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DTAB's Process for Evaluating the Scientific Supportability of the Hair Specimen for Federal Workplace Drug Testing

Janine Denis Cook, Ph.D.

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DEPARTMENT OF HEALTH & HUMAN SERVICES • USA

SAMHSA's Objective - DTAB

- SAMHSA's only scientific advisory council
- "SAMHSA seeks to improve the quality of services for forensic workplace drug testing, assess the science and technology used in drug analyses, improve the quality of related laboratory services and systems for drug testing, generate standards for laboratory certification for Federal workplace drug testing programs, and guide national policy in these areas by the establishment of the CSAP DTAB"

DTAB's Duties

- Per its charter,
  - "The CSAP DTAB provides advice to the Administrator, SAMHSA, based on an ongoing review of the direction, scope, balance, and emphasis of the Agency's drug testing activities and the drug testing laboratory certification program
  - It shall recommend areas for emphasis or de-emphasis, new or changed directions, and mechanisms or approaches for implementing recommendations
  - Periodically, the CSAP DTAB shall review specific science areas on new drugs of abuse and the methods necessary to detect their presence"

History

- Notice of Proposed Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs
  - Federal Register, April 13, 2004 (69 FR 19673)

SUMMARY: The Department of Health and Human Services (“HHS” or “Department”) is proposing to establish scientific and technical guidelines for the testing of hair, sweat, and oral fluid specimens in addition to urine specimens;

HHS's Decision

- Mandatory Guidelines for Federal Workplace Drug Testing Programs
  - Federal Register, November 25, 2008 (73 FR 71858)
  - Effective 10/1/2010

SUMMARY: This Final Notice of Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Revisions to Mandatory Guidelines) addresses collection and testing of urine specimens.

73 FR 71858 Background

The submitted public comments and additional comments raised by Federal Agencies during subsequent internal review of the proposed changes to the Guidelines raised significant scientific, legal, and public policy concerns about the use of alternative specimens and POCT devices in Federal agency workplace drug testing programs. Since each alternative specimen and drug testing using POCT devices poses different concerns, the Department established a staggered timeline for issuing final guidance that allows for further study and research. In assessing the complexity of the task, the Department has decided to publish these final Guidelines with regard to collection and testing urine specimens, establishing the requirements for the certification of IITFs, and establishing specific standards for collectors and MROs. The Department considered several options for issuing one or more Final Notices in the **Federal Register** that may require additional public comment periods, concerning the use of alternative specimens and drug testing technologies such as POCT devices. Since the scientific, legal, and public policy information for drug testing oral fluid, hair, and sweat patch specimens, and using POCT devices is not as complete as it is for the laboratory-based urine drug testing program, developing Final Notices concerning the use of these is more challenging. As described in the notice of Proposed Revisions to Mandatory Guidelines issued April 13, 2004, the performance of alternative specimens in pilot performance testing (PT) programs has been encouraging, with individual laboratory and group performance improving over time. However, there are still three areas of concern. First, the data from the pilot PT programs to date show that not all participants have developed the capability to test for all required drug classes, nor to perform such tests with acceptable accuracy. Second, some drug classes are more difficult to detect than others, for any given type of specimen. Third, the specific drug classes that are difficult to detect vary by type of specimen. As a result, it will require additional study to assist agencies in determining how to select the appropriate type of specimen to be collected from a specific donor, when the use of a specific drug is suspected. Nevertheless, HHS believes that the addition of alternative specimens to the Federal Workplace Drug Testing Program would complement urine drug testing and aid in combating the risks posed from available methods of suborning urine drug testing through adulteration, substitution, and dilution. Thus, HHS will continue to pursue testing using alternative specimens. HHS anticipates issuing further revisions to the Mandatory Guidelines addressing the use of oral fluid, sweat patch, and hair, and the use of POCT devices for urine and oral fluid. These revisions will be published in the **Federal Register**, with opportunity for public comment.

Key Issues from the Preamble

- Use of alternative specimens
  - "Submitted public comments and additional comments raised by Federal Agencies during subsequent internal review of the proposed changes to the Guidelines raised significant scientific, legal, and public policy concerns about the use of alternative specimens"

HHS Concern

- “The scientific, legal, and public policy information for drug testing oral fluid, hair, and sweat patch specimens … is not as complete as it is for the laboratory-based urine drug testing program”

Three Issues

- “First, the data from the pilot PT programs to date show that not all participants have developed the capability to test for all required drug classes, nor to perform such tests with acceptable accuracy.
- Second, some drug classes are more difficult to detect than others, for any given type of specimen.
- Third, the specific drug classes that are difficult to detect vary by type of specimen.”

HHS Position

- “HHS believes that the addition of alternative specimens to the Federal Workplace Drug Testing Program would complement urine drug testing and aid in combating the risks posed from available methods of suborning urine drug testing through adulteration, substitution, and dilution.”

HHS Approach

- HHS approach
  - “Each alternative specimen … poses different concerns”
  - “Department established a staggered timeline for issuing final guidance that allows for further study and research.”
  - “Issuing one or more Final Notices in the Federal Register that may require additional public comment periods, concerning the use of alternative specimens”

HHS Goal

- “HHS will continue to pursue testing using alternative specimens. HHS anticipates issuing further revisions to the Mandatory Guidelines addressing the use of oral fluid, sweat patch, and hair…”
- “These revisions will be published in the Federal Register, with opportunity for public comment.”

Alternate Specimens

- DTAB will follow the HHS-recommended staggered timeline for evaluating the scientific supportability of alternative specimens for use in federal workplace drug testing programs
  - The Board has completed its evaluation of oral fluid specimen
  - Today it will begin its evaluation of the hair specimen

Step 1

- Task the DTAB with assessing the state of the science of hair as an alternate specimen for drug testing for the federal workplace drug testing programs
- *July 2013 meeting*

"The scientific, legal, and public policy information for drug testing hair… specimens … is not as complete as it is for the laboratory-based urine drug testing program"

Step 2

- Review:
  - The historical perspective of hair as a drug testing matrix
  - The current perspective of hair specimen drug testing, including
    - Specimen characteristics, collection, preparation, and stability
    - Drug analytes, analyte stability, and analyte cutoffs initial and confirmatory testing methodologies; proficiency testing
    - Best practices experiences
    - Hair drug testing data
- *July 2013 meeting*

Step 3

- Perform an exhaustive hair specimen literature search
- *Already in progress*

Step 4

- Identify specific questions associated with hair testing issues that require in-depth discussion by the Board
  - Hair specimen
  - Hair collection and specimen preparation
  - Drugs and/or metabolites and cut-off levels
  - Specimen validity, initial, and confirmation testing
  - Quality control/performance testing
  - MRO review
- *July 2013 meeting*

Step 4, Continued

- For each of these questions, possible outcomes include:
  - Consensus answer
  - Request for more in-depth literature review
  - Request for Information
  - Request for research studies
  - Assignment to the appropriate federal officials for significant scientific, legal, and public policy concerns

Step 5

- Deliberate on the scientific supportability of the Hair Specimen for Federal Workplace Drug Testing
- *Future meeting*

End Result

- Based on its state of the science research and after DWP addresses the significant scientific, legal, and public policy concerns raised by previous public commenters and Federal agencies, DTAB will either recommend or not recommend proposed revisions to the Mandatory Guidelines to include hair as an alternate specimen
  - If recommended by the Board and that recommendation is approved by the SAMHSA Administrator, the proposed revisions will be drafted by DWP, reviewed by the Board, and published in the Federal Register for public comment