an NDMC to enrollees upon denial, in whole or in part, of an enrollee's coverage request. This denial may be subject to a series of administrative review levels, involving defined steps and timeframes. The NDMC was developed to ensure Medicare enrollees have access to information needed to navigate the Medicare beneficiary appeals process. The NDMC meets requirements for both Medicare's standard and expedited appeals processes.

Medicare health plans provide an NDP to enrollees upon denial, in whole or in part, of payment for a service or item that the enrollee received. This denial may be subject to a series of administrative review levels, involving defined steps and timeframes. The NDP was developed to ensure Medicare enrollees have access to information needed to navigate the Medicare beneficiary appeals process. The NDP meets requirements for Medicare's standard appeals process. *Form Number:* CMS–10003 (OMB#: 0938–0829); *Frequency:* Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 740; *Total Annual Responses:* 1,168,368; *Total Annual Hours:* 194,728. (For policy questions regarding this collection contact Stephanie Simons at 206–615–2420. For all other issues call 410–786–1326.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Federal Qualification Application (42 CFR 417.140) and Medicare Health Care Prepayment Plan Application (42 CFR 417.800); *Use:* The application is the collection form used to obtain information to determine if an applicant meets the regulatory requirements to enter into a contract with CMS as a Federal Qualified health maintenance organization (HMO) or to provide health benefits to Medicare beneficiaries as a Medicare Health Care Prepayment Plan contractor. *Form Number:* CMS–901A & 901D (OMB#: 0938–0470); *Frequency:* Once; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 20; *Total Annual Responses:* 20; *Total Annual Hours:* 800. (For policy questions regarding this collection contact Heidi Arndt at 410–786–1607. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *August 16, 2010.*

OMB, Office of Information and Regulatory Affairs, *Attention:* CMS Desk Officer, *Fax Number:* (202) 395–6974, *E-mail: OIRA_submission @omb.eop.gov.*

Dated: July 9, 2010.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2010–17181 Filed 7–15–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

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

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

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

SAMHSA's Mandatory Guidelines for Federal Workplace Drug Testing Programs will request OMB approval for the Federal Drug Testing Custody and Control Form for Federal agency and federally regulated drug testing programs which must comply with the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs (73 FR 71858) dated November 25, 2008, and for the information provided by laboratories for the National Laboratory Certification Program (NLCP).

The Federal Drug Testing Custody and Control Form (Federal CCF) is used by all Federal agencies and employers regulated by the Department of Transportation to document the collection and chain of custody of urine specimens at the collection site, for laboratories to report results, and for Medical Review Officers to make a determination. The current Federal CCF approved by OMB has a November 30, 2011 expiration date. SAMHSA has resubmitted the Federal CCF with revisions to the form for OMB approval.

- The first change is to add a new item in Step 1 of Copy 1, which lists the acronyms for the Federal testing authorities under which the specimen is collected. The new Step 1 (d) would read as follows: "D. Specify Testing Authority: HHS, NRC, DOT—Specify DOT Agency: FMCSA, FAA, FRA, FTA, PHMSA, USCG" with a checkbox beside each agency name.
- The second change is to revise the Federal CCF Copy 1 to permit use by Instrumented Initial Test Facility (IITF), in addition to laboratories.
- The third change is to add the new drug analytes required by the revised Guidelines to the Primary Specimen Report section in Step 5(a) on Copy 1. The new drug analytes are methylenedioxymethamphetamine (MDMA), commonly known as "ecstasy"; methyleneamphetamine (MDA), and methylenedioxyethylamphetamine (MDEA). MDA and MDEA are both close chemical analogues of MDMA.
- The fourth change is to revise the Medical Review Officer (MRO) reporting sections on Copy 2 for primary specimens (Step 6) and for split specimens (Step 7) to facilitate reporting in accordance with the Guidelines.

Below is a copy of the revised Federal CCF:

BILLING CODE 4162–20–P

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO. 0000001

STEP 1: COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE ACCESSION NO.

A. Employer Name, Address, I.D. No. B. MRO Name, Address, Phone No. and Fax No.

C. Donor SSN or Employee I.D. No. _____

D. Specify Testing Authority: ☐ HHS ☐ NRC ☐ DOT – Specify DOT Agency: ☐ FMCSA ☐ FAA ☐ FRA ☐ FTA ☐ PHMSA ☐ USCG

E. Reason for Test: ☐ Pre-employment ☐ Random ☐ Reasonable Suspicion/Cause ☐ Post Accident ☐ Return to Duty ☐ Follow-up ☐ Other (specify) _____

F. Drug Tests to be Performed: ☐ THC, COC, PCP, OPI, AMP ☐ THC & COC Only ☐ Other (specify) _____

G. Collection Site Address:

Collector Phone No. _____

Collector Fax No. _____

OMB No. 0930-0158

STEP 2: COMPLETED BY COLLECTOR (make remarks when appropriate) Collector reads specimen temperature within 4 minutes.

Temperature between 90° and 100° F? ☐ Yes ☐ No, Enter Remark	Collection: ☐ Split ☐ Single ☐ None Provided, Enter Remark	☐ Observed, Enter Remark

REMARKS

STEP 3: Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s). Donor completes STEP 5 on Copy 2 (MRO Copy)

STEP 4: CHAIN OF CUSTODY - INITIATED BY COLLECTOR AND COMPLETED BY TEST FACILITY

I certify that the specimen given to me by the donor identified in the certification section on Copy 2 of this form was collected, labeled, sealed and released to the Delivery Service noted in accordance with applicable Federal requirements.

X _____ Signature of Collector

_____ (PRINT) Collector's Name (First, MI, Last) ___/___/___ Date (Mo/Day/Yr) _____ Time of Collection AM PM

SPECIMEN BOTTLE(S) RELEASED TO:

_____ Name of Delivery Service

RECEIVED AT LAB OR IITF:

X _____ Signature of Accessioner

_____ (PRINT) Accessioner's Name (First, MI, Last) ___/___/___ Date (Mo/Day/Yr)

Primary Specimen Bottle Seal Intact ☐ YES ☐ NO If NO, Enter remark in Step 5A.

SPECIMEN BOTTLE(S) RELEASED TO:

STEP 5A: PRIMARY SPECIMEN REPORT - COMPLETED BY TEST FACILITY

☐ NEGATIVE ☐ POSITIVE for: ☐ Marijuana Metabolite (Δ9-THCA) ☐ 6-Acetylmorphine ☐ Methamphetamine ☐ MDMA
☐ DILUTE ☐ Cocaine Metabolite (BZE) ☐ Morphine ☐ Amphetamine ☐ MDA
☐ PCP ☐ Codeine ☐ MDEA

☐ REJECTED FOR TESTING ☐ ADULTERATED ☐ SUBSTITUTED ☐ INVALID RESULT

REMARKS: _____

Test Facility (if different from above) : _____

I certify that the specimen identified on this form was examined upon receipt, handled using chain of custody procedures, analyzed, and reported in accordance with applicable Federal requirements.

X _____ Signature of Certifying Technician/Scientist _____ (PRINT) Certifying Technician/Scientist's Name (First, MI, Last) ___/___/___ Date (Mo/Day/Yr)

STEP 5b: COMPLETED BY SPLIT TESTING LABORATORY

_____ Laboratory Name

_____ Laboratory Address

☐ RECONFIRMED ☐ FAILED TO RECONFIRM - REASON _____

I certify that the split specimen identified on this form was examined upon receipt, handled using chain of custody procedures, analyzed, and reported in accordance with applicable Federal requirements.

X _____ Signature of Certifying Scientist _____ (PRINT) Certifying Scientist's Name (First, MI, Last) ___/___/___ Date (Mo./Day/Yr.)

PRESS HARD - YOU ARE MAKING MULTIPLE COPIES

0000001 A
SPECIMEN ID NO.

PLACE OVER CAP

0000001 SPECIMEN BOTTLE SEAL

___/___/___ Date (Mo/Day/Yr)

_____ Donor's Initials

0000001 B (SPLIT)
SPECIMEN ID NO.

PLACE OVER CAP

0000001 SPECIMEN BOTTLE SEAL

___/___/___ Date (Mo/Day/Yr)

_____ Donor's Initials

COPY 1 - TEST FACILITY COPY

Back of Copy 1 - 4

Public Burden Statement

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0930-0158. Public reporting burden for this collection of information is estimated to average 5 minutes/donor, 4 minutes/collector, 3 minutes/test facility, and 3 minutes/Medical Review Officer. Send comments regarding this burden estimate or any other aspect of this collection information, including suggestions for reducing this burden, to SAMHSA Reports Clearance Officer, 1 Choke Cherry Road, Room 7-1044, Rockville, Maryland 20857.

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO. 0000001

STEP 1: COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE ACCESSION NO.

A. Employer Name, Address, I.D. No. B. MRO Name, Address, Phone No. and Fax No.

OMB No. 0930-0158

C. Donor SSN or Employee I.D. No. _____

D. Specify Testing Authority: ☐ HHS ☐ NRC ☐ DOT – Specify DOT Agency: ☐ FMCSA ☐ FAA ☐ FRA ☐ FTA ☐ PHMSA ☐ USCG

E. Reason for Test: ☐ Pre-employment ☐ Random ☐ Reasonable Suspicion/Cause ☐ Post Accident ☐ Return to Duty ☐ Follow-up ☐ Other (specify) _____

F. Drug Tests to be Performed: ☐ THC, COC, PCP, OPI, AMP ☐ THC & COC Only ☐ Other (specify) _____

G. Collection Site Address:

Collector Phone No. _____

Collector Fax No. _____

STEP 2: COMPLETED BY COLLECTOR (make remarks when appropriate) Collector reads specimen temperature within 4 minutes.

Temperature between 90° and 100° F? ☐ Yes ☐ No, Enter Remark	Collection: ☐ Split ☐ Single ☐ None Provided, Enter Remark	☐ Observed, Enter Remark

REMARKS

STEP 3: Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s). Donor completes STEP 5 on Copy 2 (MRO Copy)

STEP 4: CHAIN OF CUSTODY - INITIATED BY COLLECTOR AND COMPLETED BY TEST FACILITY

I certify that the specimen given to me by the donor identified in the certification section on Copy 2 of this form was collected, labeled, sealed and released to the Delivery Service noted in accordance with applicable Federal requirements.

X _____ Signature of Collector

(PRINT) Collector's Name (First, MI, Last) | Date (Mo/Day/Yr) | Time of Collection: AM / PM

SPECIMEN BOTTLE(S) RELEASED TO: Name of Delivery Service

STEP 5: COMPLETED BY DONOR

I certify that I provided my urine specimen to the collector; that I have not adulterated it in any manner; each specimen bottle used was sealed with a tamper-evident seal in my presence; and that the information provided on this form and on the label affixed to each specimen bottle is correct.

X _____ Signature of Donor | (PRINT) Donor's Name (First, MI, Last) | Date (Mo/Day/Yr)

Daytime Phone No. ( ) _____ Evening Phone No. ( ) _____ Date of Birth ___/___/___ (Mo/Day/Yr)

After the Medical Review Officer receives the test results for the specimen identified by this form, he/she may contact you to ask about prescriptions and over-the-counter medications you may have taken. Therefore, you may want to make a list of those medications for your own records. THIS LIST IS NOT NECESSARY. If you choose to make a list, do so either on a separate piece of paper or on the back of your copy (Copy 5). – DO NOT PROVIDE THIS INFORMATION ON THE BACK OF ANY OTHER COPY OF THE FORM. TAKE COPY 5 WITH YOU.

STEP 6: COMPLETED BY MEDICAL REVIEW OFFICER - PRIMARY SPECIMEN

In accordance with applicable Federal requirements, my verification is:

☐ **NEGATIVE** ☐ **POSITIVE** for: _____ ☐ DILUTE

☐ **REFUSAL TO TEST** because – check reason(s) below: ☐ **TEST CANCELLED**

☐ ADULTERATED (adulterant/reason): _____

☐ SUBSTITUTED

☐ OTHER: _____

REMARKS: _____

X _____ Signature of Medical Review Officer | (PRINT) Medical Review Officer's Name (First, MI, Last) | Date (Mo/Day/Yr)

STEP 7: COMPLETED BY MEDICAL REVIEW OFFICER - SPLIT SPECIMEN

In accordance with applicable Federal requirements, my verification for the split specimen (if tested) is:

☐ **RECONFIRMED** for: _____ ☐ **TEST CANCELLED**

☐ **FAILED TO RECONFIRM** for: _____

REMARKS: _____

X _____ Signature of Medical Review Officer | (PRINT) Medical Review Officer's Name (First, MI, Last) | Date (Mo/Day/Yr)

COPY 2 - MEDICAL REVIEW OFFICER COPY

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO. 0000001

STEP 1: COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE ACCESSION NO.

A. Employer Name, Address, I.D. No. B. MRO Name, Address, Phone No. and Fax No.

OMB No. 0930-0158

C. Donor SSN or Employee I.D. No. _____

D. Specify Testing Authority: ☐ HHS ☐ NRC ☐ DOT – Specify DOT Agency: ☐ FMCSA ☐ FAA ☐ FRA ☐ FTA ☐ PHMSA ☐ USCG

E. Reason for Test: ☐ Pre-employment ☐ Random ☐ Reasonable Suspicion/Cause ☐ Post Accident ☐ Return to Duty ☐ Follow-up ☐ Other (specify) _____

F. Drug Tests to be Performed: ☐ THC, COC, PCP, OPI, AMP ☐ THC & COC Only ☐ Other (specify) _____

G. Collection Site Address:

Collector Phone No. _____

Collector Fax No. _____

STEP 2: COMPLETED BY COLLECTOR (make remarks when appropriate) Collector reads specimen temperature within 4 minutes.

Temperature between 90° and 100° F? ☐ Yes ☐ No, Enter Remark	Collection: ☐ Split ☐ Single ☐ None Provided, Enter Remark	☐ Observed, Enter Remark
REMARKS		

STEP 3: Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s). Donor completes STEP 5 on Copy 2 (MRO Copy)

STEP 4: CHAIN OF CUSTODY - INITIATED BY COLLECTOR AND COMPLETED BY TEST FACILITY

I certify that the specimen given to me by the donor identified in the certification section on Copy 2 of this form was collected, labeled, sealed and released to the Delivery Service noted in accordance with applicable Federal requirements.

SPECIMEN BOTTLE(S) RELEASED TO:

X _____
Signature of Collector

_____ / / _____ AM / PM _____
(PRINT) Collector's Name (First, MI, Last) Date (Mo/Day/Yr) Time of Collection Name of Delivery Service

STEP 5: COMPLETED BY DONOR

I certify that I provided my urine specimen to the collector; that I have not adulterated it in any manner; each specimen bottle used was sealed with a tamper-evident seal in my presence; and that the information provided on this form and on the label affixed to each specimen bottle is correct.

X _____ _____ / / _____
Signature of Donor (PRINT) Donor's Name (First, MI, Last) Date (Mo/Day/Yr)

Daytime Phone No. (_____) _____ Evening Phone No. (_____) _____ Date of Birth / / _____ (Mo/Day/Yr)

After the Medical Review Officer receives the test results for the specimen identified by this form, he/she may contact you to ask about prescriptions and over-the-counter medications you may have taken. Therefore, you may want to make a list of those medications for your own records. THIS LIST IS NOT NECESSARY. If you choose to make a list, do so either on a separate piece of paper or on the back of your copy (Copy 5). – DO NOT PROVIDE THIS INFORMATION ON THE BACK OF ANY OTHER COPY OF THE FORM. TAKE COPY 5 WITH YOU.

STEP 6: COMPLETED BY MEDICAL REVIEW OFFICER - PRIMARY SPECIMEN

In accordance with applicable Federal requirements, my verification is:

☐ **NEGATIVE** ☐ **POSITIVE** for: _____
☐ DILUTE

☐ **REFUSAL TO TEST** because – check reason(s) below: ☐ **TEST CANCELLED**
☐ ADULTERATED (adulterant/reason): _____
☐ SUBSTITUTED
☐ OTHER: _____

REMARKS: _____

X _____ _____ / / _____
Signature of Medical Review Officer (PRINT) Medical Review Officer's Name (First, MI, Last) Date (Mo/Day/Yr)

STEP 7: COMPLETED BY MEDICAL REVIEW OFFICER - SPLIT SPECIMEN

In accordance with applicable Federal requirements, my verification for the split specimen (if tested) is:

☐ **RECONFIRMED** for: _____ ☐ **TEST CANCELLED**

☐ **FAILED TO RECONFIRM** for: _____

REMARKS: _____

X _____ _____ / / _____
Signature of Medical Review Officer (PRINT) Medical Review Officer's Name (First, MI, Last) Date (Mo/Day/Yr)

COPY 3 - COLLECTOR COPY

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO. 0000001

STEP 1: COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE ACCESSION NO.

A. Employer Name, Address, I.D. No. B. MRO Name, Address, Phone No. and Fax No.

OMB No. 0930-0158

C. Donor SSN or Employee I.D. No. _____

D. Specify Testing Authority: ☐ HHS ☐ NRC ☐ DOT – Specify DOT Agency: ☐ FMCSA ☐ FAA ☐ FRA ☐ FTA ☐ PHMSA ☐ USCG

E. Reason for Test: ☐ Pre-employment ☐ Random ☐ Reasonable Suspicion/Cause ☐ Post Accident ☐ Return to Duty ☐ Follow-up ☐ Other (specify) _____

F. Drug Tests to be Performed: ☐ THC, COC, PCP, OPI, AMP ☐ THC & COC Only ☐ Other (specify) _____

G. Collection Site Address:

Collector Phone No. _____

Collector Fax No. _____

STEP 2: COMPLETED BY COLLECTOR (make remarks when appropriate) Collector reads specimen temperature within 4 minutes.

Temperature between 90° and 100° F? ☐ Yes ☐ No, Enter Remark	Collection: ☐ Split ☐ Single ☐ None Provided, Enter Remark	☐ Observed, Enter Remark
REMARKS		

STEP 3: Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s). Donor completes STEP 5 on Copy 2 (MRO Copy)

STEP 4: CHAIN OF CUSTODY - INITIATED BY COLLECTOR AND COMPLETED BY TEST FACILITY

I certify that the specimen given to me by the donor identified in the certification section on Copy 2 of this form was collected, labeled, sealed and released to the Delivery Service noted in accordance with applicable Federal requirements.

SPECIMEN BOTTLE(S) RELEASED TO:

X _____ AM / PM

Signature of Collector

(PRINT) Collector's Name (First, MI, Last) | Date (Mo/Day/Yr) | Time of Collection | Name of Delivery Service

STEP 5: COMPLETED BY DONOR

I certify that I provided my urine specimen to the collector; that I have not adulterated it in any manner; each specimen bottle used was sealed with a tamper-evident seal in my presence; and that the information provided on this form and on the label affixed to each specimen bottle is correct.

X _____ _____ _____

Signature of Donor | (PRINT) Donor's Name (First, MI, Last) | Date (Mo/Day/Yr)

Daytime Phone No. (____) _____ Evening Phone No. (____) _____ Date of Birth ____/____/____ (Mo/Day/Yr)

After the Medical Review Officer receives the test results for the specimen identified by this form, he/she may contact you to ask about prescriptions and over-the-counter medications you may have taken. Therefore, you may want to make a list of those medications for your own records. THIS LIST IS NOT NECESSARY. If you choose to make a list, do so either on a separate piece of paper or on the back of your copy (Copy 5). – DO NOT PROVIDE THIS INFORMATION ON THE BACK OF ANY OTHER COPY OF THE FORM. TAKE COPY 5 WITH YOU.

STEP 6: COMPLETED BY MEDICAL REVIEW OFFICER - PRIMARY SPECIMEN

In accordance with applicable Federal requirements, my verification is:

☐ **NEGATIVE** ☐ **POSITIVE** for: _____
☐ DILUTE

☐ **REFUSAL TO TEST** because – check reason(s) below: ☐ **TEST CANCELLED**
☐ ADULTERATED (adulterant/reason): _____
☐ SUBSTITUTED
☐ OTHER: _____

REMARKS: _____

X _____ _____ _____

Signature of Medical Review Officer | (PRINT) Medical Review Officer's Name (First, MI, Last) | Date (Mo/Day/Yr)

STEP 7: COMPLETED BY MEDICAL REVIEW OFFICER - SPLIT SPECIMEN

In accordance with applicable Federal requirements, my verification for the split specimen (if tested) is:

☐ **RECONFIRMED** for: _____ ☐ **TEST CANCELLED**

☐ **FAILED TO RECONFIRM** for: _____

REMARKS: _____

X _____ _____ _____

Signature of Medical Review Officer | (PRINT) Medical Review Officer's Name (First, MI, Last) | Date (Mo/Day/Yr)

COPY 4 - EMPLOYER COPY

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO. 0000001

STEP 1: COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE ACCESSION NO.

A. Employer Name, Address, I.D. No. B. MRO Name, Address, Phone No. and Fax No.

OMB No. 0930-0158

C. Donor SSN or Employee I.D. No. _____

D. Specify Testing Authority: ☐ HHS ☐ NRC ☐ DOT – Specify DOT Agency: ☐ FMCSA ☐ FAA ☐ FRA ☐ FTA ☐ PHMSA ☐ USCG

E. Reason for Test: ☐ Pre-employment ☐ Random ☐ Reasonable Suspicion/Cause ☐ Post Accident ☐ Return to Duty ☐ Follow-up ☐ Other (specify) _____

F. Drug Tests to be Performed: ☐ THC, COC, PCP, OPI, AMP ☐ THC & COC Only ☐ Other (specify) _____

G. Collection Site Address:

Collector Phone No. _____

Collector Fax No. _____

STEP 2: COMPLETED BY COLLECTOR (make remarks when appropriate) Collector reads specimen temperature within 4 minutes.

Temperature between 90° and 100° F? ☐ Yes ☐ No, Enter Remark	Collection: ☐ Split ☐ Single ☐ None Provided, Enter Remark	☐ Observed, Enter Remark
REMARKS		

STEP 3: Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s). Donor completes STEP 5 on Copy 2 (MRO Copy)

STEP 4: CHAIN OF CUSTODY - INITIATED BY COLLECTOR AND COMPLETED BY TEST FACILITY

I certify that the specimen given to me by the donor identified in the certification section on Copy 2 of this form was collected, labeled, sealed and released to the Delivery Service noted in accordance with applicable Federal requirements.

SPECIMEN BOTTLE(S) RELEASED TO:

X _____
Signature of Collector

_____ (PRINT) Collector's Name (First, MI, Last) _____ / _____ / _____ Date (Mo/Day/Yr) _____ AM / PM Time of Collection _____ Name of Delivery Service

STEP 5: COMPLETED BY DONOR

I certify that I provided my urine specimen to the collector; that I have not adulterated it in any manner; each specimen bottle used was sealed with a tamper-evident seal in my presence; and that the information provided on this form and on the label affixed to each specimen bottle is correct.

X _____ _____ _____ / _____ / _____
Signature of Donor (PRINT) Donor's Name (First, MI, Last) Date (Mo/Day/Yr)

Daytime Phone No. (_____) _____ Evening Phone No. (_____) _____ Date of Birth _____ / _____ / _____ (Mo/Day/Yr)

After the Medical Review Officer receives the test results for the specimen identified by this form, he/she may contact you to ask about prescriptions and over-the-counter medications you may have taken. Therefore, you may want to make a list of those medications for your own records. THIS LIST IS NOT NECESSARY. If you choose to make a list, do so either on a separate piece of paper or on the back of your copy (Copy 5). – DO NOT PROVIDE THIS INFORMATION ON THE BACK OF ANY OTHER COPY OF THE FORM. TAKE COPY 5 WITH YOU.

STEP 6: COMPLETED BY MEDICAL REVIEW OFFICER - PRIMARY SPECIMEN

In accordance with applicable Federal requirements, my verification is:

☐ **NEGATIVE** ☐ **POSITIVE** for: _____
☐ DILUTE

☐ **REFUSAL TO TEST** because – check reason(s) below: ☐ **TEST CANCELLED**
☐ ADULTERATED (adulterant/reason): _____
☐ SUBSTITUTED
☐ OTHER: _____

REMARKS: _____

X _____ _____ _____ / _____ / _____
Signature of Medical Review Officer (PRINT) Medical Review Officer's Name (First, MI, Last) Date (Mo/Day/Yr)

STEP 7: COMPLETED BY MEDICAL REVIEW OFFICER - SPLIT SPECIMEN

In accordance with applicable Federal requirements, my verification for the split specimen (if tested) is:

☐ **RECONFIRMED** for: _____ ☐ **TEST CANCELLED**

☐ **FAILED TO RECONFIRM** for: _____

REMARKS: _____

X _____ _____ _____ / _____ / _____
Signature of Medical Review Officer (PRINT) Medical Review Officer's Name (First, MI, Last) Date (Mo/Day/Yr)

COPY 5 - DONOR COPY

Back of Copy 5

Instructions for Completing the Federal Drug Testing Custody and Control Form

When making entries use black or blue ink pen and press firmly

Collector ensures that the name and address of the HHS-certified Instrumented Initial Test Facility (IITF) or HHS-certified laboratory are on the top of the Federal CCF and the Specimen identification (I.D.) number on the top of the Federal CCF matches the Specimen I.D. number on the label(s)/seal(s).

STEP 1:

- Collector ensures that the required information is in STEP 1. Collector enters a remark in STEP 2 if Donor refuses to provide his/her SSN or Employee I.D. number.
- Collector gives collection container to Donor and instructs Donor to provide a specimen. Collector notes any unusual behavior or appearance of Donor in the remarks line STEP 2. If the Donor's conduct at any time during the collection process clearly indicates an attempt to tamper with the specimen, Collector notes the conduct in the remarks line in STEP 2 and takes action as required.

STEP 2:

- Collector checks specimen temperature within 4 minutes after receiving the specimen from Donor and marks the appropriate temperature box in STEP 2. If the temperature is outside the acceptable range, Collector enters a remark in STEP 2 and takes action as required.
- Collector inspects the specimen and notes any unusual findings in the remarks line in STEP 2 and takes action as required. Any specimen with unusual physical characteristics (e.g., unusual color, presence of foreign objects or material, unusual odor) cannot be sent to an IITF and must be sent to an HHS-certified laboratory for testing, as required.
- Collector determines the volume of specimen in the collection container. If the volume is acceptable, Collector proceeds with the collection. If the volume is less than required by the Federal Agency, Collector takes action as required and enters remarks in STEP 2. If no specimen is collected by the end of the collection process, Collector checks the *None Provided* box, enters a remark in STEP 2, discards Copy 1, and distributes remaining copies as required.
- Collector checks the Split or Single specimen collection box. If the collection is observed, Collector checks the Observed box and enters a remark in STEP 2.

STEP 3:

- Donor watches Collector pour the specimen from the collection container into the specimen bottle(s), place the cap(s) on the specimen bottle(s), and affix the label(s)/seal(s) on the specimen bottle(s).
- Collector dates the specimen bottle label(s) after placement on the specimen bottle(s).
- Donor initials the specimen bottle label(s) after placement on the specimen bottle(s).
- Collector turns to Copy 2 (Medical Review Officer Copy) and instructs the Donor to read and complete the certification statement in STEP 5 (signature, printed name, date, phone numbers, and date of birth). If Donor refuses to sign the certification statement, Collector enters a remark in STEP 2 on Copy 1.

STEP 4:

- Collector completes STEP 4 on Copy 1 (signature, printed name, date, time of collection, and name of delivery service), places the sealed specimen bottle(s) and Copy 1 in a leak-proof plastic bag, seals the bag, prepares the specimen package for shipment, and distributes the remaining CCF copies as required.

Privacy Act Statement: (For Federal Employees Only)

Submission of the requested information on the attached form is voluntary. However, incomplete submission of the requested information, refusal to provide a urine specimen, or substitution or adulteration of a specimen may result in delay or denial of your application for employment/appointment or may result in removal from the Federal service or other disciplinary action.

The authority for obtaining the urine specimen and identifying information contained herein is Executive Order 12564 ("Drug-Free Federal Workplace"), 5 U.S.C. Sec. 3301 (2), 5 U.S.C. Sec. 7301, and Section 503 of Public Law 100-71, 5 U.S.C. Sec. 7301 note. Under provisions of Executive Order 12564 and 5 U.S.C. 7301, test results may only be disclosed to agency officials on a need-to-know basis. This may include the agency Medical Review Officer, the administrator of the Employee Assistance Program, and a supervisor with authority to take adverse personnel action. This information may also be disclosed to a court where necessary to defend against a challenge to an adverse personnel action.

Submission of your SSN is not required by law and is voluntary. Your refusal to furnish your number will not result in the denial of any right, benefit, or privilege provided by law. Your SSN is solicited, pursuant to Executive Order 9397, for purposes of associating information in agency files relating to you and for purposes of identifying the urine specimen provided for testing for the presence of illegal drugs. If you refuse to indicate your SSN, a substitute number or other

identifier will be assigned, as required, to process the specimen.

Public Burden Statement

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0930-0158. Public reporting burden for this collection of information is estimated to average 5 minutes/donor, 4 minutes/collector, 3 minutes/test facility; and 3 minutes/Medical Review Officer. Send comments regarding this burden estimate or any other aspect of this collection information, including suggestions for reducing this burden, to SAMHSA Reports Clearance Officer, 1 Choke Cherry Road, Room 7-1044, Rockville, Maryland 20857.

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Prior to an inspection, a laboratory is required to submit specific information regarding its laboratory procedures. Collecting this information prior to an inspection allows the inspectors to thoroughly review and understand the laboratory's testing procedures before arriving at the laboratory.

The annual total burden estimates for the Federal Drug Testing Custody and Control Form, the NLCP application, the NLCP inspection checklist, and NLCP recordkeeping requirements are shown in the following table.

Form/respondent	Burden/ response (hrs.)	Number of responses	Total annual burden (hrs.)
Custody and Control Form:			
Donor	.08	7,096,000	567,680
Collector	.07	7,096,000	496,720
Laboratory	.05	7,096,000	354,800
Medical Review Officer	.05	7,096,000	354,800
Laboratory Application	3.00	3	9
Laboratory Inspection Checklist	3.00	100	300
Laboratory Recordkeeping	250.00	50	12,500
Total			1,786,809

Written comments and recommendations concerning the proposed information collection should be sent by August 16, 2010 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202–395–6974.

Dated: July 12, 2010.

Dennis O. Romero,

Deputy Director, Office of Program Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

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

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Pretesting of Substance Abuse Prevention and Treatment and Mental Health Services Communication Messages—(OMB No. 0930–0196)—Extension

As the Federal agency responsible for developing and disseminating authoritative knowledge about substance abuse prevention, addiction treatment, and mental health services and for mobilizing consumer support and increasing public understanding to overcome the stigma attached to addiction and mental illness, the Substance Abuse and Mental Health Services Administration (SAMHSA) is responsible for development and dissemination of a wide range of education and information materials for