# Electronic Custody and Control Form (CCF)

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# Federal CCF

- http://edocket.access.gpo.gov/2010/pdf/2010-17400.pdf

# Notice of OMB action 2010 Federal CCF

- OMB Control #: 0930-0158
- Expiration Date: 08/31/2013
- A sample of the 2010 Federal CCF is available
  - SAMHSA website: (http://www.workplace.samhsa.gov/)
  - OMB website: http://www.reginfo.gov/public/do/PRAViewIC?ref_nbr=201007-0930-002&icID=193835

# OMB

- Federal CCF from OMB
- **Approved consistent with the following terms of clearance**:
  - Previous terms of clearance (Prior to the next approval of this package, the Agency shall provide a progress update on adoption of electronic forms in an effort to reduce burden. SAMHSA is encouraged to explore ways to convert the Federal Drug Testing Custody and Control Form (Federal CCF) into an electronic form) remain in effect.

# Federal Register Notice (FR 75 59196 November 17, 2009)

- Notice of Proposed Revisions to the Federal Custody and Control Form (CCF)
  - 60 day comment period
  - 161 responses from individual commenters with multiple comments on the proposed changes to the Federal CCF
  - In addition, another 427 letters with identical content were sent by one central submitter and postmarked on or before the closing date of the comment period (January 19, 2010)
  - HHS-certified laboratories, third party administrators (TPA), collection sites, MROs, printing firms, employers, health organizations, and interested individuals
  - The majority of the commenters supported the proposed changes to the Federal CCF, and a similar majority also commented on the desired availability for an **"On-Demand CCF"**

# Benefits “On-Demand” CCF

- Employers and C/TPA can enter information electronically
- Software systems governing the collection process improve collector compliance
- Federal CCF printed at the collection site will have the most up-to-date employer, laboratory, and MRO information
- Federal CCF produced with collection site software and laser printers are more legible than handwritten carbonless forms
- Federal CCF copies can be distributed electronically from the collection site
- Electronic archival and retrieval systems are superior to paper-based
- Federal CCF printed at the collection site reduces the likelihood that the Federal CCF will be lost or labels/seals damaged in transit to the collection site brought by the donor or shipped by the C/TPA and or employer

# Problems Pre-Printed CCF

- Untimely distribution of CCF Copies: Copy 2 to MRO and Copy 4 to Employer.
- Poor legibility of pre-printed CCF.
- Incorrect/outdated information printed on CCF.
- Waste
- Required storage of hardcopy forms.
- Problematic impact (dot-matrix) printers needed to print information on the 5-part CCF.

# HHS Electronic Document Policy

- FDA:
  - 21 (CFR), Part 11 (62 FR 13430)
    - Criteria under which FDA would consider electronic signature to be equivalent to full handwritten signatures
- Office of the Secretary for HHS:
  - 45 (CFR), Part 160,162,164 (68 FR 8334)
    - Adopt national standards for safeguards to protect the confidentiality, integrity, and availability of electronic-protected health information

# Government Paperwork Elimination Act (GPEA)

- (OMB) provides procedures and guidance to implement the GPEA of October 21, 1998
- GPEA requires Federal agencies, by October 21, 2003, to allow individuals or entities that deal with the agencies the option to submit information or transact and maintain records with the agency electronically, when practicable
- The Act specifically states that electronic records and their related electronic signatures are not to be denied legal effect, validity, or enforceability merely because they are in electronic form
- Encourages Federal government use of a range of electronic signature alternatives

# Characteristics of Trustworthy Records

- Reliability
- Authenticity
- Integrity
- Usability

# SAMHSA’s Objective

- SAMHSA will seek public comment specifically on the standards to be established concerning:
  - Electronic signature
  - Non-repudiation agreement for digital signatures
  - Third party software for managing Federal CCF information
  - Unique specimen identification number
  - The legally-binding equivalent of traditional hand-written signatures in a forensic arena
  - The security data transmission over telecommunications systems/networks
  - The integrity of document content