US Department of Health and Human Services

Privacy Impact Assessment

Date Signed:
05/30/2014

OPDIV:
SAMHSA

Name:
ECCF

PIA Unique Identifier:
P-3946423-404481

The subject of this PIA is which of the following?
Unknown

Identify the Enterprise Performance Lifecycle Phase of the system.
Initiation

Is this a FISMA-Reportable system?
No

Identify the operator.
Agency

Is this a new or existing system?
Existing

Does the system have Security Authorization (SA)?
No

Indicate the following reason(s) for updating this PIA.
Providing additional/clearer language to leverage cross collaboration with DOT and NRC.

Describe in further detail any changes to the system that have occurred since the last PIA.
None

Describe the purpose of the system.
The Federal Drug Free Workplace Program was established by Executive Order 12564 on September 15, 1986, and further mandated by Congress in section 503 of Public Law 100-71 (July 11, 1987). The Department of Health and Human Services (HHS) is responsible for providing comprehensive scientific and technical standards to satisfy this mandate. The Mandatory Guidelines for Federal Workplace Drug Testing Programs, first published on April 11, 1988, include chain of custody procedures designed to ensure the integrity and security of specimens from the time the specimen is collected until the time the testing results are reported by the test facility, and require use of a uniform Federal Drug Testing Custody and Control Form, otherwise known as the Federal CCF. The Federal CCF is the tool by which agencies and participants in the testing process are assured that the specimen collected is actually that of the tested individual. In addition to the drug testing requirements for federal drug testing programs, agencies, such as the U.S. Department of Transportation and the Nuclear Regulatory Commission, also require the use of the Federal CCF in drug testing programs they require of their regulated industries and federal contractors. To date, the Federal CCF only has been authorized for use in paper-copy form. HHS will now allow its use in both paper and electronic formats, as outlined in further detail below.
The Mandatory Guidelines require chain of custody procedures to document the integrity and security of a urine specimen from the time it is collected until the specimen is reported as tested to the Medical Review Officer (MRO) by the laboratory. To ensure uniformity among all federally regulated workplace drug testing programs, the Mandatory Guidelines require using an OMB-approved Federal CCF. In addition, Subpart F, K and L of the Mandatory Guidelines requires certified laboratories to maintain and document a quality assurance program, a quality control program, quality assurance and quality control procedures, and validated analytical procedures. Additionally, laboratories are required to report test results in accordance with the specifications and to participate in a performance testing and inspection program. Subpart P describes the procedures that are used to review the suspension or proposed revocation of a certified laboratory.
HHS will approve the use of an electronic CCF through its laboratory certification and inspection process. For laboratories seeking an initial certification, the laboratory would submit an application to the NLCP for review and evaluation. If the NLCP application form submitted by the laboratory is complete and satisfactory, the laboratory would be scheduled to test specimens that are part of scientifically supportable procedures, and also has procedures for using an eCCF that satisfy the security and quality assurance and control procedures in the Mandatory guidelines, the initial certification process will begin. Once the certification has been completed, the laboratory would be certified by HHS.
For currently certified laboratories who wish to implement an eCCF, HHS will request prior to the laboratory's maintenance inspection (which are conducted every six months by NLCP), that the laboratory update its Sections B and C of the NLCP information checklist. The updates should specify the procedures the laboratory will implement and follow, consistent with the requirements for security and quality control and access in the Mandatory Guidelines, for using an eCCF. The procedures will be reviewed and validated through this inspection process. For more information on the inspection and validation of the eCCF, refer to the guidance to the laboratories published in the eCCF in Federally Regulated Workplace Drug Testing Programs: Security, Confidentiality, and Integrity of Drug Test Information.

Describe the type of information the system will collect, maintain (store), or share.
The Federal CCF is used to identify a specific urine specimen in documents in the handling of the collection site. The paper Federal CCF is a five-copy, carbonless form consisting of 5 pages:
Copy 1: Test Facility Copy
Copy 2: Medical Review Officer Copy
Copy 3: Collector Copy
Copy 4: Employer Copy
Copy 5: Donor Copy
The electronic Federal CCF has the same format as the OMB-approved form. Because Copies 2-5 are identical, the electronic CCF contains 2 copies (Copy 1 (Test Facility Copy) and Copy 2 (which is distributed to the MRO, collector, employer, and donor). The electronic Federal CCF is the functional equivalent of a paper CCF as described in Section B and C of the NLCP information checklist. The updates should specify the procedures the laboratory will implement and follow, consistent with the requirements for security and quality control and access in the Mandatory Guidelines, for using an eCCF. The procedures will be reviewed and validated through this inspection process. For more information on the inspection and validation of the eCCF, refer to the guidance to the laboratories published in the eCCF in Federally Regulated Workplace Drug Testing Programs: Security, Confidentiality, and Integrity of Drug Test Information.

Provide an overview of the system and describe the information it will collect, maintain (store), or share.
A separate Federal CCF is used for each donor's specimen. To minimize privacy risks, personal information is collected on different CCF copies (i.e., Copy 1, Copies 2 – 5) so the information can be limited to the appropriate entities. Question 12 above describes the distribution of each copy.
The personal information on any one CCF copy (Copies 1-5) of the Federal CCF includes Social Security Number (SSN) or, alternatively, an employee I.D. number or other identifier. This is shared with the collection site, test facility, and MRO.
The personal information collected on Copies 2 – 5 is shared with the MRO and collector/collection site and is not shared with the test facility (which only receives Copy 1). This personal information includes:
Name;
Birthdate;
Daytime and evening telephone numbers.
The test facility records the drug test result on Copy 1 and reports the result to the MRO. On Copy 2, the MRO records the final, MRO-verified result, signs and prints his/her name, and records the date of verification.
HHS requires drug testing service providers to maintain the confidentiality and security of the Federal CCF for the entire "life cycle." For both paper and electronic Federal CCFs, service providers must ensure the security of Federal CCF transmission and limit access to any transmission, storage, or record to authorized persons. Federal CCFs must be securely stored for a minimum of two years.
In transitioning to the eCCF, HHS, DOT, and NRC are not requiring collection of any new information. The same information that is currently provided and noted on the paper Federal CCF will be provided on the eCCF; only the mechanism for collecting and transmitting that information will change. The electronic format of the Federal CCF will require collection of the same information currently collected on the paper Federal CCF.

Does the system collect, maintain, use or share PII?
Yes

Indicate the type of PII that the system will collect or maintain.
Social Security Number
Date of Birth
Name
Driver's License Number
E-Mail Address
Mailing Address
Phone Numbers
Employment Status
Taxpayer ID
Unique employee ID number
MRO comments/notes
Collector comments/notes

Indicate the categories of individuals about whom PII is collected, maintained or shared.
Employees
Business Partner/Contacts (Federal/state/local agencies)
Vendor/Suppliers/Contractors
Job applicants

How many individuals' PII is in the system?
1,000,000 or more

For what primary purpose is the PII used?
to link the biological specimen and drug test results to the donor

Describe the secondary uses for which the PII will be used.
none

Describe the function of the SSN.
SSNs may be used to identify the donor and track or link the specimen and test results to the donor. However, use of the SSN is not required by law and is voluntary. If a donor does not to provide his or her SSN, another identifier, such as an employee identification number, will be used to link the specimen and test results to the donor.

Is the legal authority to use the SSN?
The information collected on the Federal CCF, both the paper and electronic versions, is collected under the authority of Executive Order 12564, 5 U.S.C. 3301(2), 5 U.S.C. 7301, and Section 503 of Public Law 100-71 (July 11, 1987), 5 U.S.C. 7301 note. For federal workplace testing programs, test results are only disclosed to an MRO, the federal agency administrator of the Employee Assistance Program, and a supervisor with the authority to take adverse personnel action.

Identify legal authorities governing information use and disclosure specific to the system and program.
The information collected on the Federal CCF, both the paper and electronic versions, is collected under the authority of Executive Order 12564, 5 U.S.C. 3301(2), 5 U.S.C. 7301, and Section 503 of Public Law 100-71 (July 11, 1987), 5 U.S.C. 7301 note. For federal workplace testing programs, test results are only disclosed to an MRO, the federal agency administrator of the Employee Assistance Program, and a supervisor with the authority to take adverse personnel action.
The U.S. DOT is required by the Omnibus Transportation Employee Testing Act (OTETA) of 1991 (Pub L. 102-143, 105 Stat. 952, Oct. 28, 1991), to use the Federal CCF. OTETA mandated that DOT develop a uniform urine specimen drug testing program for its regulated entities, and in doing so, directed that the Department "incorporate the [HHS] scientific and technical guidelines dated April 11, 1988, and any amendments to those guidelines, including mandatory guidelines establishing . . . strict procedures governing the chain of custody of specimens collected for controlled substances testing." For further information regarding disclosure of information collected on the Federal CCF under the DOT program, please review the DOT supplemental statement, available at www.dot.gov/privacy/privacy-impact-assessments.

Are records on the system retrieved by one or more PII data elements?
No

Identify the sources of PII in the system.
Directly from an individual about whom the information pertains
In-Person
Online

Government Sources
Other Federal Entities

Non-Governmental Sources
Private Sector
Other

Identify the OMB information collection approval number and expiration date
OMB No. 0930-015, expires August 31, 2013

Is the PII shared with other organizations?
Yes

Identify with whom the PII is shared or disclosed and for what purpose.

Other Federal Agencies
For federal workplace drug testing programs, PII is shared with the agency representative ordering the test of the employee, the specimen collector, the test facility analyzing the specimen, and the Medical Review Officer reviewing the test results. Fur

Private Sector
PII is shared with the employer representative ordering the test of the employee, the specimen collector, the test facility analyzing the specimen, and the Medical Review Officer reviewing the test results. For additional information about sharing and di

Describe any agreements in place that authorizes the information sharing or disclosure.
With respect to the federal workplace drug testing programs, the Mandatory Guidelines for Federal Workplace Drug Testing Programs govern the extent to which information may be accessed, used, or disclosed. With respect to the DOT and NRC programs, the regulations set forth at 49 CFR part 40 and 10 CFR §26.31, respectively, govern access, sharing, and disclosure of information.

Describe the procedures for accounting for disclosures.
At the time of specimen collection, a Privacy Act Statement is provided to inform federal employees how their information will be used and explains their rights with respect to the information collected. This statement is printed on the back of Copy 5 (Donor Copy) of the paper Federal CCF and provided as a separate sheet or provided when an electronic Federal CCF is used. The Mandatory Guidelines for Federal Workplace Drug Testing Programs address federal employee access to and disclosure of information.

Describe the process in place to notify individuals that their personal information will be collected. If no prior notice is given, explain the reason.
At the time of specimen collection, a Privacy Act Statement is provided to inform federal employees how their information will be used and explains their rights with respect to the information collected. This statement is printed on the back of Copy 5 (Donor Copy) of the paper Federal CCF and provided as a separate sheet or provided when an electronic Federal CCF is used. The Mandatory Guidelines for Federal Workplace Drug Testing Programs address federal employee access to and disclosure of information.
For testing conducted under the DOT program, please review the DOT supplemental statement, available at www.dot.gov/privacy/privacy-impact-assessments.

Describe the process to notify individuals that their personal information will be collected.
Voluntary

Describe the method for individuals to opt-out of the collection or use of their PII. If there is no opportunity to object to the information collection, provide a reason.
The donor's SSN is not required. If a donor refuses to provide his or her SSN, an alternate identifier will be used to process the specimen. The provision of other PII is also voluntary. However, incomplete submission of the information may result in delay or denial of the individual's application for employment/appointment or may result in removal from the federal service or other disciplinary action.

Process to notify and obtain consent from individuals whose PII is in the system when major changes occur to the system.
This would be addressed in each federal agency's drug/free workplace plan.

Describe the process in place to resolve an individual's concerns when they believe their PII has been inappropriately obtained, used, or disclosed, or that the PII is inaccurate.
The Mandatory Guidelines for Federal Workplace Drug Testing Programs address the laboratory information available to a Federal employee who is the subject of a drug test. Federal agencies and private sector are subject to law including the Privacy Act and E-Government Act. Processes should be the same regardless of whether a paper or electronic Federal CCF is used.

Describe the process in place for periodic reviews of PII contained in the system to ensure the data's integrity, availability, accuracy and relevancy.
HHS has established standards and oversight procedures to ensure the authenticity, integrity, and confidentiality of drug test information when a Federal CCF is used. HHS provides compliance with those requirements through the National Laboratory Certification Program (NLCP) and also provides guidance for agencies and service providers choosing to use a Federal eCCF for regulated workplace drug testing. The HHS Guidelines and the DOT and NRC Regulations allow secure electronic transmission of the Federal CCF and both specify that service providers must ensure the security of the data transmission and limit access to any data transmission, storage, or retrieval system.

Identify who will have access to the PII in the system and the reason why they require access.
Users:
Collectors are responsible for ensuring the integrity of the testing process when it first begins. Collectors must be able to verify that the person they are testing is actually the person who was ordered by the employer to be tested; thus, they need access to PII to confirm the donor's identity and first associate the specimen with the donor.
Test Facility Staff: A limited number of staff need access to the PII on Copy 1 for inclusion on the required
MROs: The MRO uses the PII to verify that the test results received are that of the individual tested, and to contact the donor if necessary.
Employers: Employers must have access to PII to associate employees with their drug test results.
Third Party Administrators (TPAs): With respect to TPA access to PII, as allowed under the DOT program, see 49 CFR Part 40 (e.g., 40.167, 40.345, and Appendix F).
With respect to who may need access to PII in the DOT program, please review the DOT supplemental statement available at www.dot.gov/privacy/privacy-impact-assessments.

Others:
Managers of computer systems utilized by drug testing service providers

Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.
For the Federal Drugfree Workplace Programs, agency personnel may access PII as allowable by law. With respect to the DOT program, please review the supplemental statement at www.dot.gov/privacy/privacy-impact-assessments.

Describe the methods in place to allow those with access to PII to only access the minimum amount of information necessary to perform their job.
Collection organizations, test facilities, MROs, and employers use an appropriate user identification and authentication process, based on their respective positions, including responsibilities for maintaining the confidentiality, integrity and accuracy of records including the Federal CCF.

Describe training system users receive (above and beyond general security and privacy awareness training).
The Mandatory Guidelines specifies training for collectors, test facility personnel, and MROs. Collector training must be documented and provided to federal agencies upon request. test facility training records are reviewed during NLCP inspections, and HHS approves MRO training/certification programs.

Do contracts include Federal Acquisition Regulation and other appropriate clauses ensuring adherence to privacy provisions and practices?
Yes

Describe the process and guidelines in place with regard to the retention and destruction of PII.
The Mandatory Guidelines require collection sites, laboratories, and MROs to maintain drug testing specimen records for two years. Test facilities must maintain records for a longer period when specified in a written request from a federal agency.

Describe, briefly but with specificity, how the PII will be secured in the system using administrative, technical, and physical controls.
Access must be restricted to those persons whose duties and responsibilities require them to have access to and knowledge of the information, and to prevent disclosure. Through the NLCP, HHS requirements that are applicable to the use of a Federal eCCF include requirements for CCF annotation, computer system validation, security, electronic records, electronic reports, electronic signatures, audit trails, and logs, system documentation, incident response, and disaster recovery. Other standards may be event reporting, physical security, encryption, and user authentication.