July 30, 2020

Via Electronic Submission

Carlos Graham
Social Science Analyst
Office of Management and Budget

Re: **Quest Diagnostics Comments on OMB No. 0930-0158 Revision (85 FR 39204)**

Dear Mr. Graham:

Attached are the comments of Quest Diagnostics Incorporated ("Quest Diagnostics") on the **Quest Diagnostics Comments on OMB No. 0930-0158 Revision (85 FR 39204)**. Quest Diagnostics annually performs more than two million Federally-mandated drug tests through our national network of three Substance Abuse and Mental Health Services Administration (SAMHSA) certified laboratories.

We appreciate the opportunity to comment on the proposed revisions to the Federal Custody and Control Form [OMB Mo. 0930-0158]. Quest Diagnostics comments are focused on the impact that several new data collection elements related to the expiration date of oral fluid collection devices.

Unlike urine specimen collection systems, most commonly used oral fluid collection systems designed for workforce drug testing utilize a buffer preservative solution (BPS) to preserve and stabilize the specimen during transport and storage. A primary function of the BPS is to ensure that the specimen does not degrade and any drug/drug metabolite present in the specimen can be reliably recovered – i.e. no false negative results – during the documented, for that collection system, post-collection specimen stability period. Consequently, it is understandable that there is a verification of the device's expiration date and documentation of validity prior to collection of the specimen.

Quest Diagnostics would encourage the consideration of the following related to specified sections of Copy-1 of the CCF:

Step 2:

> It is appropriate and we agree that the collector should document the type of specimen (urine or oral fluid) being collected. The new elements for an oral fluid collection – split type, verification of device dating and verification of sufficient volume collected – are all appropriate and unique for this specimen type. As compared with a urine collection, the additional time required to document this information is negligible.

Step 4:

The revised CCF has fields for the laboratory to record the expiration date of the primary and split oral fluid specimens. The recording of this information by the ***laboratory*** results in labor costs and increased forms manufacturing costs. The labor hours associated with identifying, recording on the CCF and keying the expiration dates are estimated to be 0.01 hours per specimen. The potential annual impact, if all Federally-mandated specimens currently tested by Quest Diagnostics were oral fluid, would be in excess of twenty-thousand (20,000) hours. This estimate assumes that the expiration is not obscured by the tamper-evident seal. Due to size of the commercially available oral fluid collection tubes, if the tamper-evident seal is not carefully placed on the tube, these dates could be partially or completely obscured. An obscured date would result in more labor to carefully peel back the seal to make it visible. Presumably the allowance of a partially transparent seal was meant to address this concern. However, a seal that is transparent on one side would still require careful placement to ensure that the transparent portion was over the expiration date portion of the collection tube label.

A new type of tamper-evident seal also raises a number of concerns –

- The increase in the material cost for a form that has a seal that is transparent on one side and has a white background on the other, facilitating both the visibility of the expiration date and barcode scanning of the specimen ID, is estimated to be $0.085-$0.09 per form. Last year, Quest Diagnostics produced 3.5 million forms which would represent an increase in material cost of approximately $300,000.
- There are decades of experience and an established history with the current paper seals. The adhesion and tamper-evident characteristics in addition to the stability under room temperature, refrigerated and frozen storage conditions are well recognized in the industry. Moreover, the integrity of the seals is an absolute requirement for the forensic defensibility of the drug test result. Such a fundamental change in the tamper-evident seal should be fully vetted and performance understood prior to implementation.
- Other potential concerns include: the ease of peeling the seal from the form; how easily the new material is handled by collectors wearing gloves; and whether certain pen types (e.g., gel pens) be incompatible and writing more easily smudged with the new material.
- It should also be noted that after accessioning the specimen in the laboratory, any laboratory accession number label that is placed on the tube would permanently obscure the expiration date even with a transparent tamper-evident seal because the laboratory would never obscure the specimen ID portion of the seal.

Quest Diagnostics believes that this information collection by the laboratory is duplicative of that required of the collector who is verifying that the device is within expiration dating. It should also be noted that for urine collections, the collector simply indicates whether the temperature is in range and is not required to document the actual temperature of the specimen. However, if SAMSHA maintains that recording the device expiration is required, then this should be a collector (Step 2) requirement rather than a laboratory (Step 4) requirement.

Moreover, to the extent that specimens are collected with an ECCF system, the collection 'wizard' could require the entry of this information and also verify the use of the device is within its dating. Moving this requirement to Step 2, would eliminate the need for changes to the CCF/tamper-evident seal and the additional, and somewhat redundant, labor hours.

One additional comment related to the expiration date is that the revised CCF presupposes that two single use devices ("serial" or "concurrent") would be used. While most devices in use today have that design, some manufacturers are working on a 'split' kit design that has two collection pads that are placed in the mouth – either singly or jointly – and two vials packaged together. In this configuration, the two tubes would be expected to have an identical lot of BPS.

Regulatory:

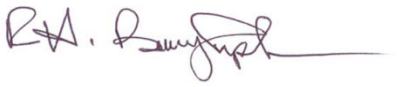
While not directly a part of the OMB CCF rulemaking process, there are questions as to process when some of the new, requested information is omitted (a 'flaw') from the CCF. While the Urine Oral Fluid Mandatory Guidelines (82 FR 7920) Section 15.1(i)

> "*The HHS-certified laboratory or IITF identifies a flaw (other than those specified above) that prevents testing or affects the forensic defensibility of the drug test and cannot be corrected*"

may address the potential flaws that are oral fluid specific – e.g., checking/recording expiration dates, volume indicator, split type – these flaws, and the actions taken when they exist, should be specifically detailed in the Mandatory Guidelines and subject to the Rulemaking process.

For further clarification on any issue or comment cited above, please do not hesitate to contact me directly at 770-800-9870.

Respectfully submitted,



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