

Welcome and Opening Remarks

SAMHSA's

Center for Substance Abuse Prevention

Drug Testing Advisory Board

Ron Flegel, BSMT (ASCP), MS
DTAB Chair

Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services

March 20, 2018
Open Session - Public



SAMHSA
Substance Abuse and Mental Health
Services Administration

Division of Workplace Programs

- Director: Ron Flegel, B.S., MT(ASCP), M.S.
- Contracting Officer Representative: LCDR Eugene D. Hayes, Ph.D., M.B.A.
- Pharmacist: Captain Sean Belouin, Pharm.D.
- Toxicologist: Vacant
- Policy Analyst: Ana Donovan
- Senior Chemist: Charles LoDico, M.S., F-ABFT
- Senior Policy Analyst: Coleen Sanderson
- Policy Oversight Lead: Hyden Shen, J.D.
- Senior Research Analyst: Deborah Galvin, Ph.D.
- Program Assistant: Giselle Hersh

Regulation

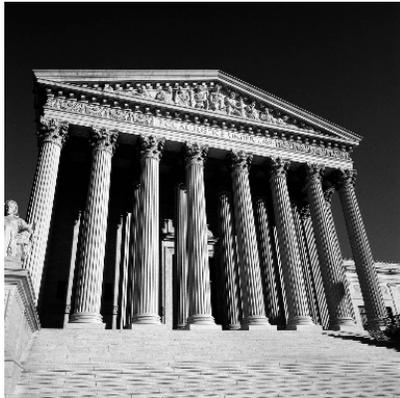
Policy

Donor
Drug Test
Result

Medical Review Officers
Trained Collectors
HHS-Certified Laboratories
National Laboratory Certification Program
Federal Agency Plan and TDP List
Mandatory Guidelines

Drug Testing Advisory Board
Interagency Coordinating Group Executive Committee
Division of Workplace Programs
Office of National Drug Control Policy
Executive Order 12564 – Public Law 100-71

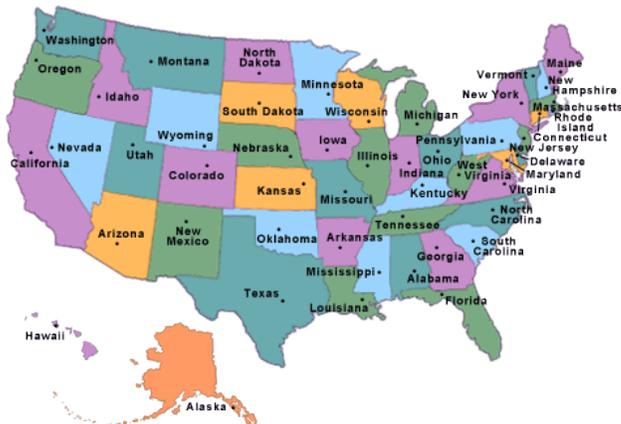
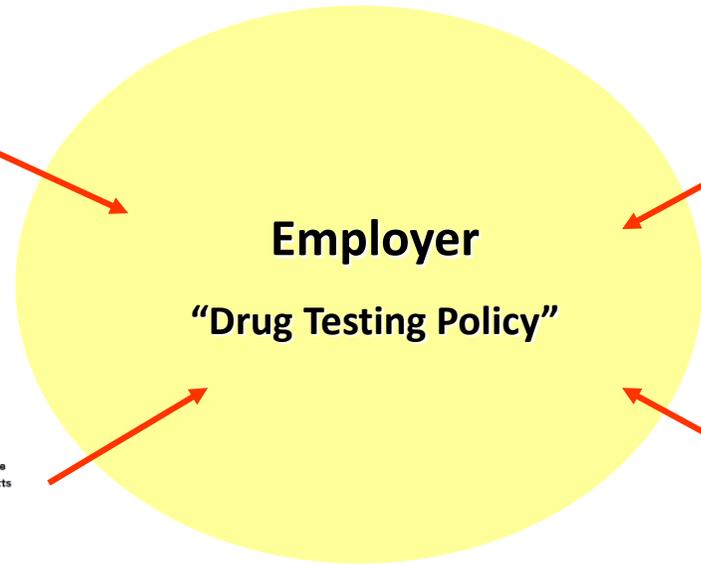
Drug Free Workplace Programs



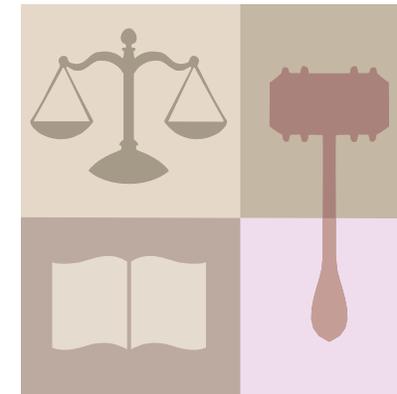
Federal Laws



Testing Issues



State Laws



Contract / Legal Issues

DWP Objectives and Goals

- **Present:** Implemented the revised urine Mandatory Guidelines on October 1, 2017 and are in the process of final approval for oral fluid as an alternative specimen in Federal Workplace Drug Testing Programs
- **Future:** Writing the Proposed Hair Mandatory Guidelines
- **Current Goal:** Continue to monitor the semi-synthetic opioid testing in the regulated programs (hydrocodone, oxycodone, hydromorphone, oxymorphone).

Revised Urine Mandatory Guidelines

- Federal Register was published January 23, 2017
 - 82 FR 7920, Pages 7920-7970
- Implementation date: October 1, 2017 (6 months ago)
- Changes
 - Added oxycodone, oxymorphone, hydrocodone, hydromorphone
 - Removed MDEA
 - Added MDA as initial testing analyte
 - Raised lower pH cutoff level for adulterated specs [3 → 4]
 - Many wording changes to address alternative specimens when authorized

Effective Date: October 1, 2017

- HHS-certified labs met the Oct 1, 2017 effective date (Qualifying Performance Testing Samples)
 - HHS would like to thank the HHS Certified Laboratories for meeting this implementation date.
- DWP continues to follow up with Federal Agency Drug Program Coordinators that oversee the agencies DFWP - consistent with the requirements in the MG and testing of opioids.
- HHS Secretary's priority has continued to be the Opioid crisis. The testing for the synthetic Opioids could help deter the illicit use of prescription opioids and provide treatment for employees in federal agencies.
- The New CCF is in effect for Federal Agencies. Use of the previous (2014) CCF has been extended to June 1, 2018 and will be no longer be approved after this date.

Oral Fluid Mandatory Guidelines

- Marijuana Studies
 - Technical and Scientific Peer Reviewed Journal Articles
 - DWP continues to update this list of reference articles
 - Thank Dr. Ed Cone and Dr. Ryan Vandrey
- Proposed FRN Notice: 2018?
- Inclusion of testing oral fluid as a new matrix in the federal program
- Semi-synthetic opioids (prescription painkillers) have been added to the federally regulated drug testing panel
- MRO Guidance Manual for Oral Fluid

Oral Fluid Mandatory Guidelines

- Final studies and data for marijuana analytes is under review.
- No single immunoassay detects both THC and THCA. There is one commercial THCA immunoassay (ELISA), has significant cross reactivity with THC.
- Laboratories could use an alternative method other than immunoassay for the initial test.
- Testing for parent drug (i.e., THC, the psychoactive component of cannabis) is very important for other uses including Driving Under the Influence of Drugs (DUID).

Hair Mandatory Guidelines

- DWP staff is drafting the proposed Hair Mandatory Guidelines
- Proposed research studies around Unique Metabolites are ongoing
- DTABs recommendation was to pursue hair testing as an alternative program. To be an effective program alternative specimens should be considered.
- Scientific and technical issues are being addressed through literature or specific studies to address these issues

Proposed Mandatory Guidelines

Proposed Hair Mandatory Guidelines

- DTAB recommendation was to pursue hair testing but address 1) *decontamination* of hair specimens and 2) *hair color impact*.
- Development of the Hair Mandatory Guidelines will require addressing these 2 specific scientific issues for the use of hair as a drug testing specimen.
- SAMHSA is continuing to develop the proposed Hair Mandatory Guidelines for Federal Workplace Drug Testing.

Challenges

- Implementing the Oral Fluid Mandatory Guidelines
- Review of the technical and scientific studies to support hair decontamination procedures and unique biomarkers/metabolites to rule out external contamination
- Addressing Emerging Issues: Marijuana, Opioids, Synthetic Drugs, Legislation and State Laws

Opportunities

- Implemented the revised urine Mandatory Guidelines which included the semi-synthetic opioids
- Oversight and standardization of semi-synthetic opioids drug testing
- Developed the MRO Guidance Manual and MRO Case Studies
- Deter the illegal use of drugs and prescription opioids
- Implement oral fluid drug testing as an alternative specimen, therefore decreasing the number of substituted and adulterated specimens
- Allow federal agencies a non-invasive alternative to urine testing

Mandatory Guideline Routing Process



MRO Guidance Manual Update

- Major Issues that are addressed
 - Addressing the addition of Rx opioid drugs to drug testing panel: Oxycodone, oxymorphone, hydrocodone, hydromorphone.
 - Hydrocodone combination drugs have been rescheduled to Schedule II
 - Consideration of a valid prescription under the Drug-Free Workplace Programs
- Mandatory Guidelines for Federal Workplace Drug Testing Programs
 - Subpart M – Medical Review Officer (MRO), Section 13.1

A large, stylized black 'Rx' symbol, commonly used to denote a prescription.

Ongoing Studies

- Cannabidiol (CBD) Study
 - Tentative start date: June 2018
- Pharmacokinetics and Pharmacodynamics Study: Oral, Smoked, and Vaporized Cannabis
 - SOFT 2017: 2 Presentations
 - Disposition of Cannabinoids in Oral Fluid and Whole Blood after Vaporized and Smoked Cannabis
 - Pharmacodynamic Comparison of Acute Cannabis Effects Following Oral, Smoked, and Vaporized Administration
- Gathering Opioid Data: revised Mandatory Guidelines
 - pH changes
 - Invalid Results
 - Substitution

Marijuana in Science

Exploring butane hash oil: a research note

Medical marijuana for
cancer

Cannabis effects on
driving lateral control
with and without alcohol

Marijuana-related issues in the DFWP

Acute cannabis consumption and
motor vehicle collision risk:
systematic review of observational
studies and meta-analysis

*“Spice,” “Kryptonite,” “Black
Mamba”:* an overview of
brand names and marketing
strategies of novel psychoactive
substances on the web

Cannabinoids and psychosis

Passive Inhalation Study



Session 1: 5.3% MJ, No Ventilation



Session 2: 11.3% MJ, No Ventilation



Session 3: 11.3% MJ, With Ventilation

Cannabis Brownie Study

- Cannabis ground into powder
- Heated for 30 min at 250°F (121°C)
- Individual doses stirred into brownie batter and baked for 30 min at 325°F (163°C)
- Individual doses of 10, 25, & 50 mg of THC



(Courtesy of Ryan Vandrey, JHU)



Cannabis Vaping Study



DUID Testing



- DWP supports the methods that minimize the rates of driving under the influence of drugs



- DWP has developed standards for federal workplace drug testing that may be helpful by other programs including law enforcement

Emerging Issues/Synthetic Drugs

- One example of synthetic marijuana is JWH-018
- Significant psychopharmacological differences exist between marijuana and JWH-018
 - Both chemicals are considered cannabinoids, which attach to the *cannabinoid*, or *CB1*, receptors in the brain
 - However, the synthetic compound and THC differ in potency due to the strength of that attachment
- Potential problem with synthetic marijuana testing is the lack of a rapid and cost-effective means to identify the substances



[Synthetic Marijuana](#) 



[Marijuana Plant](#) 



[Shatter](#) 

Thank You
Division of Workplace Programs

Please Visit our Website

<http://workplace.samhsa.gov/>