

FirstLab
1364 Welsh Road
Suite C-2
North Wales, PA 19454-1903
<http://www.firstlab.com/>

January 18, 2010

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

Dear Mr. Stephenson;

In response to the Proposed Revisions to Federal Drug Testing Custody and Control Form, published in the Federal Register / Vol. 74, No. 220 / Tuesday, November 17, 2009, FirstLab, Inc. submits the comments outlined below. FirstLab, Inc. is a Medical Review Officer and Third Party Administrator (TPA) Company providing drug and alcohol testing program management services to private and public sector employers throughout the US. FirstLab processes approximately 10,000 federal drug testing custody and control forms (CCF) each month. FirstLab employs several DOT/DHHS qualified specimen collectors, processes CCF correction memoranda from collectors, and conducts collector initial, refresher, and error correction training.

Overall, FirstLab commends DHHS for its efforts in revising the federal custody and control form to address the changes in the Mandatory Guidelines that take effect in May 2010. FirstLab's comments request DHHS to consider some further modifications to the CCF that FirstLab, based on its experience with the federal CCF, believes will contribute to improvement in the collector's accurate completion of the CCF and the quality of the data and information provided on the CCF.

1., Step 1A - Because the majority of specimen collections are conducted at collection facilities located off the employers' premises, it is essential that the collector have telephone and fax contact information for the employer's representative. The ability of the collector to contact the employer during a specimen collection is especially critical when there are problems or questions concerning the collection. Step 1A currently prompts for the employer name, address and ID number. Use of an employer ID number is rarely, if ever applicable. FirstLab recommends adding Phone No. and Fax No. in Step 1A.

2. Step 1C - Use of the donor's SSN as the donor ID number on the CCF is becoming increasingly questionable due to state laws restricting the use of an individual's name and SSN on documents that are transmitted or distributed electronically (facsimile, email, etc.) and due to individuals' reluctance to provide their SSN for fear of identity

theft or other compromises to confidentiality. Additionally most forms of photo identification presented by the donor at the time of collection, rarely, if ever have the individual's social security number, and thus, the collector has no means to verify or validate that the individual is providing his/her own correct SSN. Many collectors have suggested that the donor ID number used on the CCF should be the number found on the photo ID and that there should be a way to document on the CCF that the photo ID was presented and checked. FirstLab recommends changing Step 1C to "Donor ID No. _____ - Employee ID - Driver's License - State ID - Passport - Other ". The collector would check the type of photo ID presented and record the number from the ID on the Donor ID No. line. For those rare circumstances when the donor does not have a photo ID and the donor's identity is established by an employer representative, the other box would be checked and any identifying number provided by the donor would be used as the Donor ID No.

3. Step 10 - While the reason for obtaining information related to the "Testing Authority" for federally-mandated drug tests is understood, it is unrealistic to think that the collector, particularly in the case of DOT agency testing, will know the correct DOT agency rule under which the donor is being conducted. For example donors who hold a CDL may present for a test being conducted under PHMSA, FTA, FRA or FMCSA authority. Somehow the burden for providing this information must lie with the employer or employer representative (C/TPA, in some cases in DOT-mandated testing). While errors in completing this information on the CCF do not constitute fatal or correctable flaws, it is extremely probable that DOT agency auditors (especially FAA and FTA) will require memos of correction and other remediation actions when the information is incorrect or incomplete. FirstLab has already received notice from Laboratory Corporation of America (LabCorp) that all DOT-mandated drug testing accounts will have to be DOT-agency specific for each employer effective May 1, 2010. Thus a public or private sector employer that is required to conduct DOT-mandated testing under the drug testing rules of more than one DOT agency will have to use CCFs that have been pre-printed for each applicable agency (e.g. FTA, FMCSA, USCG). This practice will create a logistical nightmare when a collection is done using the CCF pre-printed for FTA and the test is in reality required for FMCSA compliance. Since the regulatory text addressing the use of the federal CCF for DOT-mandated drug testing is contained in 49 CFR Part 40, the use of "DOT" rather than each DOT agency should be sufficient for identifying the testing authority. Correcting the test in the laboratory's database to the correct DOT-agency specific account will involve needless expenditure of time and effort. For the reasons stated above, FirstLab recommends that Step ID be changed to read "Specify Testing Authority: - HHS - NRC - DOT".

4. Step 2 - The Collector remarks area/space in Step 2 needs to be larger. A collector cannot adequately document atypical collections (e.g. requirement for second collection, multiple attempts to produce an adequate specimen, etc.) in the space provided, especially since entries must be handwritten.

5. Steps 4 & 5 - One of the more frequent omissions collectors make in completing the federal CCF is "forgetting" to have the donor complete and sign Step 5. In part, this

error is contributed to by the instructions that the collector is to "do" Step 5 before completing Step 4. This is further confusing for some collectors because Step 5 is not on Copy I of the CCF, but Steps 5a and 5b are on Copy I. All other Steps on the CCF are numbered in accordance with their chronological order. FirstLab recommends the following changes so that the numbered steps on the CCF accurately reflect the correct chronological order of the tasks.

Step 3 - Delete "Donor completes Step 5 on Copy 2 (MRO copy)"

Step 4 - Change to read "Donor completes Step 4 on Copy 2 (MRO copy)"

Add Step 5 line that reads "Chain of Custody-Initiated by collector and completed by test facility"

6. While the DHHS Federal Register Notice did not solicit comments on the printing or paper requirements for the federal CCF, FirstLab recommends that the DHHS take this opportunity to consider options for printing and completing the federal CCF that allow the use of software applications for printing and entering data on the form at the collection facility or site. There are currently drug testing laboratories, collection sites, TPAs, and other service providers that are using technology to produce forensically viable carbonless drug testing custody and control forms for non-Federal testing. Experience with these applications has demonstrated that data entry on the forms is more accurate, legible and complete, and that electronically imaged transmission of copies of the CCF to the MRO and employer is more efficient.

FirstLab appreciates the opportunity to comment on the DHHS proposed revisions to the federal CCF. As we all know, the most vulnerable part of the federal drug testing process is the specimen collection and its accurate, complete documentation. It is with this in mind that FirstLab's comments are submitted in hopes that errors in the completion of the CCF, inaccurate and illegible information provided, and time and resources spent in tracking the distribution of the CCF copies can be measurably reduced.

Respectfully submitted,

Donna R. Smith
Regulatory Affairs and Program Development Officer
FirstLab, Inc.