

Welcome and Opening Remarks

**SAMHSA's
Center for Substance Abuse Prevention
Drug Testing Advisory Board**

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Welcome - SAMHSA's Role

- **Substance Abuse and Mental Health Services Administration (SAMHSA)**
- An agency in the **U. S. Department of Health and Human Services (HHS)**
- Under a delegation of authority from the Secretary of Health and Human Services, SAMHSA's **Division of Workplace Programs** carries out the HHS role in the Federal Drug-Free Workplace Program

Welcome – SAMHSA's Direction

- Mission: To reduce the impact of substance abuse and mental illness on America's communities
- Roles:
 - Voice & Leadership
 - Funding Service-Capacity Development
 - Information/Communications
 - Regulation and Standard Setting
 - Improve Practice
- 8 Strategic Initiatives

Welcome – SAMHSA Key Messages

- Behavioral health is essential to health
 - Improves health status
 - Lowers costs for families, businesses, and governments
- Prevention works
- Treatment is effective
- People recover

Welcome – SAMHSA Principles

- People
 - *Stay focused on the goal*
- Partnership
 - *Cannot do it alone*
- Performance
 - *Make a measurable difference*

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.”

Next Steps

- DTAB will follow the HHS-recommended staggered timeline for evaluating the scientific sufficiency of alternative specimens for use in federal workplace drug testing programs
 - Begin with the evaluation of oral fluids
 - Decision supported by:
 - Peer-reviewed literature (~620 publications)

Next Steps

- Based on its scientific research, DTAB will/will not recommend proposed revisions to the Mandatory Guidelines to include oral fluid for publication in the Federal Register, with opportunity for public comment