Regulatory Program Updates and Mandatory Guidelines
Center for Substance Abuse Prevention
Drug Testing Advisory Board

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U.S. Department of Health and Human Services
Division of Workplace Programs

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Open Session - Public
Division of Workplace Programs

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Drug Testing Advisory Board Members

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- D. Faye Caldwell, J.D. (extended)
- Jason E. Schaff, Ph.D.
- Barry R. H. Sample, Ph.D.
- Deborah Motika, M.S., D-ABFT-FT, TC(NRCC), MT(ASCP)
- Stephen Mark Taylor, MD, M.P.H., F.A.S.A.M.
- Alison Stockdale
- David Engelhart, Ph.D.
- Elizabeth Stuyt, MD
- David Roberts, Ph. D. (nominee)
DWP Objectives and Goals

- **Overall Goal:** “SAMHSA is continually assessing the science and technology used in drug detection to advance national drug policy that is based on the latest scientific findings.”

- **Goals:** Implementation of the first HHS-Certified Oral Fluid Testing Laboratory and Federal Register Notice publication of the Mandatory Guidelines using Hair.

- **Present:** Program implementation of the Mandatory Guidelines using oral fluid as an alternative specimen to enhance the Federal Workplace Drug Testing Program.

- **DFWP:** Conduct a high-level review of the Drug Free Workplace Program to identify key policy and technical issues as well as the existing challenges.

- **Future:** Referral of the proposed Mandatory Guidelines using Hair as a final Federal Register Notice.
Division of Workplace Programs
Legislative Authority and Main Roles

**Science**
Forensic Drug Testing

DWP's Science Responsibilities:

1. **Mandatory Guidelines for Drug Testing:** Scientific & Technical Guidance
2. **National Laboratory Certification Program (NLCP):** Certifies labs for federal (and federally-regulated) forensic drug testing
3. **Drug Testing Advisory Board (DTAB):** National Advisory Council of experts on federal and federally regulated drug testing activities
4. **Medical Review Officer (MRO)* Training:**
   - Establish MRO certification standards
   - Certify MRO training entities

* MROs interpret drug testing results on drug use.

Programs Outcomes:
- National drug testing standards
- Alternative specimen testing (Urine, Oral Fluid, Hair)
- HHS Certified Laboratories
- DTAB Recommendations for the Assistant Secretary
- National MRO certification standards

**Policy**
Drug Free Workplace Program

DWP's Policy Responsibilities:

1. **Technical Assistance to all Federal Agencies:** Assistance and review of agency plans in implementing the DFWP
2. **Plan Certification:** Certify federal agency DFWP plans, transmit agency plan Reports to Congress. Agency plans establish agency policy and procedures.
3. **Executive Committee:** Interagency Coordinating Group Executive Committee (ICGEC) established policy and approves federal Testing Designated Positions (TDP's) or safety-sensitive positions
4. **Policies/Legislation:** Evaluating impact of policies and legislation on the DFWP, i.e., Farm bill, state marijuana decimalization,

Programs Outcomes:
- Certified DFWP plans for all federal agencies
- DFWP policy and procedures for all federal agencies
- Policy Discussions with ONDCP
- Policy and Legislation Impact on the DFWP

The DWP Emerging Issues group addresses both components of science and policy.
**Mandatory Guideline Routing Process**

1. **DWP, DOJ, OGC and DTAB**
   - (Concept and Recommendations)
   - Timeframe: Approximately 12 - 18 Months

2. **SAMHSA Assistant Secretary**
   - (Reviews Recommendations)
   - Timeframe: Approximately 6 Months

3. **HHS SECRETARY & BEHAVIORAL HEALTH COORDINATING COMMITTEE**
   - (committee includes scientific/technical rep. from each HHS Operating Division: HRSA, CDC, FDA, HHS, OGC, SAMHSA, NIH)
   - (Reviews and approves recommendations)
   - Timeframe: Allow 60 days

4. **DWP SUBMITS PROPOSED MANDATORY GUIDELINES**

5. **SAMHSA REVIEW OF DRAFT MANDATORY GUIDELINES**

6. **DEPARTMENT OF HEALTH AND HUMAN SERVICES/ OPDIVS REVIEW**

7. **OMB DISTRIBUTES TO EXECUTIVE BRANCH FEDERAL AGENCIES FOR REVIEW**
   - Timeframe: Allow 60 days

8. **RECOMMENDATIONS SENT TO DWP FOR SAMHSA FINAL REVIEW AND ACTION**
   - Timeframe: Allow 60 days

9. **REVISES RE-ROUTED THROUGH HHS.**
   - Timeframe: __________
   - DWP received approx.

10. **ONCE OMB RECEIVES ALL COMMENTS, THE MG WILL BE RETURNED TO HHS FOR FINAL NOTICES WITH Assistant Secretary’s SIGNATURE**
    - Timeframe: __________

11. **OMB REVIEW AND APPROVAL OF PROPOSED MANDATORY GUIDELINES**
    - Timeframe: _______

12. **FEDERAL REGISTER NOTICE POSTED FOR PUBLIC COMMENT**
    - Timeframe: 60 - 90 days —optional

13. **PUBLIC COMMENTS AND RECOMMENDATIONS REVIEWED BY DWP**
    - Timeframe: _______

14. **PREPARE FINAL MANDATORY GUIDELINES**
    - Timeframe: _______

15. **ROUTE FINAL GUIDELINES THROUGH SAMHSA FOR APPROVAL BY Assistant Secretary**
    - Timeframe: _______

16. **SAMHSA Assistant Secretary SIGNS FINAL NOTICE FOR FEDERAL REGISTER**
    - Timeframe: _______

17. **POST FINAL NOTICE OF MANDATORY GUIDELINES AND IMPLEMENTATION DATE IN FEDERAL REGISTER**

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**Clarifications**

- **Timeframes** vary depending on processes and reviews.
- **OMB and HHS** coordinate with federal agencies for concurrence.
- All comments and recommendations are consolidated for review.
- A final decision or meeting is set up if needed.
- Federal Register notices are posted for public comment, followed by comments and reviews.
- Final guidelines are approved and signed by the Assistant Secretary, then distributed through Samhsa for federal register implementation.
Drug-Free Workplace Program Impact

Federal Executive Branch

Department of Transportation
(Federally regulated program that uses DWP’s drug testing standards)

Nuclear Regulatory Commission
(Federally regulated program that uses DWP’s drug testing standards)

DFWP Program Impacts 14 million+ employees

Approximately 150 Departments and Agencies
Civilian Employees 2 million +
Random Testing Positions (Safety/Security/Public Health) 400K+

Regulated Transportation Industry Employees Tested for Drugs (and Alcohol) 12 million +
Power Plants 100
Research and Test Reactors 36
Drug Free Workplace Programs

Federal Laws

Employee/Employer

“Drug Testing Policy”

CBD/Hemp Products

“Farm Bill”

Testing Issues

State Laws

Contract / Legal Issues

SAMHSA
Substance Abuse and Mental Health Services Administration
Urine and Oral Fluid Mandatory Guidelines

1) Cocaine
2) Amphetamines
3) Marijuana
4) Phencyclidine (PCP)
5) Opioids
   - Codeine
   - Morphine
   - 6-AM
   - Hydrocodone
   - Hydromorphone
   - Oxycodone
   - Oxymorphone

Note: If the Agency desires to add any other drug to its drug testing panel, advance written approval from the Secretary, Department of Health and Human Services is required. However, the Agency may test for any other Schedule I or Schedule II drug on a case by case basis.
Mandatory Guidelines Update

**Urine**

Urine Mandatory Guidelines - Testing for 4 semi-synthetic opioids:
- Hydrocodone
- Hydromorphone
- Oxycodone
- Oxymorphine


**Oral Fluid**

Mandatory Guidelines for Federal Workplace Drug Testing using Oral Fluid (OFMG) was published October 25, 2019, in the Federal Register (84 FR 57554), with an effective date of January 1, 2020.

Policies, procedures and documents needed for certification of laboratories for testing of oral fluid are under final review.

**Hair**

The Division of Workplace Programs has included hair as a proposed specimen for drug testing. Further studies are being considered to address using hair as an authorized matrix.

SAMHSA published the proposed Mandatory Guidelines for Federal Workplace Drug Testing using Hair on September 10, 2020, in the Federal Register (85 FR 56108) for public comment.
Establishment of new standards and technical requirements for hair collection procedures and hair collection materials.

Inclusion of the same list of substances allowed to be tested in urine and oral fluid.

Establishment of the initial and confirmatory drug test analytes, cutoffs, and methods for hair testing.

Requirements for each laboratory to have procedures for decontamination and for identifying hair that has been damaged to the extent that a drug test may be affected.

Revision of the requalification requirements for individuals serving as Medical Review Officers to include the review of hair drug test results.

Inclusion, where appropriate, of references to the use of an alternate specimen (e.g., urine, oral fluid) in the federal workplace drug testing program.
Proposed NEW matrix in the Federal Drug Testing Program
• Proposed Mandatory Guidelines using Hair published Sept. 10, 2020
• HHS requested public comment and scientific information addressing multiple topics, including hair color impact and external contamination

HHS will publish an FRN with supplemental revisions to the proposed Mandatory Guidelines (same as proposed for Urine and Oral Fluid)

Publication of final Mandatory Guidelines will be based on OMB review and conclusion to publish the final FRN. Once the final FRN is published, hair would be an authorized matrix that may be used in federal agency programs.

DOT will publish a separate Notice for Public Rule Making to include Hair.
Hair Mandatory Guidelines – Status

- SAMHSA comment review:
  - Organized public comments by subject (over 700 individual comments from 213 commenters)
  - Reviewed all comments, submitted information, and scientific studies referenced by commenters
  - Continued to monitor the scientific literature

- March 2021 DTAB closed meeting: summarized public comments presented for DTAB discussion

- June 2021 DTAB closed meeting: DTAB members reviewed the draft HMG and provided input.

- SAMHSA is continuing to prepare the final HMG.
The goals of these proposed revisions would be to facilitate modifications to the authorized drugs and cutoffs as needed, based on the science and emerging drug trends, and to aid in the detection of donor attempts to subvert their drug test.

We are currently engaged in reviewing potential frameworks that incorporate the best available research and advice, including input from relevant stakeholders.
Revision Timelines for Mandatory Guidelines

1. Publish proposed (revised) Urine Mandatory Guidelines and Oral Fluid Mandatory Guidelines in a Federal Register Notice for public comment

2. Publish supplement to the proposed Hair Mandatory Guidelines (revised like UrMG and OFMG)

3. Publish Final UrMG and Final OFMG

4. Publish Final HMG

5. Starting in 2022: Conduct a high-level review of the Drug Free Workplace Program to identify key policy and technical issues as well as the existing challenges.
Current National Laboratory Certification Program Studies

- Hair Inventory
- Exploratory Blind Investigation
- Delta-8 THCA Cross Reactivity
- CBD Metabolites in Urine
- Q-TOF Screening Method
- Urine Adulterants
- Analysis of acidic foods containing CBD
- Hair Extract-Analyte Formation
- JHU study for chronic dosing of CBD
- JHU topical application of CBD products (Phase 1)
- THC/CBD pulse study
- Presence of fentanyl in opiate positive specimens

Legend:
- Research plan and budget proposal submission
- Research proposal approval
- Regulatory and IRB clearances
- Recruit study participants
- Purchase study materials
- Sample collection
- Sample collection
- Data analysis/Publication
- Sample collection
- Sample collection
Emerging Issues - Legislation

- 2015 FAST Act – required development of Mandatory Guidelines for Hair testing while issues of hair color impact and external contamination issues continue to exist
- 2018 Farm bill – defined hemp and set a legal limit for THC content, making it nearly impossible to discern between legal and illegal sources of THC.
- 2018 Opioids Crisis Response Act

Changes in Science and Technology

- Drug testing and specimen collection technology are improving – Mandatory Guidelines for Drug Testing using Oral Fluid, effective Jan. 2020

Evolving Environment

- New and novel drug use continues to emerge, e.g., synthetic designer drugs
- Increased public acceptability and availability of marijuana and CBD products and implications for workplace safety/security – e.g., Delta-8-THC or other THC isomers and State initiatives to decriminalize marijuana
- Increased demands on the DFWP – e.g., COVID-19 return-to-office challenges
Ongoing Challenges

- Review of the technical and scientific studies to support hair decontamination procedures and unique biomarkers / metabolites to rule out external contamination
  - Finalizing the Hair Mandatory Guidelines
  - Implementation and funding the new program

- Addressing Emerging Issues such as Marijuana/Hemp (CBD), Opioids, Synthetic Drugs, Federal and State Legislation

- Funding for the Oral Fluid Program
Plan

- Begin accepting OF applications in Dec. 2021
- Certification process
  - Application
  - 3 initial PT cycles
  - Initial inspection

Oral Fluid Documents

- 2020 Federal CCF
- Guidance for Using the 2020 Federal CCF
- NLCP Application
- NLCP Manual
- NLCP Checklists
- HHS Specimen Collection Handbook

- HHS MRO Guidance Manual (including OF)
- HHS MRO Case Studies (including OF)
- HHS Collection Site Manual
- HHS Collection Site Checklist
Marijuana Studies

- Technical and Scientific Peer Reviewed Journal Articles.

- DWP continues to update this list of reference articles on the website.

- I want to thank Dr. Ed Cone, Dr. Ryan Vandrey, Dr. Tory Spindle and Dr. Dave Kuntz for all of their work on these projects.

- Studies (CBD) and data for marijuana analytes are under review.
Drug-Free Workplace Program Meeting

Conduct a high-level review of the Federal Drug-Free Workplace Program (DFWP) and to:

- Assess critical issues affecting the program now and in the future;
- Review the state of the art and science;
- Identify key policy and technical challenges; and
- Highlight best practices for DFWP implementation.
DFWP Resources

Division of Workplace Programs (DWP) Main Website:
https://www.samhsa.gov/workplace

Executive Order 12564:

Public Law 100-71:

Mandatory Guidelines:
https://www.samhsa.gov/sites/default/files/workplace/frn_vol_82_7920_.pdf

Model Plan for a Comprehensive Drug-Free Workplace Program:

2013 Guidance for Selection of Testing Designated Positions:
Thank You
Division of Workplace Programs

Please Visit our Website
https://workplace.samhsa.gov/