

eScreen

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Robert L. Stephenson II,
M.P.H., Director, Division of Workplace Programs (DWP),
Center for Substance Abuse Prevention (CSAP),
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Rockville, MD 20857

Dear Robert;

Please consider this my comments to the Department of Health and Human Services (HHS) Substance Abuse and Mental Services Administration's (SAMHSA) Notice of Proposed Revisions to Federal Chain of Custody Control (CCF) Forms found in the Federal Register November 17, 2009.

We applaud HHS for considering revisions to the CCF and urge HHS to go even further by implementing an electronic CCF (eCCF) that the integrity of the federal drug testing program and the safety of the public require. We, the service providers (SP) of the drug testing industry perform administrative duties in transportation industries that rely on safety, efficiency and timely information to safely operate airlines, buses, trucks, ships and railroads and to transport passengers and cargo without the fear of drug use impacting public safety. The current paper-based CCF encumbers the drug testing process by adding delays, and creates a mosaic of disintegrated information resulting in errors, compliance difficulties and safety concerns that can be easily solved with an electronic version of the CCF.

The CCF has its origins in the early 1980's and was designed to track the custody of a forensic sample from the point of collection to a laboratory. In keeping with traditional laboratory specimen requisition and tracking systems of its time, this paper based laboratory-centric system allowed specimens to "find their way home" with preprogrammed laboratory specimen identifiers, and client coding specific to the laboratory data systems that prepared the form. This system of laboratory driven coding preprogrammed into the unique specimen identifier and reduced to a 5-part paper form, guarantees that specimens collected sometime in the future are hard-coded to the laboratory system. Unfortunately, it creates a myriad of problems for each and every SP and federally regulated employer in the process because it is an open-loop, manual and often outdated form system.

The CCF is the only common platform for each regulated drug test. The stakeholders and SP who contribute or receive information from each CCF are as follows:

- 1) Employer (supervisor)
- 2) Employer (DER)
- 3) Employee (donor)

- 4) Collector (SP)
- 5) Laboratory (SP)
- 6) MRO (SP)
- 7) C/TPA (SP)
- 8) DOT (federal agency)

The common factor linking all of them is the 5-part CCF, making it the information backbone of the drug testing process. This creates a platform from which each SP builds systems to manage their portion of the process. Each of the stakeholders and SP must rely on information which originates on the CCF, and before a test is completed, a symphony of events must occur with each of the SP working in harmony to deliver an accurate result and manage compliance. The current system forces each of the above parties to transcribe information on and of the CCF, vacillate between analog and digital systems, and manual vs. electronic processes. Within each of the SP paper is shuffled from one location to another with little traceability.

Open-loop vs. Closed loop

An open-loop system is "a system operating without feedback, with no measurement of result or feedback to give self-correcting action", such as the 5-part federal CCF.

A closed-loop system is "a method of control in which feedback is used to link a controlled process back to the original command", such as an eCCF controlled by software-enabled feedback to ensure compliance.¹

Problems associated with a 5-part paper CCF

SP cannot easily integrate and exchange information in the current paper system. This had lead to the disintegration of the information pathways required to monitor federally regulated drug testing programs. As the current process begins, after forms are preprinted and shipped to the employer, a blindly-driven paper chain of events unfolds. Without any advanced warning to the SP in the drug testing process, we are totally blind to what is happening. Like dropping a letter in a mailbox, we, the SP have no knowledge or expectation of the events that will ensue. Not even the laboratory knows that a specimen will ever be collected until it is received in the laboratory. Or not received, when they get a complaint days or weeks later. The same lack of awareness is true for every SP-collector, MRO and TPA who first learns of a drug test when the donor or results show up. Or, when the employer complains of missing results.

The best example of information disintegration is the classic complaint of an employer calling the MRO 7-10 days after sending a donor in for a dug test in search of the expected result. The MRO finds that they don't have the result and have never received the result, and calls the laboratory in search of the result. The laboratory finds that there is no such specimen in their system, and have never received a specimen from the donor. The laboratory then calls the collection site, to learn that the donor never showed up for a drug test, and the employer has lost a week and is frustrated that no one could

have known that the process hadn't started or been underway. A minimum of 3 phone calls was required to integrate the information and find the answer. All SP are in need of a feedback system to make sure things are working and to maintain compliance with Federal procedures. This can be done automatically with an electronic version of the CCF and software currently in use and perfected over the past 20 years. This constellation of service problems and nearly all others associated with a paper-based system has been solved by eScreen and has been proven by non-regulated employers and SP for more than 10 years.

Non-DOT drug testing programs are far superior in compliance and efficiency, and have fewer errors and omissions than the more regulated safety sensitive employees in the transportation industry.

CCF requires weeks to start testing

In the current model of federally regulated drug testing, the end-user (employer) must have their account information pre-programmed into the lab computer and must wait many weeks for forms to be printed and shipped, before they can send their first donor in for a test. Each DOT program starts with this poor service.

CCF can result in duplicate specimen identifiers

CCF is illegible and result in errors

Pre-printed paper forms are handwritten, and when faxed are often illegible. Transcription of information from handwritten forms to other information systems leads to translation and transcription errors.

CCF must be overnighted for remote hiring

An added frustration occurs when an employer needs to hire or test an individual who resides or is working at another location not close to their pre-programmed location. The preprinted CCF must be sent overnight at considerable expense in order for the result to be properly reported back to the appropriate MRO and DER, and find its way into the proper file. This can add an additional 1-2 days and up to \$25 in added costs for a single "remote" hire. Many employers are frustrated by numerous remote hires, and incur substantial costs and delays.

CCF Copy 2 cannot be sent to the MRO with assurance

Faxing the MRO copy is an outdated form of electronic transmission of a document and makes the copy more illegible. This is an open loop without the proper feedback to

ensure that the MRO has received their copy, that it is legible, and results in a significant burden on SP to find and receive their copies of the CCF.

CCF paper management costs \$4 per test

A recent survey conducted by Clinical Reference Laboratories and eScreen, found that the cost of each CCF due to:

- • Printing
- • Shipping
- • storing
- • scanning
- • faxing
- • mailing
- • sOliing
- • manying
- • filing
- • storage and
- • copying

add \$4 to the cost of each federally drug testing program. It is common practice for MRO to charge substantially more (up to \$2 or \$3 more) for reviewing a DOT regulated test compared to a non-DOT regulated test which uses the eCCF solely because of the extra costs of managing the paper. eCCF would reduce employer costs by \$2-\$3 per test and be consistent with non-regulated drug test costs.²

What is an eCCF?

First of all, it is a CCF identical to the current 5-part paper Federal CCF, which can be electronically transmitted, opened and viewed on a computer screen, filled out by the collector with a keyboard, and printed at the point of collection. This can be a secure document with an identical format approved by HHS. The client, MRO, laboratory, donor and collector demographic data may be pre-programmed in an optional third party software application to populate the form fields and avoid much of the data entry at the collection site. Prior to printing the form, after the specimen is collected in accordance with HHS guidelines, it is sealed in the presence of the donor with a tamper evident seal and specimen barcode label attached to the specimen. The collector scans the bar-coded specimen, and the electronic CCF links the specimen ID to the donor by this unique identifier. The form is then printed, with 1-5 copies printed locally by the collector. Both the donor and collector sign a paper copy. (Print on Demand)

Additionally, the donor and collector can have their signatures captured electronically to facilitate electronic distribution of copies 2-5 to the SP via secure internet, or web access allowing all SP immediate access and "closing the loop". (Electronic signature) One printed copy of the eCCF always travels with the specimen to the laboratory.

Unbundling the bar-code from the form until a collection is performed adds value to all SP, employers, and DOT.

The unique specimen identifier, can be a barcode or human readable number or both, and should preferably be available separately from the form, provided by the SAMHSA laboratory, so that the form can be printed on a standard laser printer on 8.5 x 11 inch standard paper.

This is identical to the current Federal CCF model, with the exception that the CCF identifier is linked to the eCCF instantly when the collection is performed, not weeks, months or years before.

eCCF has 3 components:

- Print on demand
- Electronic signature
- optional software

In its simplest form, the electronic CCF is simply an electronic document which can be printed on demand at the point of collection. This makes the form easily portable and "changeable fields changeable" at any time before collection, such as the name of the MRO, addresses, phone numbers, etc. Other components of the form are non-changeable – as it is today. This is the first component, and the most valuable change which can be immediately implemented today by HHS by merely unbundling the label from the form and allowing the form to be printed at the point of collection.

The second component which makes the form easily portable after printing is the electronic capture of the signatures of the donor and collector. This could completely eliminate paper altogether if HHS recognizes the legal defensibility of signature capture, as other federal agencies, banks, FDA, hospitals, retailers, etc. have done.

Federal legislation that validates the equal level of contract enforceability of both "electronically signed" and "blue ink" documents includes:

- Electronic Signature Global and National Commerce Act
- Uniform Electronic Transaction Act
- Uniform Computer Information Transaction Act

"Where the rule of law requires a signature, or provides for certain consequences in the absence of a signature, that rule is satisfied by a digital signature which is affixed by the signer with the intention of signing the message, and verified by reference to the public key listed in a valid certificate".³

The third component is third party software which manages the CCF information. These systems already exist today and are intelligent, robust, and are integrated into the SP methods of business. The first two components create an electronic CCF; the third

makes the CCF and its data much more useable and allow secure exchange of information.

eCCF creates a digital point of entry at the point of collection

The goal of an eCCF is to insert the digital entry point at the point of collection. All SP after the collection site no longer need to perform data entry functions and get the identical information in real time. Upon completion of the collection; the laboratory, MRO, and employer all have access to their eCCF on line. Each know the process has started and what to expect.

eCCF allows instant form set-up

New employers can call or log into a SP website and set up a drug testing account and have a linked eCCF sent, opened and printed by the collection site in minutes. Employers can begin testing with properly configured accounts and SP immediately at any of the more than 4000 collection sites nationwide that are installed with the eCCF system.

eCCF allows same day remote testing

eCCF forms are easily forwarded by email to a donor, or collector to be printed at the point of collection enabling employers to use collection sites more convenient to the employee, avoid overnighting forms, or bringing employees long distances to be tested.

eCCF can never be outdated

Changes to the approved form, or changes to SP can be done instantly without waste since the forms are not printed until used.

eCCF is never illegible, reduces collection errors, and MRO always gets their copy

Since the information is entered on computer via keyboard there is no handwritten information other than signatures. This allows the information to be easily transmitted to authorized users to receive this information instantly. Electronic CCF guarantees completeness of the form, and guides the collector on proper procedures. Electronic CCF ensures that the MRO receive their copy, and cannot be lost, misplaced, or vanish, as we know so often occurs today. Beginning with the employer, and providing an integrated platform for collectors, labs, MRO and TPA, the information is immediate, closed-loop, and ensures compliance.

eCCF guarantees unique specimen identifiers

Another major advantage of eCCF is that the barcode is scanned by the collector, and can be transmitted to the laboratory database to confirm "uniqueness" and be accepted or rejected by the laboratory before the collection is completed.

eCCF prevents unauthorized DOT collections

Electronically completed CCF, not only drives compliance with federally mandated collection procedures, but could allow Federal inspectors and auditors easier access for compliance issues.

eCCF queries DOT database

eCCF can search a database of previous positive drug and alcohol results, and noncompliance at the time of collection to comply with the DOT's pre-employment requirement of prior positive test verification. Previous positive information can then be forwarded to the employer coupled to a DOT pre-employment test. This immediately ends the problem of positive donors surreptitiously moving from DOT employer to DOT employer without notice.

eCCF has been used for 10 years without a single legal challenge

4 million eCCF are now in use each year by the nation's largest non-DOT employer programs. Since inception, eScreen has produced more than 15 million electronic CCF without a single legal challenge. In fact, the eScreen system checks each step of the collection process for errors and omissions, and prevents the completion of the CCF until all of the appropriate fields are complete. This is one example of feedback use to ensure compliance. To date, not a single eScreen eCCF has required an affidavit from a collector, or a donor, or been canceled due to a fatal flaw. In comparison to 15 million federal CCFs, this has eliminated approximately 100,000 affidavits, fatal flaws, and canceled tests.⁴

The following SP already use electronic CCF today for non-DOT tests:

- eScreen
- FormFox
- LabCorp
- MedTox
- Quest Diagnostics

Electronic CCF technology is already being successfully used to improve the drug testing program of the U.S. Postal Service, and these -to name a few--companies:

- Wal-Mart
- Sam's Club
- FedEx
- Sears
- KMart
- ServiceMaster
- Time Warner

Hertz
Dollar General
Pep Boys
Travelers
MV Transportation
Foster Farms
Sprint
Comcast
Hallmark
ConocoPhillips
Neiman Marcus
Dollar General
The Gap
Radio Shack
Longs Drugs
Target Stores

More than 4000 Collection sites are already enabled and perform electronic CCF

The only hardware requirements of the collector are a computer with an internet connection, a printer, a barcode scanner, and a signature capture device. The supplies required are barcode labels supplied by the SAMHSA laboratory that are compatible with their system and guarantee uniqueness.

eCCF is real time information with real time feedback

Digitally enabled systems, like electronic CCF, have an inherent "closed-loop" feature and a real-time distribution system to notify the DER and SP that an event leading to a drug test result has begun, and they can expect a donor, a specimen, or a result to appear in the next several hours. If it doesn't, they can proactively pursue the missing element. Like a package scanned at the point of departure or pick-up, it can be traced along its entire path by all who need to know its whereabouts and when to expect it in the future.

Starting with the employer, who can schedule a drug test on-line, the collector is waiting for the donor to arrive. Subsequently, once the donor has arrived and a collection is complete, instantly, the laboratory, MRO, employer, and administrator all know what has occurred, and what to expect in the future. Any problems can be immediately and proactively pursued by exception reports. Employers know immediately if the donor failed to appear at the scheduled collection site. And when the collection is complete, the employer's copy of the CCF appears on their secure website in real time.

This is entirely the result of the backbone of the drug testing process- the electronic CCF. eScreen's commercial success in non-federal drug testing is due to its ability to integrate an electronic CCF to all SP that drive the drug testing process from end to end.

eCCF improves compliance

Another feature of the eScreen system is that client-specific and regulatory procedures are embedded into the software. Examples of improved compliance are the methods of handling exceptions to a nOIIDal collection, when the proper federal regulation or client policy (non-DOT) pops up to guide the collector on the appropriate next steps. This eliminates errors often seen on the paper CCF.

A major disadvantage to current Federal drug testing is the lack of traceability from the employer to the collection site. Employers attempting to enforce compliance with policy and federal regulations, have no visibility or method of tracking donors from the point of request for a drug test to the point of collection. Scheduling and electronic CCF closes this loop, and forces compliance with pre-employment, random, and other tests that require monitoring the time to test. Donors who appear outside of the prescribed window can be excluded from testing or a report sent to the DER denoting the exception. Federally mandated random tests that require donors to "immediately proceed" to a collection site, or pre-employment programs that require testing within 24 hours have no efficient method to track pre-collection times. Drug using donors use this loop hole to extend the time before providing a sample in the hope that they will test negative if given extra time to "clean up". Scheduling software and electronic CCFs can monitor these pre-collection times.

eCCF solves nearly every problem of information bottlenecks

In 2001, eScreen, Inc. introduced the first FDA cleared instrumented point of collection drug testing system. Incorporated into the eScreen system is an electronic version of the CCF modeled after the federal form. The process of completing the electronic version of the CCF is almost identical to the process of completing a paper federal CCF with the exception that the information is not hand written but rather typed on a keyboard at the point of collection. Today, there are over 2000 eScreen systems installed in Occupational Medical clinics in the US. These systems are used to manage both DOT and non-DOT drug testing programs. However eScreen's electronic CCF is used exclusively for nonDOT drug testing specimens.

The eScreen electronic CCF is created in real-time when the donor presents for a collection. This allows for a CCF to be printed at the point of collection. More importantly, the account information, and the SP specific information, e.g. laboratory, MRO, TPA, and collector are instantly changeable by employers on their secure portal at any time and for any reason. By placing control of the SP in the hands of employers who are responsible for properly managing their programs, they are empowered and in better compliance.

The eScreen, "donor-centric" system properly reverses the generation of a custody and control form. The classic laboratory-centric form requires the bar-coded seal to be preprinted on the CCF and removed from the form and placed on the sample. A donor-centric system is that the specimen is first labeled, and the CCF produced from the

unique identifier scanned off the specimen. This may seem trivial; however, the effects are dramatic. Creating a digital "data entry point" at the beginning of the collection process with an electronic version of a federal CCF, allows all SP access to needed information in real time. It is analogous to a FedEx package scanned at the point of pick-up compared to dropping a letter in a mailbox, and it's done at a fraction of the cost and in real time.⁵ An interactive demonstration is available at <http://www.escreen.com/eScreenSchedulingProcess.html/>

Prior to printing the eCCF, the eScreen system scans an employer's previous positive results database to ensure compliance with company policy, and checks the CCF barcode number for uniqueness.

The donor and collector sign the form with a signature capture device, hosted by a third party independent verification system, to ensure that once signed, the signature is time stamped and cannot be altered. At this point, each copy of the CCF is immediately available via a secured 128 bit encrypted web portal to each party- the laboratory, MRO, collector, employer and donor. Additionally, the collector may print one or all parts of the CCF, only copy I need be printed and shipped with the sample at this time, assuming all others have chosen to get their copies electronically. If not, the paper method can be used.

Within eScreen's eCCF software, the laboratory is presented with pre-accession data the day before receiving the specimen, and no longer must data enter or accession the information from an illegible paper form, while each MRO has each and every copy of their eCCF before the specimen leaves the collection site. The software then "marries" the laboratory report and laboratory copy of the eCCF with the MRO eCCF automatically. This has reduced the MRO burden dramatically, and reduced the cost of printing, shipping, storing, writing, scanning, faxing, mailing, sorting, "marrying", filing, storage and maintaining each CCF from \$4 per test to less than \$0.40, a 90% reduction in the cost of public burden.

eCCF saves trees and millions of hours of time.

In fact, in our experience the public burden is much greater than estimated, and that the MRO burden is much greater than 3 minutes. There is a considerable effort and burden on the post-analytical process falling upon the MRO to manually sort, collate, "marry" to lab copy, store and maintain, and verify federal CCF files.

eCCF Strengthens Program Integrity

The DOT has repeatedly stated that the collector and collection process are the "weak-link" in the drug testing program. One reason for this is that the Federal CCF does not allow collectors the proper tools to effectively perform their task and ensure the integrity and security of the donor's sample. Paper CCF will always produce human errors, as evidenced by the required affidavits, fatal and non-fatal flaws, and post-collection site

service requirements as the system lacks the feedback controls available to every laboratory, collection site, MRO, and employer in the US.

eCCF properly integrates the critical information to effectively execute federal drug testing programs. In short, electronic CCF is about 100% compliance with federal drug testing procedures.

We are more than 2 decades into the information era, and it is unconscionable not to have access to the essential information tools to manage transportation safety and compliance to the best of our abilities. I would be pleased to work with you, HHS/DTAB, and DOT to explore solutions to an improved federal CCF.

Yours truly,

Murray I. Lappe, MD
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Founder and Chairman,
Chief Medical Officer, eScreen, Inc.

Formerly, Chief Medical Officer and CEO
National Medical Review Offices, Inc.

NOTES:

1. <http://www.merriam-webster.com>
2. Survey, 2007 performed by eScreen and Clinical Reference Laboratories

A recent survey of SAMHSA laboratories and collection sites revealed that 2.3 forms are printed for each form eventually used. This is inherently wasteful of paper and natural resources, to the tune of 60 million sheets of unused paper, or 7000 trees each year. This year marks the 20th anniversary of the Federal CCF, and 140,000 trees destroyed for unused CCF forms. In fact, over the past 20 years, it is estimated that over 2 billion pages of federal CCF have been printed. Of the 160 million forms actually used during this time, the public burden of time estimated at 17 minutes per form has consumed 1.9 million man-days of labor.

3. Per the Information Security Committee, Section of Science & Technology, American Bar Association (/998, Information Security Committee, Section of Science & Technology, American Bar Association)
4. Based on 0.6 % rate of incomplete forms
<http://www.escreen.com/JeScreen-SchedulingProcess.html/>

Log into the above site for an interactive demonstration of eScreen eCCF collection.

Sample electronic custody and control form (eCCF)