July 30, 2020

Via www.reginfo.gov/public/do/PRAMain

Mr. Carlos Graham
Social Science Analyst

Re: Mandatory Guidelines for Federal Workplace Drug Testing Programs (OMB No. 0930-0158)—Revisions.
ICR Reference No. 202006-0930-004

Dear Mr. Graham:

I am writing on behalf of Clinical Reference Laboratory, Inc. (CRL), which is certified by the National Laboratory Certification Program to perform Federal agency and federally-regulated drug testing. CRL is one of the largest privately held clinical testing laboratories in the United States. The Substance Abuse and Mental Health Services Administration (SAMHSA) has proposed several modifications to the Federal Custody and Control Form (CCF) to update the CCF to conform with changes related to the approval of oral fluid specimens for use in Federal agency and federally-regulated drug testing programs. CRL provides the following comments and recommendations regarding SAMHSA's proposed modifications to the CCF.

SAMHSA proposes that Step Four of Copy-1 of the CCF be modified to require that laboratories record the expiration dates of the primary (and apparently split) oral fluid specimen device on the CCF upon receipt at the laboratory. To accommodate this proposed requirement, SAMHSA also proposes to allow the use of transparent or partially-transparent seals so that laboratory personnel may read the expiration dates on oral fluid specimen devices when those dates are covered by the seal. SAMHSA's proposed modifications to the CCF would impose undue personnel and monetary costs, and may not be feasible. The proposals also raise regulatory compliance concerns. CRL recommends that SAMHSA withdraw the proposed modification to the CCF requiring laboratory personnel record the expiration date of oral fluid specimen devices on the CCF, thus making any seal modification unnecessary.

STEP FOUR – BURDEN AND COST

SAMHSA's proposed modification of Step Four of Copy-1 to require that receiving laboratories record the expiration date of the oral fluid specimen devices on the CCF presents significant new costs to laboratories in laboratory operations. CRL urges that additional

consideration be given to the relative merit of having laboratories record the oral fluid specimen device expiration dates on the CCF rather than the collector. The proposed modifications create an unnecessary redundancy because a separate proposed modification requires the collector also confirm that each collection device is within the expiration date by marking a box on the CCF either "yes" or "no."

From the perspective of laboratory operations, the additional burden on laboratory personnel to record the expiration date of oral fluid specimen devices on the CCF represents a significant increase in the time necessary to accession specimens for testing. Some laboratories may eventually receive thousands of oral fluid specimens for testing on a daily basis. CRL regularly receives thousands of specimens at the same time for processing and accessioning for testing. CRL estimates that the additional time its accessioners will have to spend accessioning oral fluid specimens will double with the requirement that expiration dates be recorded on Copy-1 upon receipt at the laboratory. This additional time will translate to additional annual costs for all laboratories. CRL currently estimates that its laboratories will incur additional annual costs of more than $85,000.00, assuming that there are no issues with reading the expiration dates. In order for the laboratory to record the expiration date after the collector has affixed the seal to the oral fluid specimen device, the collector must properly affix the seal to ensure the expiration date is visible (this is true even if the seal is partially transparent). CRL anticipates that if an expiration date is not visible or otherwise legible, the time its accessioners will be required to spend to record the required information—and associated personnel costs—would increase even further.

CRL has also been informed by its paper CCF vendor that the estimated cost to implement transparent or partially-transparent seals would cost CRL approximately fifty percent more that its current CCF and tamper-evident paper seals. CRL estimates this increased cost, which would apply to all CCFs—whether urine or oral fluid, would also be an additional $85,000.00 annually.

If the seal is improperly placed on an oral fluid specimen device and the expiration date is concealed, the information that SAMHSA has proposed must be recorded by laboratories as part of the testing process will not be available. This situation—which experience demonstrates is inevitable—can be avoided entirely by requiring that collectors record the information at collection. Alternatively, SAMHSA could reconsider its proposal that device expiration dates be recorded on the CCF at all, which is redundant of the collector confirming that the device is not expired at Step Two. However, if SAMHSA determines that recording device expiration dates on the CCF is necessary, that requirement should be moved to Step Two to be completed by the collector. CRL has confirmed with its electronic CCF (ECCF) vendor that the ECCF collection process could be upgraded without significant effort to require that collectors record device expiration dates in the ECCF system at the time of collection.

CRL recommends that SAMHSA withdraw the proposed modification to the CCF requiring laboratory personnel record the expiration date of oral fluid specimen devices on the CCF. This task is more appropriately performed by the collector at the time the specimen is collected, if at all.

SEAL MODIFICATION – FEASIBILITY

SAMHSA proposes to allow the modification of the specimen seals affixed to the bottom of Copy-1. These proposed modifications include possible "perforations, label with transparent seal on one side, and separate label and seal." It appears that permitting the use of transparent seals is intended to address concerns that laboratories may not be able to read the expiration date of the oral fluid specimen device upon receipt at the laboratory. CRL does not believe sufficient study has been given to this proposed modification of the CCF seal. The current CCF seal is a tamper-evident paper seal on which the specimen identification number (SID) associated with a specific donor specimen is pre-printed. In order to be transparent, at least a portion of the seal will have to be something other than paper. CRL has no information, and is unaware of any feasibility study confirming, that a transparent (not paper) seal will provide the same security as a tamper-evident paper seal. In order to ensure the integrity of Federal agency and federally-regulated drug testing programs, both U.S. Department of Health and Human Services (HHS) and U.S. Department of Transportation (DOT) regulations provide that broken seals on specimens are fatal flaws. A transparent seal that does not provide the same security as a tamper-evident paper seal would negatively impact the integrity of those testing programs.

CRL recommends that transparent seals not be permitted for use for Federal agency and federally-regulated drug testing until a study of the security and long-term stability (i.e., in a freezer after use or warehouse prior to use) can be conducted.

Additionally, the use of a transparent seal raises issues regarding the use of bar codes and optical scanners by laboratories to positively identify specimens received for testing. Bar codes and optical scanners greatly reduce human error in the process of confirming that the SID affixed to a donor specimen matches the SID on the CCF accompanying the specimen. However, CRL has been informed by its paper CCF vendor that optical scanning of bar codes requires contrast between the bar code and the background on which the bar code is printed. This contrast would not exist on a transparent seal.

CRL therefore recommends that transparent seals not be permitted for use for Federal agency and federally-regulated drug testing until a study of the use of optical scanners to read bar codes printed to the seal can be conducted.

A misplaced seal on either the primary or split oral fluid specimen device would conceal the expiration date. This raises program issues for laboratories regarding specimen flaws (are they recoverable and how) and specimen acceptance criteria for testing. Even if the seal were partially-transparent (one-half plastic or some other substance and one-half paper), experience demonstrates that collectors would on occasion improperly place the seal on a specimen device and conceal the expiration date. There also does not appear to be any study of whether a partial paper and transparent seal is actually feasible. Finally, laboratories affix accession numbers (LAN) printed on labels to specimen bottles upon receipt as an additional means of identification and security. LAN labels affixed to oral fluid specimen devices during accessioning would also likely cover or conceal the device expiration dates.

CRL recommends that SAMHSA withdraw the proposed modification to the CCF requiring laboratory personnel record the expiration dates of oral fluid specimen devices on the CCF upon receipt at the laboratory, which would obviate the need for transparent seals.

STEP FOUR – REGULATORY ISSUES

The proposed modification to Step Four of Copy-1 requiring laboratory personnel record the expiration date of the primary (and apparently split) oral fluid specimen device also creates regulatory compliance issues related to the split specimen. In those instances in which the expiration date on either oral fluid specimen device is not visible during initial accessioning, the primary testing laboratory will be forced to make a decision as to how to proceed. With regard to the primary specimen, this may require entering the information *after* the preparation of the specimen for testing has occurred. With regard to the split specimen, the primary laboratory would have few, if any, options in recording the required information. HHS prohibits the primary laboratory from opening or tampering (i.e., lifting the seal to read the expiration date) with the seal on the split specimen.

Additionally, HHS and DOT regulations and guidance prohibit a laboratory from notifying the Medical Review Officer (MRO) of the availability for testing, or condition, of the split specimen. It appears that the proposed modification to the CCF requiring laboratory personnel record the expiration date of oral fluid specimen devices on the CCF would violate federal testing guidelines where the split specimen is collected using an expired collection device, or is unavailable, because Copy-1 is used to report test results to the MRO.

CRL recommends collectors record the expiration date of the primary and split oral fluid specimen device at collection, if at all. CRL also recommends that SAMHSA remove the proposed addition of the split oral fluid specimen device expiration date from the CCF and address the issue in the same manner as the condition of the seal of Bottle B is currently addressed.

CRL would welcome the opportunity to discuss its comments and recommendations with SAMHSA. Please do not hesitate to contact me to arrange such a discussion.

Sincerely,

Allen G. Jones
Vice President - Legal Affairs