

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 2020 Federal Custody and Control Form (CCF)
for Urine Specimens**

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1. When can a federally regulated program begin using the 2020 Federal CCF?

The Office of Management and Budget (OMB) has approved the use of the 2020 Federal CCF as of August 17, 2020. 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 2020 Federal CCF?

The Federal CCF may be used as a paper (hardcopy) or electronic (digital) document, or in a combination electronic and paper format. All Federal CCFs must conform to the formatting requirements of the OMB-approved Federal CCF.

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.

3. Can the 2017 Federal CCF be used after August 31, 2020?

Yes, OMB has granted an extension for using the 2017 Federal CCF **for urine specimens only**. The 2017 Federal CCF is not authorized for use with oral fluid specimens.

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 with the four new analytes - oxycodone, oxymorphone, hydrocodone, and hydromorphone - listed in Step 5A) is authorized for use until August 30, 2021.

The 2017 Federal CCF is not authorized for use with oral fluid specimens; the 2020 Federal CCF should be used for oral fluid specimens. As of August 30, 2021, the 2020 Federal CCF must be used for federally regulated specimens, and the test facility (laboratory or instrumented initial test facility, IITF) must treat the use of the 2017 Federal CCF for urine specimens as a correctable discrepancy.

4. How does a test facility (laboratory or instrumented initial test facility, IITF) report urine specimen test results using the 2017 Federal CCF during the period of September 1, 2020 to August 30, 2021?

If a urine specimen is received at the test facility with the 2017 Federal CCF during this period (i.e., through August 29, 2021), the laboratory or IITF must report the results using the same procedures used prior to the CCF’s extended date. (As noted under question 3 above, as of August 30, 2021, the test facility must treat the use of the 2017 Federal CCF for urine specimens as a correctable discrepancy. The 2017 Federal CCF is not authorized for use with oral fluid specimens.)

5. Where can a sample proof of the 2020 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.

6. What statements must appear on the 2020 Federal CCF?

- a. 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.
- b. 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: **Privacy Act Statement (For Federal Employees Only)** and **Public Burden Statement**. Wording must be identical to that on the OMB-approved Federal CCF.

7. What are the requirements for tamper-evident labels/seals?

- a. Once applied to the specimen bottles/tubes, 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.
- b. The label/seal material and ink must prevent smearing and smudging that could cause the specimen identification number to become illegible.
- c. Labels/seals must be designed to not tear when the donor initials the label and the collector dates the label on the specimen bottle/tube. To conserve space and facilitate required annotations on labels/seals, a manufacturer may, but is not required to, provide specimen bottles or tubes with a tamper-evident label applied during production, with an area for the donor to initial and/or the collector to record the collection date. The donor and/or collector annotations may be made to the manufacturer-applied labels instead of the labels/seals applied by the collector during the collection.
- d. 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 (e.g., by the form manufacturer or when printed on-demand at the collection site).
- e. For an electronic CCF or a combination electronic and paper CCF: The unique specimen identification number may be preprinted on the labels/seals and applied to the electronic Federal CCF by the collector (i.e., by typing or scanning the barcoded number on both the A and B specimen labels/seals into the

system). Alternatively, the unique specimen identification number on the electronic CCF may be printed onto the A and B specimen labels/seals during the collection.

- f. A single pair of labels/seals may be provided (i.e., one for specimen A and one for specimen B), or two pairs of labels/seals may be provided (i.e., two for urine specimens A and B, and two for oral fluid specimens A and B) of which only one pair is used. The size of the tamper-evident labels/seals may vary, but each must be wide enough to serve as a tamper-evident seal and to include the human-readable specimen identification number, with space for the donor to initial and the collector to date (i.e., unless a manufacturer-applied label is used for these annotations, as described in item c above).
- g. For a single pair of labels/seals (to be used for either specimen type): The labels/seals must be suitable as tamper-evident seals for both urine bottles and oral fluid tubes. The labels/seals may be perforated to enable the collector to apply the entire (longer) labels to urine bottles or tear at the perforation to create smaller (shorter) labels for oral fluid tubes.
- h. For two pairs of labels/seals (one A and B pair for urine bottles and one A and B pair for oral fluid tubes): **The collector cannot have multiple pairs of labels/seals with the same specimen identifier.** To ensure unique identifiers for each label/seal pair, each pair may have the same specimen identification number as the Federal CCF plus an alpha-numeric character added to distinguish urine specimen labels/seals from oral fluid specimen label/seals. It is not acceptable to use multiple labels with the same specimen identification number, distinguished only by color. When an electronic Federal CCF system is used, as described under item e above, the unique specimen identification number may be preprinted on the labels/seals and applied to the electronic Federal CCF, or the unique specimen identification number on the electronic Federal CCF may be printed on the labels/seals. Therefore, the label/seal pairs may be preprinted with different specimen identification numbers based on the specimen type, or the specimen identification number may be printed only on the label/seal pair designed for the specimen type collected.

8. Can the 2020 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. Certified test facilities must request approval to use electronic processes that may conflict with current program guidance and requirements. The test facility must submit the request with proposed procedures and example documents to SAMHSA's National Laboratory Certification Program (NLCP) and receive approval prior to implementing the revised procedures.

General

- a. The OMB number may appear either vertically or horizontally in the upper righthand corner of the form.
- b. 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.
- c. 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.
- d. 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.
- e. The spaces for the employer name and address, MRO name and address, and the collection site address may have lines.
- f. The space for the donor's SSN, Employee I.D. No., or Commercial Driver's License (CDL) No. and State may have combs, boxes, or a single line.
- g. The size of each checkbox may vary slightly.
- h. The font size and style used for letters may vary to enhance readability.
- i. 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

- a. 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.
- b. 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).
- c. Preprinting and/or overprinting the employer name and address, MRO name and address, and collection site information is permitted.
- d. The exact location for each item on the printed form may vary slightly from the location indicated on the OMB-approved Federal CCF.
- e. 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.

- f. 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

- a. The legend (i.e., copy number and name) at the bottom of Copies 2 through 5 may be omitted.
- b. An ECCF system may prompt the collector to scan the oral fluid collection device expiration date on each specimen tube (i.e., both A and B specimens) and record the information in Step 4 of the Federal CCF. This may be acceptable, providing that the expiration dates remain visible on each tube, to enable the laboratory accessioner to verify the date and document verification upon receipt.

Labels/Seals

- a. The unique specimen identification number on the tamper-evident labels/seals may be either a barcode with an associated human-readable number or a human-readable number only.
- b. The color of the printed information on the “A” specimen bottle label/seal may be different than the color of the printed information on the “B” specimen bottle label/seal.

(See also question 7 above for acceptable options for labels/seals.)

9. 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, and their ECCF system providers, 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:

- a. System validation
- b. 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)
- c. Protection of records to enable accurate and ready retrieval through the records retention period

- d. Limiting system access to authorized individuals
- e. 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)
- f. 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 2020 ECCF, the test facility must submit updated ECCF information to the NLCP including the Process Overview, Topic Outline of Proposed SOP Revisions, the 2020 ECCF, Training Plans for Federal ECCF Users, and System Validation Plan.

10. Has the HHS Specimen Collection Handbook been revised for use with the 2020 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 (UrMG) and a new HHS Oral Fluid Specimen Collection Handbook has been developed to reflect the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG). Both handbooks describe how the collector completes the 2020 Federal CCF. The handbooks are available on the SAMHSA website (www.samhsa.gov/workplace).

11. Has the HHS MRO Guidance Manual been revised for use with the 2020 Federal CCF?

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

12. Does a test facility (laboratory or IITF) need to change its Standard Operating Procedure (SOP) manual for the 2020 Federal CCF?

Yes. A certified laboratory or IITF must revise all SOP sections, where appropriate, to address the 2020 Federal CCF (e.g., accessioning, chain of custody, and reporting procedures). Since a laboratory or IITF may continue receiving urine specimens collected using the 2017 Federal CCF, the SOP manual will need to have procedures applicable to both forms until August 30, 2021, when the 2017 Federal CCF is no longer approved for use. At that time, the laboratory must have procedures to handle urine specimens submitted with the 2017 Federal CCF as having a recoverable discrepancy. Because the 2017 Federal CCF is not authorized for use with oral fluid specimens, an oral fluid testing laboratory needs to address the 2020 Federal CCF throughout its SOP and include procedures for rejecting oral fluid specimens received with the 2017 Federal CCF.

13. How does a test facility (laboratory or IITF) document specimen receipt using the 2020 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, records the expiration date of each collection device (i.e., on the A and B specimen tubes for oral fluid specimens), and releases custody of the specimen (e.g., to a storage area). This process is also used for the authoritative Test Facility copy (Copy 1) of combination electronic and paper CCFs.

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 marks the appropriate checkbox to document the condition of the primary specimen seal, records the expiration date of each collection device (i.e., on the A and B specimen tubes for oral fluid specimens), 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. Note: See also questions 8 and 9 above.

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 a copy of the Federal CCF (copy of Copy 1) and the original 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.

14. How does a test facility (laboratory or IITF) report primary specimen results to MROs using the 2020 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.

15. How does a laboratory report split (Bottle B) specimen results to MROs using the 2020 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.

16. 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.