Billing Code: 4162-20 - P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning the opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer at (240) 276-0361.

Comments are invited on: (a) whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Mandatory Guidelines for Federal Workplace Drug Testing Programs (OMB No. 0930-0158) - Revision

SAMHSA will request OMB approval for a revision of the Federal Drug Testing Custody and Control Form (CCF) for federal agency and federally regulated drug testing programs which

must comply with the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG) dated January 23, 2017 (82 FR 7920) and using Oral Fluid (OFMG) dated October 25, 2019, and OMB approval for information provided by test facilities (laboratories and Instrumented Initial Test Facilities, IITFs) for the National Laboratory Certification Program (NLCP).

The CCF is used by all federal agencies and employers regulated by the Department of Transportation (DOT) and the Nuclear Regulatory Commission (NRC) to document the collection and chain of custody of urine specimens at the collection site, for HHS-certified test facilities to report results, and for Medical Review Officers (MROs) to document and report a verified result. SAMHSA allows the use of the CCF as a paper or electronic form.

The current OMB-approved CCF has an August 31, 2020 expiration date. SAMHSA has resubmitted the CCF with major content revisions to the form for OMB approval. These revisions are:

Copies 1-5

Revised Step 1

1. Added "Collector Contact Info:" and "Other" line (e.g., email)

Revised Step 2

1. Put Urine and Oral Fluid checkboxes above Step 2 for collector to annotate
2. Expanded to 4 lines for collector entries:
   - General entry for Split, Single, or None Provided (same as current)
   - Entries specific to urine collection (moved "Collector reads urine temperature within 4 minutes" here; other entries same as current)
   - Entries specific to oral fluid collection: added "Split Type" with checkboxes for Serial, Concurrent, and Subdivided; "Each Device Within Expiration Date?" with checkboxes Yes or No; and Volume Indicator(s) Observed checkbox)
   - Remarks (same as current)

Revised Step 3

1. Edited instruction to state "collector affixes seal(s) to bottle(s)/tube(s)"

Revised Step 4 (Collector section)

1. Edited "Specimen Bottle(s) Released To" box to state "Specimen Bottle(s)/Tubes(s) Released To"

Copy 1 (Test Facility Copy)

Revised Step 4 (Accessioner section)

1. Edited "Specimen Bottle(s) Released To" box to state "Specimen Bottle(s)/Tubes(s) Released To"
2. Added "Primary/Single Specimen Device Expiration Date" and "Split Specimen Device Expiration Date" fields for accessioner to annotate expiration dates of oral fluid collection devices

Revised Step 5a (Certification and Reporting section)

1. Removed analyte names and checkboxes
2. Repositioned results and checkboxes: moved REJECTED FOR TESTING, ADULTERATED, SUBSTITUTED and INVALID RESULT checkboxes; moved POSITIVE checkbox to be under DILUTE
3. Added line for certifying scientist to record positive analytes and concentrations, and added "*Analyte(s) in ng/mL*" instruction (aligned under "POSITIVE for:")

Copy 2 (Medical Review Officer Copy)

Revised Step 6 (Donor section)

1. Edited donor certification statement to state "specimen bottle/tubes"

Revised Step 7 (MRO section – Primary Specimen)

1. Put Urine and Oral Fluid checkboxes above Step 6 for MRO to annotate

Bottom of **Copies**

Revised Copy 1:

1. Edited label/seal at bottom of Copy 1 to allow for modification (e.g., perforations, label with transparent seal on one side, and separate label and seal)

Revised Copies 3-5:

1. Removed Steps 6 and 7 (MRO sections)
2. Moved Public Burden Statement from the back to the front of the copies

Additional edits to Copy 5:

1. Moved Privacy Act Statement (for federal employees) from the back to the front of the copy
2. Removed Instructions for Completing the CCF from the back. SAMHSA will post instructions for completing the Federal CCF for urine and oral fluid on their website.

Based upon information from federal agencies and from DOT concerning their regulated industries, the number of respondents has increased from 5.4 million to 6.7 million, which increases the total burden hours by 170,701.8.

Laboratories and IITFs seeking HHS certification under the NLCP must complete and submit the NLCP application form. The NLCP application form has not been revised compared to the previous form.

Prior to an inspection, an HHS-certified laboratory or IITF is required to submit specific information regarding its procedures. Collecting this information prior to an inspection allows the inspectors to thoroughly review and understand the testing procedures before arriving for the onsite inspection. The NLCP information checklist has not been revised compared to the previous form.

The annual total burden estimates for the CCF, the NLCP application, the NLCP information checklist, and the NLCP recordkeeping requirements are shown in the following table.

Form/Respondent	Number of Respondents	Responses per Respondent	Total Number of Responses	Burden per Response (hours)	Annual Burden (hours)
Custody and Control Form[1]:					
Donor	6,726,610	1	6,726,610	0.08	538,128.8
Collector	6,726,610	1	6,726,610	0.07	378,000
Laboratory	6,726,610	1	6,726,610	0.05	336,330
IITF	1	0	0	0.05	0
Medical Review Officer	6,726,610	1	6,726,610	0.05	270,000
NLCP Application Form[2]:					
Laboratory	5	5	5	3	15
IITF	0	0	0	3	0
Sections B and C - NLCP Inspection Checklist:					
Laboratory	29	1	29	1	29

Form/Respondent	Number of Respondents	Responses per Respondent	Total Number of Responses	Burden per Response (hours)	Annual Burden (hours)
IITF	0	0	0	1	0
Record Keeping:					
Laboratory	29	1	29	250	7,250
IITF	0	0	0	250	0
Total	6,726,673		26,906,503		1,529,753

Send comments to Carlos Graham, SAMHSA Reports Clearance Officer, Room 15-E-57-A, 5600 Fishers Lane, Rockville, MD 20857 ***OR*** e-mail a copy to **Carlos.Graham@samhsa.hhs.gov**. Written comments should be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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[FR Doc. 2020-02671 Filed: 2/10/2020 8:45 am; Publication Date: 2/11/2020]