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Via www.reginfo.gov/public/do/PRAMain
Substance Abuse and Mental Health Services Administration
Attention: Division of Workplace Programs
1 Choke Cherry Road, Room 7-1045
Rockville, MD 20857

Re: SAMHSA Agency Information Collection Activities: Submission for OMB Review; Comment Request

Project: Mandatory Guidelines for Federal Workplace Drug Testing Programs (OMB No. 0930-0158) - Revision; FR Doc. 2020-13986, 85 Fed. Reg. 39204 (June 30, 2020)

Ladies and Gentlemen:

Laboratory Corporation of America Holdings ("LabCorp") is one of the largest occupational substance abuse testing providers in the world, with multiple SAMHSA-certified laboratories throughout the United States. As a provider of Federal workplace drug testing services, LabCorp would be directly affected by the changes to the Federal Drug Testing Custody and Control Form (CCF) for Federal agency and federally regulated drug testing programs described in the above-captioned comment request. We agree with the proposal to revise the existing form so that it may be used for both Urine and Oral Fluid matrices and appreciate the challenges in design; however, we have some concerns regarding the proposed form and manner in which the required information is proposed to be collected. Our comments follow.

Revised Step 2: <u>Completed by the Collector</u>

The proposed form has added entries specific to oral fluid collection (Split Type, Device Within Expiration Date, and Volume Indicator observations). We believe that recording this information specific to oral fluid collection devices is relevant and should be recorded at the time of collection by the individual performing the collection. We fully support this change and believe it is both appropriate and sufficient for the collector to record those key observations at that time.

Revised Step 4: Chain of Custody – Initiated by Collector and Completed by Test Facility

The proposed form has added "Primary/Single Specimen Device Expiration Date" and "Split Specimen Device Expiration Date" fields for the accessioner to record the expiration dates of the collection devices on the CCF. We strongly disagree with the requirement that this information be annotated on the form by the laboratory. It is redundant and a duplication of effort already expended by the collector at the time of collection in step 2 ("Each Device Within Expiration Date? Yes/No"). This additional step adds time and cost to the specimen receiving process, and in addition may require that the accessioner attempt to peel back the tamper-evident seal on the "A" and/or "B" oral fluid specimen if the seal obscures the expiration date on the device. Is the intention that the specimen(s) will be rejected for testing if the device is beyond the expiration date? It seems that identifying this potential flaw at the time of the collection provides the best opportunity to avoid an error that may require an additional collection event.

We recognize that the bottom of copy 1 has been revised to permit modification to the tamper-evident seals to facilitate observation of the expiration date; however, we submit that the implementation of a hybrid seal or an alternate material seal has not been sufficiently explored or tested to have an understanding of issues that may arise.

Revised Copy 1:

The proposed revision indicates that the labels or seals at the bottom of copy 1 have been edited to allow for modification with examples provided (e.g., perforations, label with transparent seal on one side, separate label and seal). The use of well-tested paper tamper-evident seals in the Federal Workplace Drug Testing Program is almost ubiquitous and has proven to be a cost-effective means of monitoring the integrity of the collected specimen. Requirements that the seals be tamper-evident and maintain their integrity under a number of transportation and storage conditions has long been understood as critical to the forensic defensibility of this program. Modification of the label material to either a hybrid or new material poses technical challenges, adds cost, and potentially creates new and unanticipated issues for multiple stakeholders. Issues involving process, cost, and stability should be more fully vetted prior to permitting a change that only facilitates recording an expiration date that has already been verified by the collector.

One modification that was not included in the examples is whether the length of the seal can be modified to better accommodate the different sample types and collection devices/containers that will be used in federal testing programs. We request clarification on whether this modification will be permitted.

In summary, we believe that the proposed revisions to the CCF requiring recording of the oral fluid collection device expiration date at the receiving laboratory add unnecessary redundancy and labor costs. In addition, potential modifications to tamper-evident seals to accommodate this redundant collection of information raise multiple questions regarding the integrity and stability of the seals as well as adding to the expense of the form.

We look forward to working with the Department to improve the CCF while avoiding unintended consequences.

Very truly yours,

Donald E. Horton, Jr.
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