

MedTox Laboratories

January 18, 2010

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

By email to <mailto:charles.lodico@samhsa.hhs.gov>

Comments RE: Proposed Revisions to Federal Workplace Drug Testing Custody and Control Form

Dear Mr. Stephenson:

We thank HHS for the opportunity to submit comments on the proposed revisions to the Federal Drug Testing Custody and Control Form published in the Federal Register on November 17, 2009. We offer the following for consideration:

General comments:

We appreciate the difficulties of revising the form to include the added information required for incorporation of initial instrumented test facilities (IITF's) while maintaining the overall structure and content of the current form. There are many end-users that will be impacted by this change making process and each will likely have a unique perspective on the potential outcome. Given the intent and scope of the revisions required to incorporate the program changes effective in May of this year, we appreciate the consideration given to each of the stakeholders in its redesign.

From a laboratory perspective, preserving the space provided for customization of the form for account-specific information as well as incorporation of barcodes and other electronic cues to facilitate the testing/reporting process is extremely important. In addition, ensuring that sufficient space is preserved for documenting specimen receipt, specimen condition and continuation of the chain of custody initiated at the collection site is crucial. It is also important to us to retain the ability to make the form amenable for use in scanning/imaging and other electronic processes. And from an implementation perspective, maintaining a similarity of flow to the current form will greatly facilitate the transition. We hope that as the opportunity arises, additional options will be considered to incorporate potential efficiencies realized from an electronic forms process.

Specific comments related to the major changes:

Copy 1: The re-labeling of the form for the more generic 'test facility' from 'testing laboratory' permits use of the form by IITF's as well as laboratories. We believe that this is a reasonable change eliminating the need for printing/storing/using multiple forms at a collection site to accommodate all potential testing paradigms. While the potential for utilization of IITF's is an unknown at this stage of the process, previous experience has demonstrated a propensity for errors in selecting the appropriate form when multiple types of forms are stored at a single collection site. Use of a single form also facilitates a collection process in which the destination of the specimen may not be determined until the specimen has been provided (e.g. temperature outside range, unusual physical characteristics, etc.).

Step 1(d) - Specify Testing Authority

We do not believe that this change will enhance the quality of information provided to designated agencies. In our experience, it is not uncommon to receive inaccurate information on CCF's related to reason for test or whether a specimen collection is regulated or non-regulated. It is unclear whether those errors are collector errors or based on inaccurate or incomplete information received from the donor/employer/entity ordering the test. Identification of the specific testing authority provides additional opportunities for errors. In addition, depending on the number of specimens received without the testing authority indicated, the information available may be incomplete as well as inaccurate and thus of limited value. From a laboratory perspective, each additional keystroke required to enter information from the CCF into the laboratory information system (LIMS) has a cost, compiling/providing this information to the agency/operating administration is currently an employer responsibility. We believe that adding this to the CCF inappropriately transfers the burden of collecting and reporting this information to the laboratory.

Step 2 - The proposed changes to step 2 to create more usable space on the form are reasonable.

Step 4 - Significant changes to this section are proposed to permit use of a single form by multiple facilities. While these changes will likely require an adjustment period, it appears that the changes accomplish the goal of incorporating the newly permitted test facilities while retaining key features of the current form. We assume that some customization will continue to be permitted (e.g. shading of specific areas designated for completion by collectors, etc.) to facilitate use by multiple individuals.

In the section used to document transfer of a specimen from an IITF to a laboratory, we recommend expanding the certification statement to include a reference to releasing it to the delivery service, similar to the collector certification statement.

e.g., I certify that the specimen identified on this form was handled using chain of custody procedures resealed and released to the delivery service in accordance with applicable federal requirements.

Step 5(a) - The proposed changes to this section are reasonable in accordance with the program changes. However, while we understand that some reorganization of the reported analytes is necessary to incorporate the new analytes, a concern is raised that repositioning the drug names from the current format may lead to errors, particularly during the transition period when both the new and old forms will likely be in significant use.

Suggest adding a box for 'corrected flaw' on the line where rejected, adulterated, substituted, invalid appear to notify the MRO that an MFR or affidavit has been retrieved.

Step 5(b) - We support the proposed changes to this section. While we appreciate that this represents a major change in reporting of split specimen results, we agree with the department's reasoning that the overall impact is minimized due to the relatively small number of specimens involved.

Step 6 - Consider adding a box to check/indicate requirement for an observed recollection (e.g. in the case of an invalid)

Thank you again for the opportunity to provide feedback in this regard.

Sincerely,

Jennifer A. Collins

Mitchell F. LeBard

Medtox Laboratories, Inc.