Department of Health and Human Services
Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Prevention
Division of Workplace Programs

Subject: Guidance for Using the 2017 Federal Custody and Control Form (CCF) for Urine Specimens

Date: August 8, 2017

Table of Contents

1. When can a federally regulated program begin using the 2017 Federal CCF?

The Office of Management and Budget (OMB) has approved the use of the 2017 Federal CCF as of August 8, 2017. Additional information is available at www.reginfo.gov (enter the OMB number 0930-0158 in the search area).

2. What are the allowable formats for the 2017 Federal CCF?

The Federal CCF may be used as a paper (hardcopy) or electronic (digital) document, or in a combination electronic and paper format.

A paper Federal CCF may be either 1) a preprinted, multiple-part carbonless form or 2) a multiple-part CCF that is printed for a specific drug test (i.e., printed "on-demand" for the collection), usually at the collection site. A paper CCF must conform to the formatting requirements of the OMB-approved Federal CCF.

3. Can the 2014 Federal CCF be used after August 31, 2017?

Yes, OMB has granted an extension for using the 2014 Federal CCF.

TERMS OF CLEARANCE: OMB approves the revised Federal Drug Testing Custody and Control Form (CCF). In addition, the previous version of the CCF (the CCF without the four new analytes - oxycodone, oxymorphone, hydrocodone, and hydromorphone - listed in Step 5A) is authorized for use until June 30, 2018. As of July 1, 2018, the 2017 Federal CCF must be used for federally regulated specimens, and the laboratory must treat the use of the 2014 Federal CCF as a correctable discrepancy.

4. How does a test facility (laboratory or IITF) report results using the 2017 Federal CCF during the period of August 8, 2017 to October 1, 2017?

If a specimen is received at the test facility with the 2017 Federal CCF during this period (i.e., through September 30, 2017), the laboratory or IITF must report the results using the same procedures as for a specimen received with the 2014 Federal CCF (also see questions 15 and 16 below). The laboratory or IITF must include the following comment on the Remarks line in Step 5a of the Federal CCF and on any electronic report: "This specimen was analyzed and reported in accordance with the HHS Mandatory Guidelines effective October 1, 2010." In addition, if the specimen is positive for methylenedioxyethylamphetamine (MDEA), the laboratory must record "MDEA" and the concentration on the Remarks line in Step 5a of the Federal CCF.

5. How does a test facility (laboratory or IITF) report results using the 2014 Federal CCF during the period of August 8, 2017 to October 1, 2017?

If a specimen is received at the test facility with the 2014 Federal CCF during this period (i.e., through September 30, 2017), the laboratory or IITF must report the results using the same procedures used prior to the CCF's extended date.

6. How does a test facility (laboratory or IITF) report results using the 2014 Federal CCF during the period of October 1, 2017 to July 1, 2018?

If a specimen is received at the test facility with the 2014 Federal CCF during this period, the laboratory or IITF must report the results on the 2014 Federal CCF using the same procedures as for a specimen received with the 2017 Federal CCF (also see questions 15 and 16 below). The laboratory or IITF must include the following comment on the Remarks line in Step 5a of the Federal CCF and on any electronic report: "This urine specimen was analyzed and reported in accordance with the HHS Mandatory Guidelines effective October 1, 2017." In addition, if the specimen is positive for an opioid analyte that is not listed on the CCF, the laboratory must record the analyte name and concentration on the Remarks line in Step 5a of the Federal CCF. (As noted under question 3 above, as of July 1, 2018, the test facility must treat the use of the 2014 Federal CCF as a correctable discrepancy.)

7. Where can a sample proof of the 2017 Federal CCF be viewed?

A sample of the Federal CCF is available on the SAMHSA drug testing website www.samhsa.gov/workplace and at www.reginfo.gov.

8. What statements must appear on the 2017 Federal CCF?

- The **Public Burden Statement** must appear on all Federal Government forms that place a reporting burden on gathering information. This statement must be included on the back of each paper copy of the Federal CCF (i.e., Copies 1 through 4). If an electronic Federal CCF is used, this statement must be provided as a separate page. Wording must be identical to that on the OMB-approved Federal CCF.

- The following must be printed on the back of the donor copy (Copy 5) of a paper Federal CCF or, if an electronic Federal CCF is used, be provided as a separate page: **Instructions for Completing the Federal Drug Testing Custody and Control Form for Urine Specimen Collection**, **Privacy Act Statement (For Federal Employees Only)**, and **Public Burden Statement**. Wording must be identical to that on the OMB-approved Federal CCF.

9. Can the 2017 Federal CCF be modified?

Yes. SAMHSA recognizes that suppliers use different hardware and software for paper and for electronic forms. Minor differences in appearance from SAMHSA's Federal CCF proof are permitted provided that they do not significantly impact the required format. The following lists some acceptable differences and modifications:

General

1. The OMB number may appear either vertically or horizontally in the upper right hand corner of the form.
2. The unique specimen identification number at the top of the form may be either a bar code with an associated human-readable number or a human-readable number only.
3. The data entry/information fields may be highlighted using different colors to show where the collector, donor, and test facility will provide information. The colors used to highlight the fields may be different for different fields but must not prevent making clear facsimiles and photocopies of the information that is printed or handwritten in those fields.
4. If a test facility uses the unique specimen identification number to track specimens after receipt and does not assign a separate accession number, the words ACCESSION NO. are not required on the top of the form.
5. The spaces for the employer name and address, MRO name and address, and the collection site address may have lines.
6. The space for the donor's SSN or Employee I.D. No. may have combs, boxes, or a single line.
7. The size of each checkbox may vary slightly.
8. The font size and style used for letters may vary to enhance readability.
9. The form may include a designated space for a collector identification number (e.g., as assigned by a collector training organization) in Step 4 beside the collector's signature or printed name.

Paper Federal CCF

1. For preprinted paper CCFs, the name and address of the test facility and the unique specimen identification number at the top of the form may be printed during the original printing process or added by overprinting after the form is assembled.
2. For individually printed ("on-demand") paper CCFs, the unique specimen identification number must be printed on the form to irrevocably link the same specimen identification number on the form and the labels/seals (i.e., it is not sufficient to place a label on the printed Federal CCF).
3. Preprinting and/or overprinting the employer name and address, MRO name and address, and collection site information is permitted.
4. The exact location for each item on the printed form may vary slightly from the location indicated on the OMB-approved Federal CCF.
5. The legend (i.e., copy number and name) at the bottom of Copies 2 through 5 may be printed using different colors, or a different color stripe may be printed at the bottom of Copies 2 through 5. To ensure consistency and correct distribution of the copies, if different color stripes or legends are used at the bottom of each copy, the following colors must be used: MRO Copy - pink, Collector Copy - yellow, Employer Copy - blue, Donor Copy - green.

6. Reference mark(s) may be used to position the form in a printer to overprint information in the correct location or to optically scan the information in the various fields.

Electronic Federal CCF

1. The legend (i.e., copy number and name) at the bottom of Copies 2 through 5 may be omitted.

Labels/Seals

1. The unique specimen identification number on the tamper-evident label(s)/seal(s) may be either a bar code with an associated human-readable number or a human-readable number only.
2. The size of the two tamper-evident labels/seals may vary, but each must be at least ¾ inch wide.
3. The color of the preprinted information on the "A" specimen bottle label/seal may be different than the color of the preprinted information on the "B" specimen bottle label/seal.
4. The unique specimen identification number must be preprinted on labels/seals for a paper Federal CCF. If the labels/seals are attached at the bottom of the paper Federal CCF, the specimen identification number may be preprinted during the original printing and form assembly process, or added by overprinting after the form is assembled. For a combination electronic/paper CCF: The unique specimen identification number may be preprinted or may be printed on the labels/seals when the collector prints Copy 1 to be sent to the test facility with the specimen.

10. What are the responsibilities of service providers choosing to use an electronic Federal CCF?

An electronic Federal CCF must be the functional equivalent of a paper Federal CCF with respect to integrity, accuracy, and accessibility. Federally regulated employers and drug testing service providers (e.g., collectors, test facilities, MROs) who use electronic or combination electronic and paper Federal CCFs must implement procedures and controls to ensure the authenticity, integrity, and confidentiality of electronic records, and to ensure that electronic signatures are the legally binding equivalent of traditional handwritten signatures. These procedures and controls include, but are not limited to:

- System validation

- The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying upon request of authorized parties (e.g., the MRO, federal agency, or SAMHSA)

- Protection of records to enable accurate and ready retrieval through the records retention period

- Limiting system access to authorized individuals

- Secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete records from the time of initiation of the Federal CCF (changes should be evident when reviewing the original record, and any electronic or paper copy of the original record)

- Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.

Before implementing an electronic Federal CCF, HHS-certified IITFs and laboratories must submit information including a detailed plan and proposed standard operating procedures (SOPs) for SAMHSA review and approval (i.e., through SAMHSA's National Laboratory Certification Program, NLCP). The review of validation records, specimen records, the collection process, SOPs, staff training records, and practices associated with the electronic Federal CCF will be part of the NLCP inspection process.

For test facilities approved to use an ECCF system: Before implementing the revised 2017 ECCF, the test facility must submit updated ECCF information to the NLCP including the Process Overview, Topic Outline of Proposed SOP Revisions, the 2017 ECCF, Training Plans for Federal ECCF Users, and System Validation Plan.

11. Has the HHS Urine Specimen Collection Handbook been revised for use with the 2017 Federal CCF?

Yes. The HHS Urine Specimen Collection Handbook has been revised to reflect the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine and how the collector completes the CCF. The revised handbook is available on the SAMHSA website (www.samhsa.gov/workplace).

12. Has the HHS MRO Manual been revised for use with the 2017 Federal CCF?

Yes. The HHS MRO Manual has been revised to reflect the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine and how test facilities will be reporting results. The revised manual is available on the SAMHSA website (www.samhsa.gov/workplace).

13. Does a test facility (laboratory or IITF) need to change its Standard Operating Procedure (SOP) manual for the 2017 Federal CCF?

Yes. A certified laboratory or IITF must revise all SOP sections, where appropriate, to address the 2017 Federal CCF (e.g., accessioning, chain of custody, and reporting procedures). Since the laboratory may continue receiving 2014 Federal CCF, the SOP manual will need to have procedures applicable to both forms until July 1, 2018, when the 2014 Federal CCF is no longer approved for use. At that time, the laboratory must have procedures to handle specimens submitted with the 2014 Federal CCF as having a recoverable discrepancy.

14. How does a test facility (laboratory or IITF) document specimen receipt using the 2017 Federal CCF?

Specimens received from a collection site

Paper CCF: The test facility that receives the specimen package from the collection site continues the specimen's chain of custody by completing the appropriate chain of custody entries in Step 4 (i.e., "Received at Lab or IITF)." In addition to signing and printing his or her name, the accessioner records the receipt date, marks the appropriate checkbox to document the condition of the primary specimen seal, and releases custody of the specimen (e.g., to a storage area). This process is also used for Combination (electronic/paper) ECCFs.

Electronic CCF: To facilitate linkage of the specimen package to the electronic Federal CCF sent to the test facility, the collector either 1) includes a printed copy of the Test Facility copy (i.e., Copy 1) of the Federal CCF with the specimen; or 2) applies a label to the outside of the specimen package, with the specimen identification number, test facility name and contact information, and collection site name and contact information. The test facility that receives the specimen package from the collection site continues the specimen chain of custody on the electronic Federal CCF. In addition to documenting receipt of the specimen using an electronic signature, the accessioner documents the condition of the primary specimen seal and releases custody of the specimen (e.g., to a storage area). Note: If a printed copy of Copy 1 is included in the specimen package, the accessioner may, but is not required to, annotate this form. This is only a replica of the Federal CCF which contains the collector's electronic signature and is not the chain of custody for the specimen.

Specimens received from an IITF

When forwarding a specimen to a laboratory, an IITF sends both the original Federal CCF (Copy 1) and an IITF Supplemental CCF with the specimen. The laboratory that receives the specimen package from the IITF continues the specimen chain of custody on the IITF Supplemental CCF. This may be a paper or electronic form.

Specimens or aliquots received from another certified laboratory for retesting

When forwarding a specimen or aliquot to another laboratory for retesting, the laboratory that tested and reported the primary specimen (Lab A) sends both a copy of the Federal CCF (copy of Copy 1) and the transmittal chain of custody form with the specimen or aliquot. The laboratory that receives the specimen package continues the specimen chain of custody on the transmittal chain of custody form. This may be a paper or electronic form.

15. How does a test facility (laboratory or IITF) report primary specimen results to MROs using the 2017 Federal CCF?

A test facility must fax, courier, mail, or electronically transmit the completed Federal CCF (copy of Copy 1) to the MRO, with one exception. The test facility may report specimens as negative using only a computer-generated electronic report, provided that the report contains sufficient information to ensure that the test result is properly associated with the MRO copy (Copy 2) of the Federal CCF.

Specimens forwarded by an IITF: A laboratory must also send a copy of the completed IITF Supplemental CCF to the MRO for all results. The laboratory may fax, courier, mail, or electronically transmit a legible image or copy of this form.

16. How does a laboratory report split (Bottle B) specimen results to MROs using the 2017 Federal CCF?

For all split specimen results, the split testing laboratory must fax, courier, mail, or electronically transmit the completed Federal CCF (i.e., the copy of Copy 1) to the MRO. For “Failed to Reconfirm” results, the laboratory must also complete and send a laboratory Split Specimen Report Form to the MRO and include a reference to this separate laboratory report in the “Reason” line in Step 5b of the Federal CCF.

17. What are tamper-evident labels/seals?

Once applied, tamper-evident labels/seals cannot be removed and replaced without visible evidence that tampering has occurred. It is the responsibility of the supplier of the labels/seals to ensure that they are tamper-evident. However, HHS-certified test facilities must perform a study to verify that the labels/seals are tamper-evident. Tamper-evident specimen bottle labels/seals must be at least ¾-inch wide.

18. How does an MRO report a verified result to the employer?

For all verified results, an MRO may fax, courier, mail, or electronically transmit a legible image or copy of the report to the agency/employer.

The result sections on the MRO Copy (Copy 2) of the Federal CCF (Step 6 for the

primary specimen and Step 7 for the split specimen) are formatted in accordance with MRO reporting requirements in the HHS Mandatory Guidelines. To complete the Federal CCF, the MRO marks the appropriate checkbox(es) for the verified result and records information in the designated spaces to specify the test results (i.e., drug analytes, substitution, adulteration). The MRO includes any explanatory comments on the “Remarks” line and signs and dates the CCF.