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Via Federal Express Overnight Courier, Facsimile and E-mail

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

Re: Quest Diagnostics Comments on the Proposed Revisions to Federal Drug Testing Custody and Control Form (74 FR 59196)

Dear Mr. Stephenson:

Attached are the comments of Quest Diagnostics Incorporated ("Quest Diagnostics") on the Proposed Revisions to Federal Drug Testing Custody and Control Form (74 FR 59196, November 17, 2009). Quest Diagnostics is the nation's leading provider of diagnostic testing, information and services, providing insights that enable healthcare professionals to make decisions that improve health. The company offers the broadest access to diagnostic testing services through its national network of laboratories and patient service centers, and provides interpretive consultation through its extensive medical and scientific staff. Quest Diagnostics is the leading provider of esoteric testing, including gene-based medical testing, and provides advanced information technology solutions to improve patient care. Quest Diagnostics performs Federal workplace drug testing through our network of four SAMHSA-certified laboratories.

We appreciate the opportunity to comment on these proposed revisions and would encourage, specifically, the department to consider the following:

- A form layout that accommodates wider (> Y," ) tamper-evident seals than proposed based on concerns on the impact to both laboratories and collectors
- Elimination of the proposal for the CCF to be used as a mechanism for tracking the testing authority. If this additional data element is required, a minimum 6 month implementation period for this aspect is needed to ensure that all service providers can make any necessary changes in their data systems.
- Modifications to the chain of custody documentation process that would permit the computer generated, "on-demand" printing of Federal Drug Testing Custody and Control Forms (CCF) at the collection site. The new, proposed form incorporates

additional data elements and chain of custody documentation and would benefit from the ability of employers and/or collectors to enter all of the required information electronically and then produce the CCF at the time of collection thereby ensuring the most accurate and up-to-date data (e.g. employer/MRO address and phone/fax number). Such a process has been used successfully in our non-Federally-mandated testing and is now utilized for approximately 15% of such tests.

Our detailed comments on the proposed CCF revisions are organized by Copy and Step number as they are outlined in the Notice.

For further clarification on any issue or comment cited above, please do not hesitate to contact me directly at .

Respectfully submitted,

R. H. Barry Sample, Ph.D.  
Director of Science and Technology  
Quest Diagnostics Incorporated  
Employer Solutions

Quest Diagnostics Incorporated  
Comments on Proposed CCF Revisions (74 FR 59196)  
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#### Copy-I. Step 1(d): Testing Authority

The inclusion of this additional employer demographic data on the Federal CCF creates an additional administrative burden for the various service providers. It is expected that there will be numerous CCFs that will not have this information pre-marked by the employer. In this event, neither the collector, laboratory, nor medical review officer (MRO) should be expected to "recover" this missing information; Quest Diagnostics agrees that the failure to document the testing authority should not hold up processing or testing of the specimen. Consequently, the absence of this information should not constitute a "flaw".

Most laboratories provide electronic results reports to MROs and statistical/management reports to MROs, employers, and regulatory agencies. It is expected that these stakeholders would want the testing authority data to be included in such reports. This would necessitate that laboratories and other service providers modify their data systems to support the inclusion of an additional "data element." This could impose an undue burden on those entities if insufficient notice is provided mandating any requirement for electronic capture of this information. We would suggest a minimum six (6) month notice for any changes to the form that would also require changes to data systems.

An alternate approach to managing this information would be for laboratories to provide each employer with a unique account number for each mode (testing authority) that they test under, with the testing authority pre-marked on the CCF. While this approach may ease the burden on data systems, it creates an additional burden for service providers especially collection sites and C/TPAs - to manage multiple stocks of CCFs for each employer/mode.

We would also expect that the use of pre-marked forms as described above or forms missing testing authority information would create numerous requests for laboratories to change (or add) the testing authority in the laboratory information management system (LIMS) and to re-report the results because either the "wrong form was used" or the information was not provided by the employer or collection site.

Moreover, if testing authority information is required by regulatory agencies for results management purposes, this information could easily be provided by the employer or those responsible for creating the employer generated reports.

A preferred approach that could ease the burden on the various service providers is to permit the use of electronic systems whereby the employer or C/TPA could pre-order the test and enter all of the appropriate demographic information. This approach coupled with computer generated forms where the CCF is printed "on-demand" at the

collection site, would help ensure that all of the required information was captured; thereby minimizing any re-work and helping to ensure the data quality.

#### Copy-1, Step 1(e): Reason for Test

We agree with the proposed change to consolidate the testing reasons to one line.

#### Copy-1, Step 2:

We agree with the proposed changes in Step 2 that consolidate the collector instructions and increase the space for collector Remarks.

#### Copy-1, Step 4: IITF

The incorporation of documentation of external specimen chain of custody when an instrumented initial test facility (IITF) is utilized for testing, consumes a large amount of space on the CCF and causes other sections (e.g. Step I and tamper-evident seals) to be condensed. While IITFs may play a role in future, it is unknown at this point to what extent they may be involved in the testing process. We would expect only a proportion of Federally-mandated to be tested at an IITF; and, of those, only 2-3% would be forwarded to a certified laboratory for rescreening and confirmation (if necessary).

Consequently, we would suggest that documentation of the external specimen chain of custody for the transfer of the specimen to a certified laboratory be accomplished through the use of a supplementary form, similar to what is proposed for documentation of split specimen testing results and to what occurs today for documentation of the specimen chain of custody when a split specimen is sent from "Lab-A" to "Lab-B". If the final version of the CCF requires the inclusion of IITF specimen transfer documentation, the use of electronic systems to generate CCFs on demand - using laser printers and plain paper at the collection site - would be helpful in clearly and legibly including all required employer, donor, and collector information on the CCF through the elimination of all hand written/printed information other than the required signatures.

#### Copy-1, Step 5(a): Primary Specimen Report

While we generally support the layout proposed for documentation of primary ("A") specimen results and the parenthetical inclusion of the specific drug metabolite tested, we would suggest that the order of the existing drug analytes not be changed - i.e., the order for opiates should remain as codeine, morphine, 6-acetylmorphine and the order for the amphetamines should remain as amphetamine, methamphetamine. Since it is expected that certifying scientists and MROs will be handling both "old" and "new" forms for an extended period of time, we believe that it be helpful to "maintain the overall familiarity to which certifying scientists and MROs are accustomed", as suggested in the proposed revisions.

## Copy-I, Step 5(ib): Split Testing Laboratory

We generally support the proposal to report split specimen test results using a separate form/report rather than reporting these results at the bottom of Copy-I. Furthermore, we would suggest that HHS specify the required elements (not the exact layout) and permit laboratories to print the split specimen report directly from their LIMS for signature by the certifying scientist and subsequent transmission to the MRO.

## Tamper-Evident Seals

The proposed revisions to the CCF include a proposal to reduce the size (width) of the tamper-evident seal from 3/4." to 1/2". This proposal raises two significant concerns:

1) The tamper-evident seals on our current CCFs are approximately 7/8" wide – slightly wider on 5-part carbonless forms, slightly narrower on the "on-demand" CCFs. These seals incorporate a patented "aliquotter friendly" design (that includes perforations) that facilitates opening on the automated aliquotters used in our laboratories for the opening, aliquotting for the initial (screening) test, and re-closing of the specimen vial. It is our experience that when a narrower (7/16") section of the tamper-evident seal containing these perforations is utilized, collectors occasionally reported premature separation at the perforations which would require completing a new CCF for the collection event. It is our concern that the use of 1/2," wide seals would result in increased difficulties for collectors if our "aliquotter friendly" design was utilized on these forms. If the "aliquotter friendly" design was eliminated from the tamper-evident seals, we would expect - based on our experience prior to implementing the "aliquotter-friendly" design - increased difficulties for laboratory operations due to having to manually score/cut the seals with the attending adhesive tape shards that would accumulate in the automated aliquotter.

2) The 5-part carbonless paper forms used by our laboratories are overprinted with a client number/requisition (specimen ID) number combination on both the paper forms and tamper-evident seals as well as a barcode on both the paper form and seal. We have significant concerns that the proposed 1/2" wide seal will provide insufficient space to overprint (using impact printing) both a high-quality barcode and a human readable client/requisition number combination. If it was permitted to use CCFs printed "on-demand" at the collection site and with respect to the barcode, we would not have this specific concern since the barcode and human readable number that is currently printed on our non-regulated "on-demand" CCFs is 3/8" and would easily fit on a narrower seal.

The notice of proposed revisions also solicited comments or recommendations on specifications/requirements for tamper-evidency of the seals. The Notice of the Final Form published in FR 6539155 (June 23, 2000) specified the following:

"It is also the responsibility of the supplier of the seals/labels to ensure that they are tamper-evident. Tamper-evident is defined as a seal/label that cannot be removed from the specimen bottle after 5 minutes contact with the specimen bottle."

We agree with this specification and would only suggest that the requirement be expanded to include specifications regarding the contents of the specimen bottle during the testing. It is our experience that the tamper-evident seals may also be pressure and temperature sensitive. Therefore the specification should include a requirement that the seals be tamper-evident when the specimen contains 30 (or 15) mL of fluid (e.g. water) at 90-100 F.

#### Copy-2, Step 4

We agree that documentation of chain of custody once the specimen is released by the collector is not required on Copy-2 (or Copies 3-5) and that this could be removed from this and subsequent plies (copies) of the CCF.

#### Copy-2, Steps 5, 6, & 7

We also concur with the proposed changes to these sections of the CCF.

#### Copy 2 and the use of "on-demand" CCFs

Technological advances by both employers who offer workplace testing and the providers who service them facilitates the use of a computer generated or "on-demand" CCF at collection sites. Use of such technologies only encourages effective testing programs and speeds the time to hire, while lowering costs and use of resources.

To facilitate workflow in the event that the use of CCFs printed "on-demand" at the collection would be permitted, we would propose that both the original collector and donor signatures be captured on this form and that all "copies" of the CCF printed at the collection site incorporate a "digitized" signature in the appropriate places on the CCF. This is analogous to the current carbonless paper process where the signature, on one copy, carries through to the other copies. From a laboratory perspective, they will still receive the collectors printed and signed name; and, from a MRO perspective, they will still receive both the donor and collector printed names and signatures.

#### Copy 3, Copy 4, Copy 5

While we support having Copy 3, Copy 4, and Copy 5, be the same as Copy 2, we would suggest that the printing of Copy 3 and Copy 4 be optional if "on-demand" CCFs are permitted. While the donor would still need a copy for their records - as well as a place to note any medications as a "memory jogger" - the use of these computer generated CCFs could eliminate the need to print these additional two copies. With computer generated CCFs, an image of the CCF containing all demographic, collection site, and donor information could be sent electronically to the MRO and employer or hosted electronically for their use. The printing of these two additional forms would be superfluous and wasteful of resources. In the process utilized by most collection sites today, these copies are rarely, if ever, used. Most often, the MRO and Employer copies are transmitted electronically - faxed or securely hosted and available via the internet. In this setting the collector retains Copy 2, Copy 3, and Copy 4. If the collector only retained Copy 2 and the on-line collection system retained an image of the CCF as well

as automatically (and immediately) transmitted a copy of the CCF to the MRO and employer, there would be more timely and reliable transmission of the CCF copies to these parties. Such a system would be less expensive and more environmentally friendly ("greener") than the current 5-part form process.

We would also suggest, if an "on-demand" CCF system is permitted, that Step 6 and Step 7 be removed from the donor copy (Copy 5) of the CCF and in its place put the Privacy Act Statement required for Federal employee collections.

We also believe that the requirement to provide the donor with a copy of the collection instructions could be met in one of two other ways if "on-demand" CCFs were permitted - collection sites could have a laminated copy of the instructions to hand to the donor if they wished to review the steps in detail or the software application could print a copy for the donor if he/she wishes to have/retain a hard-copy of the instructions.

#### Transition Period for New CCF

Upon the effective date of the new CCF, laboratories should discontinue shipping the old version (Aug. 2000) of the CCF and only provide the new CCF. However, since the current version of the CCF is approved for use until September 2012, the use of an "old" form prior to that date should not constitute a "flaw" requiring correction. After that date, laboratories should be required to contact the collection site to instruct them to discontinue the use of any old forms they may have in stock. In any event, the accidental use of an old form should not result in the cancellation of a test as the use of an older version of the form should not be treated as a fatal flaw.