

American Medical Review Officers? L.L.C.

<http://www.americanmro.com/>

7 Compound Drive
Hutchinson, Kansas 67502

Pipeline Testing Consortium, Inc.

<http://www.pipelinetesting.com/>

9 Compound Drive
Hutchinson, Kansas 67502

January 11, 2010

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

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

By email

Dear Mr. Stephenson,

Your office is seeking comment on the proposal to make major modifications to the Federal Drug Testing Custody and Control Form (CCF). Pipeline Testing Consortium, Inc. (PTC), providing drug and alcohol testing services to DOT-regulated businesses in the oil and gas industry for 19 years, and American Medical Review Officers, LLC (AMRO), performing medical review officer duties for DOT-regulated companies for 7 years, do not support many of the proposed changes. Our objections are based on the speculative nature surrounding the development of Instrumented Initial Test Facilities (IITF). Changing the standard, universal CCF to be used in such a unique and highly doubtful setting is a huge waste of time and money.

General Comments

The IITF was proposed, by HHS, in 2004 (69 FR 19673) and became part of the mandatory guidelines in 2008 (73 FR 71858). Well over 200 comments were generated on "alternative specimens," the main issue of the NPRM. IITFs received approximately one comment for every ten submissions. A few of the commenters, including your own prime contractor (RTI) simply asked that IITFs and labs have the same PT requirements. A few more commenters asked that IITFs be held to all the standards that a "regular" laboratory has to meet. You dutifully addressed groups with similar comments: four commenters wanted this, three wanted that, etc. However, the most asked question came from a group of ten commenters (three HHS-certified labs, four TPAs (each having an MRO), two independent MROs, and the industry's largest drug

and alcohol testing association which represented hundreds of service agents and employers conducting drug tests). Those commenters asked why IITFs were being proposed in the first place. That question never got an answer.

Comments on the Proposed Federal CCF

Changes to the CCF to accommodate the IITF qualify as non-essential. A survey of the large labs, the most likely source for an IITF, has produced not a single plan to develop an IITF. For something that no one has plans to build, the changes qualify only as a huge waste of time and money. If and when one might be built, then and only then develop a CCF -- one that is separate and unique for use in IITFs. As much time as IITF development and certification would take, HHS would have the time it would take to develop an "IITF-CCF." It makes sense that an IITF have a separate and unique CCF to record its separate and unique role in the overall program.

The decisions that HHS makes have a huge impact on the entire drug-testing community. DOT is bound by law to follow your lead with respect to decisions in and around the laboratory, such as adding new drugs or modifying the standard CCF. Modifying the CCF to allow for something that may never happen is pure speculation. It is not a good time to speculate with our time and money. Regardless of the economy, it is never a good time to throw good money after bad.

The Federal government conducts about 200,000 tests a year. DOT conducts approximately 7 million tests annually. Changing the standard CCF - and impacting each and every one of those 7.2 million, Federally-required drug tests - to cater to a near impossibility is irresponsible. DOT is already proposing to change Part 40 to include the words "or IITF" after every usage of the word "laboratory." That change is going to ripple through every DOT mode-required employer plan (hundreds of thousands of them) for the sake of adding empty words.

Comments to CCF changes, Step 1 to Step SB:

The NPRM to modify the CCF highlighted "major changes" in an order of significance that was defined by HHS. To give each its proper due, we will address the proposed changes top-to-bottom, in step-number ascending order.

Step 1, B: Inserting "No." to become "Phone No.": We have no objection to this change. While we think that the existing "Phone and Fax No." is quite clear, if this addition is helpful to you, it is acceptable to us.

Step 1, C: Replacing the hash marks for SSN with a single underline: We do not support this change. The vast majority of employees use their SSN to document their drug test. The nine spaces, in SSN-representation-order, help remind the collector that an SSN has nine numbers. In the "real world," that is helpful. It is true that not all employee 10 numbers fill up nine spaces. However, our philosophy, which is derived from our

experience of conducting tests and dealing with CCFs on a daily basis, is to design the form for the most likely collection, rather than the exceptional collection.

Step 1, (New) 0: Adding modal acronyms for DOT collections: We do not support this change. We believe that changes to the form should be limited to only those that better ensure the integrity of the collection, or simplify the collection process. Adding another data element for the collector to determine and later taking the time to rectify donor inaccurate responses (this data is guaranteed to be generally inaccurate, and especially so in situations where the donor is affected by more than one mode).

The rationale that these data elements will have a positive effect on DOT modal reporting requirements is unrealistic. Modes that need reports from their industry convey those requirements directly to those they regulate through rules. Those companies will know what their reporting requirements are without sorting through data elements on the CCF. This is certainly the case with modes that you mention (FAA, USCG) and ones you don't (FRA, FTA) - all of whom are getting reports now without these data elements. Since companies will already know their reporting requirements, new data elements will not help - but they can hurt by becoming compliance issues for modal inspectors (coded incorrectly at the collection site). Time and money will have to be invested to correct something everyone knows will need correcting. Finally, the reference to FMCSA and a (national) database is more speculative than someone building an IITF. Adding this data element goes against our, previously stated, philosophy of simplifying the form and allowing only those changes that would make the collection better. Remember, any error in the collection process opens up the question line: If this is wrong, what else could be wrong? These data elements will be the source of countless errors.

Step 2: Inserting "make remarks when appropriate" and moving "Collector reads specimen temperature within 4 minutes" away from temperature-check block: We do not support this change. The collector should make a remark if it is appropriate, but to add a statement for this process is unnecessary and makes the CCF more cluttered in an area that needs to be kept as simple and as uncluttered as possible. Likewise, to move the reminder to read the temperature in 4 minutes away from the area where the check is made, defeats the purpose of the reminder.

Step 3: No changes proposed.

Step 4: "" AND COMPLETED BY TEST FACILITY": We do not support this change. We believe that the standard CCF should be used only for collections going to "regular," full-service laboratories. If and when an IITF becomes a reality, develop a unique CCF for the IITF.

Step 4, Replacing blocks for time and date with a line and "AM-PM": We do not support this change. We realize that this change was made to save vertical space to accommodate IITF use. However, the blocks are currently well used by the collector for noting time and date. These are critical data elements and the blocks help highlight their recording. Writing inside a block and checking a block helps ensure an item is filled in: it

is easier to review a CCF and see an empty block (missing data element) than it is to see the same missing item on a multi-purpose line.

Step 4, Delivery Service block: This block was reduced in size and lost some of its wording ("transferring specimen to laboratory"). We do not support this change. We feel that to write or stamp the name of the courier in this block, more space is needed. Removing the purpose of the transfer (from collector to courier) removes explanation of how the chain of custody works. This is a critical item to remove, and is only being done as a result of the IITF domino effect (gaining space). Back when the CCF went from a seven-part to a five-part format the legal department at the Dept. of Justice liked the changes that were made. One area, specifically being, the transfer-of-specimens explanation sections. We highly recommend you keep the explanation of the transfer from collector to courier.

Step 4, Primary Bottle Seal Intact: The changes to the CCF for IITF use are filled with procedural problems, ones that will end up be litigated. This change presents a procedural problem when a primary seal is broken at an IITF and then the specimen must be sent to a full-service laboratory. When the full service lab receives the specimen how can they check that the primary seal is intact? The problem is: they will not be able to do so. They will have to note the condition of the seal applied by the IITF, which is NOT the primary seal. This is another reason why, if or when, any IITF gets built, that HHS prepare a unique form for the IITF to explain anomalies like this. A specimen bottle can have only one primary seal- the one applied at the collection site. This is an accepted fact.

Step 4, Addition of area "Received at IITF": We do not support this change. The current CCF is very simple; your proposed CCF is very complicated. There are no examples of a collector writing in the "Received at Lab" area, or the lab writing in the "Initiated by Collector" area. Two sections; two responsibilities, with the lab coming directly under the collector, makes it very simple (as it should be). However, making the vertical spacing and fonts smaller, and placing the IITF block directly under the collector block makes the lab accessioner vulnerable to errantly writing in the wrong location.

Step 4, Step 5A, and bottom-of-page title, use of the word "facility": Previously specimens went to laboratories. Your proposal sends specimens to "facilities." Laboratories are specific places where things are tested and where scientists work. Employees and unions accept laboratories but may not want anything to do with facilities. (You should be aware of, and concerned, about problems you are creating in tangential areas of the program.) An employee (or a judge) might view a facility as a poor substitute; a place unable to do what a laboratory can do when it comes to drug testing. Of course this argument is against the concept of IITFs. We oppose dropping the word "laboratory," in lieu of the term "facility," in order to make the standard CCF flexible enough for both. This is one more reason why an IITF should be given its own unique form.

Step 5A, addition of new drugs, rearranging drug order, and rewording: We do not oppose the change to add the new drugs; however, we oppose rearranging the current order listing the "old" drugs. Laboratory certifiers are used to drugs being in a certain order since the outset of the program. It will take a long time to purge old CCFs from the system. During that time, certifiers will have to deal with old forms and new forms simultaneously. Keeping the drug order unchanged minimizes the chance for reporting errors. We also oppose shortening "Rejected for Testing" to "Rejected." The former was crystal clear; the latter is somewhat cloudy - rejected for what? (testing, of course). Keep the term as is.

Step 5 of current CCF. removal of Split Specimen Test Results: Your 2008 data shows that this capability of the CCF was only used in .07% of the positives. While that statistic is lower than what we see in the oil and gas industry, look at it this way: you are making a proposal to swap this item, which has a use, for IITF information that is not likely to ever have a use. Keeping this section as is allows one piece of paper to show both primary and split results. One piece of paper is a very good and very simple system for certifying related test results.

Labels, reduction in size: We oppose this change. The %" label-size is small enough as is. We oppose reducing the label size to 1/2". Thinner labels are more prone to tear than wider labels. Reducing the label size by 33% greatly increases the possibility of tearing.

Public Burden Statement: The burden hours associated with each collection and handling of each CCF are misleading with respect to the time it takes for each entity (e.g., donor, collector, lab) to execute his or her part of the CCF. The MRO exhausts more work hours than depicted when trying to obtain the "MRO copy" from the collector. Based on AMRO data and conversations with several other MRO offices, a conservative estimate is that MROs spend 8 hours per week per 1500 tests on the "paper chase." (The MRO copy of the CCF contains the donor's signature. It is necessary that the MRO obtain this piece of paper prior to the release of a drug test result to the employer for a Federally-regulated test.) Using a conservative estimate of 5000 MRO offices, this amounts to an additional 40,000 hours of MRO burden. There is also an associated burden on collectors (to find missing forms), employers (delay in hiring), and safety (the interview cannot begin and the employee cannot be removed until the MRO Copy is received). The purpose of our testing is safety and saving time could reduce accidents and save lives.

We propose you modify the first page of the CCF to include the donor's name, certification signature, and contact information. This change could save employers a lot of money and increase safety throughout the industry. The MRO would be able to conduct the interview and report the result using only the Lab Copy of the CCF, which always ends up in the hands of the MRO. There is nothing that is "illegal" about placing the name of the donor on the first page of the CCF. Non-regulated testing – which amounts to four times more testing than regulated testing - uses a CCF with the donor's name on the first page. Other government agencies (e.g., IRS, SSA) routinely use "sensitive" forms that require the name of the individual on the first page. The benefits

of this change would: 1) maintain the integrity of the collection; 2) allow the interview process to begin immediately upon receipt of the confirmed test result; 3) increase safety, by getting verified results to employers faster and drug-using employees out of safety-sensitive jobs quicker; and 4) ensure that no positive tests have to be canceled due to the lack of receiving the MRO Copy of the CCF containing the donor's signature. In summary, we oppose the changes on the Federal Drug Testing Custody and Control Form that accommodate IITF information. While some of the proposed changes are needed, we believe a total overhaul of the form would be better served to the entire industry by adding the donor information to Copy 1 of the CCF.

Thank you for the opportunity for our comments to be considered.

Sincerely,

Mike Neuway
Vice President
Pipeline Testing Consortium, Inc.

David W. Paine, M.D., FAAFP
Medical Review Officer
American Medical Review Officers, LLC