

Behavioral Health is Essential To Health



Prevention Works



Treatment is Effective



People Recover



Welcome and Opening Remarks

SAMHSA's

Center for Substance Abuse Prevention

Drug Testing Advisory Board

Ron Flegel, BSMT (ASCP), MS
DTAB Chair

September 19, 2017
Public Session



Division of Workplace Programs

3

- 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: Brian Makela
- 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

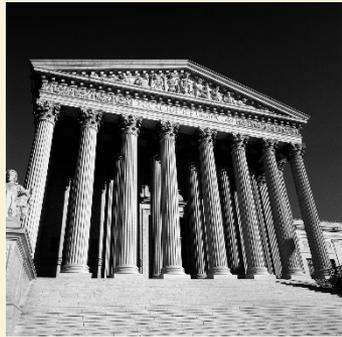
Policy

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

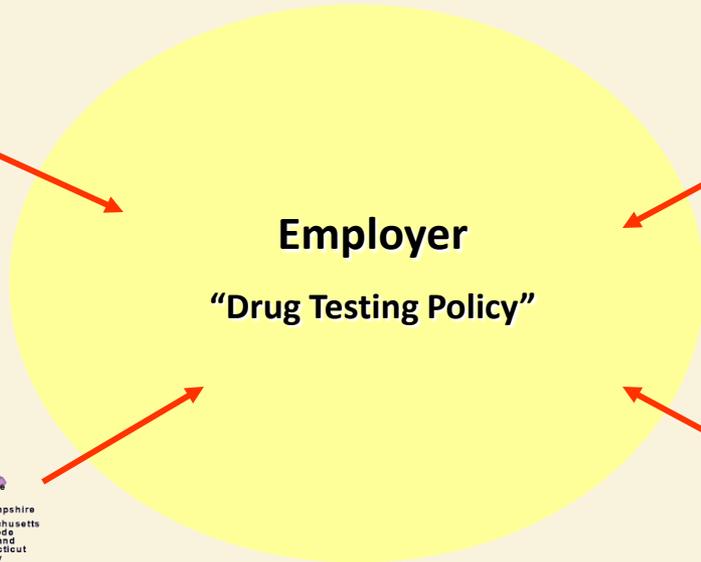
Drug Free Workplace Programs



Federal Laws



Testing Issues



State Laws



Contract / Legal Issues

DWP Objectives and Goals

- **Present:** Implementation of the revised urine Mandatory Guidelines and in the process of approving oral fluid as an alternative specimen in Federal Workplace Drug Testing Programs
- **Future:** Writing the Proposed Hair Mandatory Guidelines
- **Overall Goal:** Implementing semi-synthetic opioid testing in the regulated programs (hydrocodone, oxycodone, hydromorphone, oxymorphone).

Revised Urine Mandatory Guidelines

- Published in Federal Register January 23, 2017
 - 82 FR 7920, Pages 7920-7970
- Effective date: October 1, 2017
- 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 an alternative specimen (oral fluid) when authorized

Revised MG Effective Date: October 1, 2017

- HHS-certified labs on target to meet the Oct 1, 2017 effective date (Qualifying Performance Testing Samples)
 - HHS understands there were laboratory Information Technology (IT) issues due to non-uniform implementation, and is here to help in any way we can.
- Federal Agency Drug Program Coordinators have been sent an assurance statement the Agencies DFWP has been changed to be consistent with the requirements in the MG and testing of opioids.
- HHS Secretary's priority is on the Opioid crisis. The testing for the synthetic Opioids could help to provide treatment for employees in federal agencies, and deter illicit use of prescription opioids.
- The New CCF will be in effect for Federal Agencies. The previous (2014) CCF has been extended to June 1, 2018

Oral Fluid Mandatory Guidelines

- THC/THCA
 - Technical and Scientific Peer Reviewed Journal Articles
 - NLCP will provide a list to Directors / MROs / Inspectors
 - Thank you to Dr. Ed Cone and Dr. Ryan Vandrey
- Proposed Implementation date: 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 under the proposed Oral Fluid Mandatory Guidelines

New Mandatory Guidelines

10

New Mandatory Guidelines for Oral Fluid

- HHS is continuing to look at options for which marijuana analytes may be used.
- No single immunoassay detects both THC and THCA at the proposed OFMG cutoffs. 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, as allowed by the mandatory guidelines.
- 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).
- HHS does not accept passive exposure as a reason to test positive.

Hair Mandatory Guidelines

11

- DWP staff is writing the draft proposed Hair Mandatory Guidelines
- Proposed research studies around Unique Metabolites
- Secretary approval of the Drug Testing Advisory Board's recommendation to pursue hair as an alternative specimen
- Scientific and technical issues have to be addressed for the proposed Mandatory Guidelines for Hair

Proposed Mandatory Guidelines

12

Hair Mandatory Guidelines for Federal Agencies

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

Challenges

13

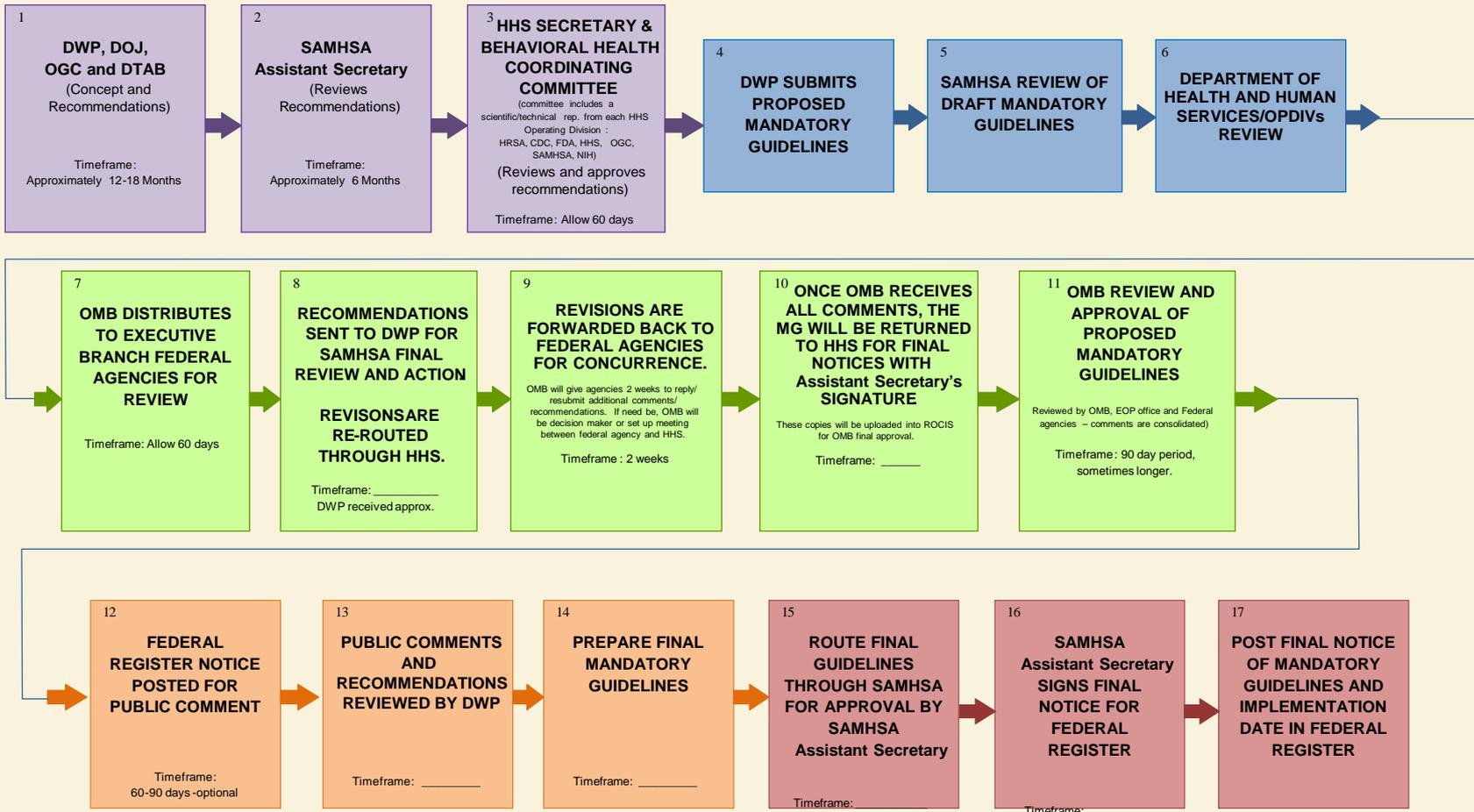
- Implementing the Oral Fluid Mandatory Guidelines
- Funding for this new program
- Review of the technical and scientific studies to support hair decontamination procedures and unique biomarkers / metabolites to rule out external contamination
- Addressing DTAB's recommendation
- Addressing the Emerging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

Opportunities

14

- Implementing the revised Mandatory Guidelines for Urine including the semi-synthetic opioids
- Oversight and standardization of the regulated industry in testing for the semi-synthetic opioids
- 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

Guideline Routing Process



MRO Guidance Manual Update

16

- Major Issues
 - Addressing the addition of Rx opioid drugs to drug testing panel: Oxycodone, oxymorphone, hydrocodone, hydromorphone.
 - Hydrocodone combination drugs have been rescheduled to Schedule II
 - “What is considered a valid prescription under the Drug-Free Workplace Programs and how will it be interpreted by the Medical Review Officer?”
- Mandatory Guidelines for Federal Workplace Drug Testing Programs
 - Subpart M – Medical Review Officer (MRO), Section 13.1

Rx

Ongoing Studies

- Cannabidiol Study
 - Tentative start date was: August 2017
- 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
- Retrospective Opioid Study: 520 de-identified specimens tested using current and revised Guidelines
 - Current: 1 confirmed positive (MOR)
 - Revised: 9 - 1 MOR, 5 HYC/HYM, 1HYM, 1 OXC/OXM, 1 OXM
 - 10 Fold Increase in Positive semi-synthetic Opioids

Marijuana in Science

18

Exploring butane hash oil: a research note

Medical marijuana for cancer

Cannabis effects on
driving lateral control
with and without alcohol

Mitigation of marijuana-related legal harms to youth in California

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

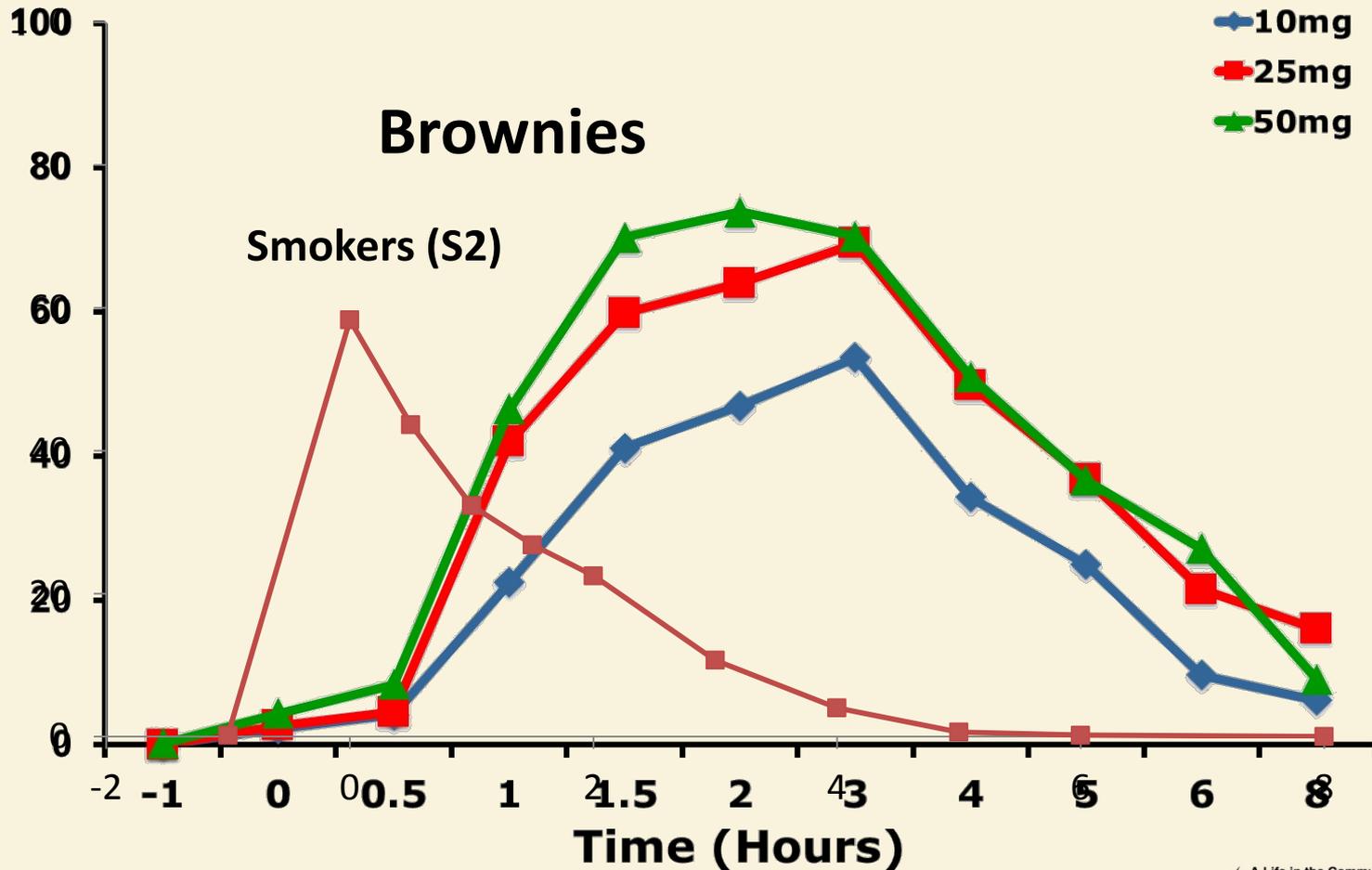


DUID Testing



- DWP supporting the methods that minimize the rates of driving under the influence of drugs
- DWP has developed guidelines for federal workplace drug testing that can be used by other programs including law enforcement

Edible Results: “Drug Effect”



(Courtesy of Ryan Vandrey, JHU)

Emerging Issues/Synthetic Drugs

24

- 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/>