneously building a body of data to support future electronic initiatives required by OMB.

Without taking this small but important step, federal testing programs will be further segregated from the much larger body of non-regulated testing. And it will be far more difficult to comply with OMB's mandate to make the CCF compatible with electronic technology in the near future. The suggestions we've made do not favor or promote any particular vendor or technology. They simply provide the industry with the option of producing a paper CCF in a more efficient and accurate fashion, while providing HHS the time needed to address the truly critical issues facing adoption of an electronic CCF (wet ink vs. digital signatures, data security, standardization, etc.). If you have any questions about our comments, please don't hesitate to contact me.

Sincerely,

Eric Quilter
President and CEO
Compliance Information Systems

ATTACHMENTS

Example of how a collector uses an existing pre-printed carbon less CCF for a different employer. This happens on a daily basis because:

- 1) The donor misplaces or destroys the form (or seals)
- 2) The collection site or employer run out of forms
- 3) The employer or CTPA overnight package fails to arrive before the donor shows up

Not only is the information difficult to read, the laboratory and MRO have to handle the transaction completely “off-line”, which creates significant time delays and opportunities for errors.

This is an example of a poor faxing technique. Because the collection site information is not legible, the MRO typically has to wait for the lab result to be completed and Copy 1 to be made available before contacting the collection site to arrange for a retransmission. This is also a significant cause of delay.

This is another example of a poor fax transmission.

This is an example of poor over-print quality, which impacts thousands of CCFs on a daily basis. Even if the collector's handwriting is heavy and legible, the specimen ID, employer and MRO information are not.

Example of COPY 1 from the pilot program (fictitious donor and collector).

Example COPY 2 Image from the pilot program (fictitious donor and collector). Original has wet signatures of the collector and donor.