

Welcome and Opening Remarks

Center for Substance Abuse Prevention

Drug Testing Advisory Board

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DTAB Chair

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

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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: CDR Eugene D. Hayes, Ph.D., M.B.A.
- 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.
- Senior Pharmacology and Regulatory Policy Advisor: Vacant
- Toxicologist: Vacant
- Program Assistant: Vacant

Drug Testing Advisory Board Members

- Kristen Burke (new member)
- D. Faye Caldwell, J.D.
- Randal E. Clouette, M.S., NRCC-TC
- David A. Green, Ph.D., DABCC, FACB
- Costantino A. Iannone
- Deborah Motika, M.S. (new member)
- Barry R.H. Sample, Ph.D.
- Jason E. Schaff, Ph.D.
- Michael I. Schaffer, Ph.D., F.A.B.F.T., NRCC-TC
- Stephen Mark Taylor, M.D., M.P.H., F.A.S.A.M. (new member)

Regulation

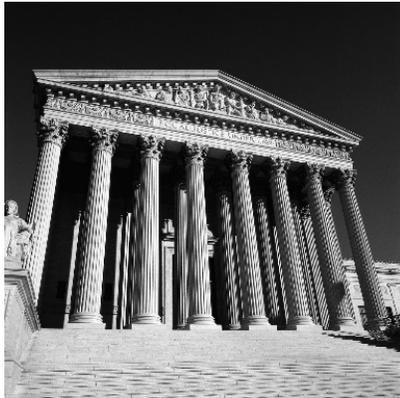
Policy

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

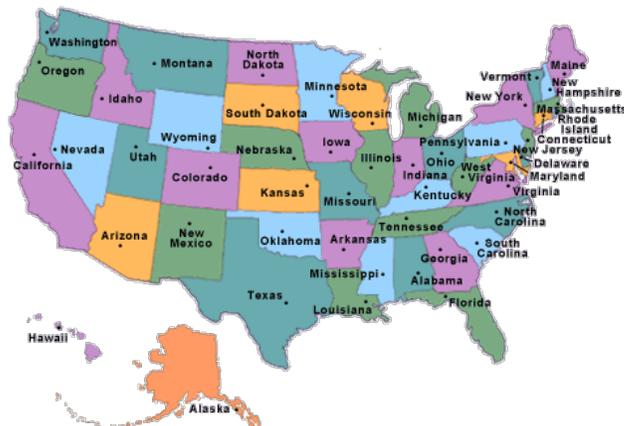
Drug Free Workplace Programs



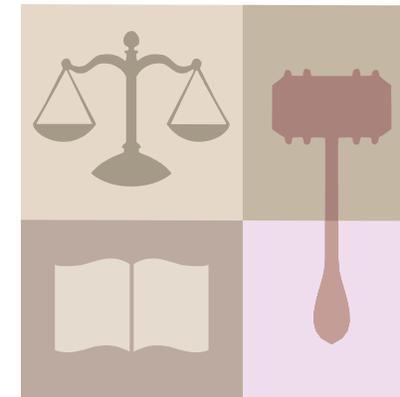
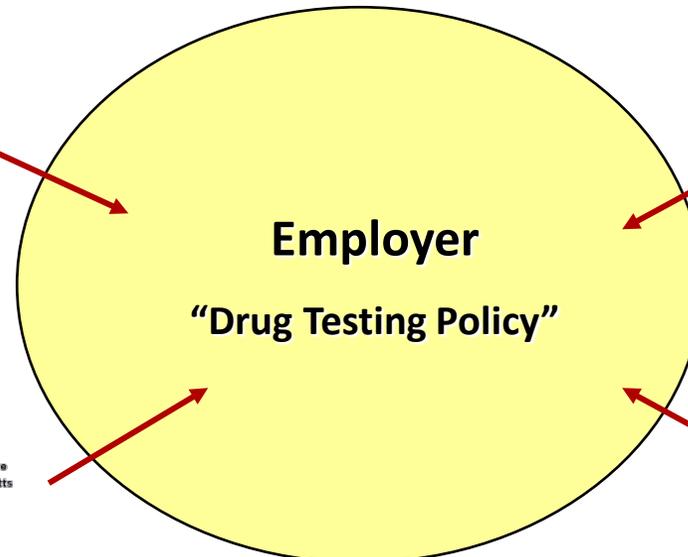
Federal Laws



Testing Issues



State Laws



Contract / Legal Issues

DWP Objectives and Goals

- **Goals:** Establish an implementation date for the Mandatory Guidelines using Oral Fluid. The Proposed Mandatory Guidelines using Hair have been referred to Office of Management and Budget for review.
- **Present:** Receive final approval for Mandatory Guidelines using Oral Fluid as an alternative specimen to enhance the Federal Workplace Drug Testing Program.
- **Future:** Referral of the Proposed Mandatory Guidelines using Hair for distribution to all federal agencies for comment and review.

Revised Urine Mandatory Guidelines

- Published in the January 23, 2017 Federal Register.
 - 82 FR 7920, Pages 7920-7970.
- Implementation date: October 1, 2017 (20 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.

Drug Testing Panel

1) Cocaine

2) Amphetamines

3) Marijuana

4) Phencyclidine (PCP)

5) Opioids

- Codeine
- Morphine
- 6-AM
- Hydrocodone
- Hydromorphone
- Oxycodone
- Oxymorphone

6) Emerging Drugs: Fentanyl?

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.

Effective Date: October 1, 2017

- 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 **current** federal Custody and Control Form (CCF) is in effect for Federal Agencies and regulated testing until June 1, 2020. The process for development of a new Oral Fluid CCF has started.

Oral Fluid Mandatory Guidelines

- Marijuana Studies:
 - Technical and Scientific Peer Reviewed Journal Articles.
 - DWP continues to update this list of reference articles.
 - Thank you to Dr. Ed Cone and Dr. Ryan Vandrey as Principle Investigators.
 - Studies (CBD) and data for marijuana analytes are under review.
- Federal Register Notice: 2019?
- Inclusion of oral fluid as a new matrix in the federal program will enhance the DFWP.
- To be developed: NLCP Oral Fluid Program documents, MRO Guidance Manual including oral fluid, Oral Fluid Specimen Collection Handbook, Collection Site Checklist and Manual.

Oral Fluid Mandatory Guidelines (continued)

- 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).
- Establish an Implementation Date for HHS Certification of Laboratories.

Hair Mandatory Guidelines

- The proposed Mandatory Guidelines for Federal Workplace Drug Testing using Hair has been sent to OMB.
- Comments and recommendations have been received from HHS Operational Divisions and incorporated.
- SAMHSA is proposing to seek federal agency comment and recommendations on the proposed Mandatory Guidelines.
- SAMHSA is proposing to seek public comment and recommendations on issues concerning the implementation of the Mandatory Guidelines using hair.

Proposed Mandatory Guidelines

Proposed Mandatory Guidelines using Hair

- DTAB recommendation was to pursue hair testing as an alternative matrix:
- As recommended by DTAB, development of the proposed Mandatory Guidelines using Hair has attempted to address some of the scientific issues for the use of hair as a drug testing specimen.
- The proposed Mandatory Guidelines using hair will be sent to other federal and federally regulated agencies for recommendations and review.

Patients and Communities Act, P.L. 115-271

Status Report on Hair Testing

- Requires the Secretary of HHS to report to Congress on the status of the final notice for the statutorily-required scientific and technical guidelines for hair testing, within 60 days of enactment of the Act and annually thereafter, until the agency publishes a final notice of guidelines for hair testing.
- Several provisions for the federal and federally regulated entities in the Fighting Opioid Abuse in the Transportation Act of 2018.

Fighting Opioid Abuse in the Transportation Act 2018.

Advantages of Hair Testing

- Directly observed specimen collection.
- Non-invasive specimen collection.
- Difficult to adulterate or substitute.
- Readily available sample, depending on length of hair tested.
- Drug metabolites are present in hair as early as one week after most recent use.

Child Adolesc Psychiatric Clin N Am 25 (2016) 549-565 <http://dx.doi.org/10.1016/j.chc.2016.02.005>

Mandatory Guideline Routing Process



MRO Guidance Manual Update

- MRO Manual Update: Urine
 - 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.
 - Expired Prescriptions.
- Mandatory Guidelines for Federal Workplace Drug Testing Programs
 - Subpart M – Medical Review Officer (MRO), Section 13.1



Patients and Communities Act, P.L. 115-271

Fentanyl

Sec. 4106. Requires the Secretary of HHS, within 180 days, to

(A) determine whether a revision of the Mandatory Guidelines for Federal Workplace Drug Testing Programs to expand the opiate category on the list of authorized substance testing to include fentanyl is justified, based on the reliability and cost-effectiveness of available testing; and

(B) consider whether to include with the determination under subparagraph (A) a separate determination on whether a revision of the Mandatory Guidelines for Federal Workplace Drug Testing Programs to expand the list of substances authorized for testing to include any other drugs or other substances listed in schedule I and II of section 202 of the Controlled Substances Act ([21 U.S.C. 812](#)) is justified based on the criteria described in subparagraph (A).

Fighting Opioid Abuse in the Transportation Act 2018.

Ongoing Studies

- Cannabidiol (CBD) Study
 - Start date: June 2018.
- Pharmacokinetics and Pharmacodynamics Study: Oral, Smoked, and Vaporized CBD
 - Disposition of CBD / Cannabinoids in Oral Fluid and Whole Blood after Vaporized and Smoked Cannabis.
 - Pharmacodynamic Comparison of CBD / Cannabinoids Following Oral, Smoked, and Vaporized Administration.
- Gathering Opioid Data under the Revised Mandatory Guidelines using Urine
 - pH Changes.
 - Invalid Results.
 - Substitution / Adulteration.

Epidiolex

- Epidiolex® is an FDA approved cannabinoid product. Approved in June 2018 for the treatment of young patients (over two years old) with seizures associated with Lennox-Gastaut syndrome (LGS) and Dravet syndrome.
- Sold as an oral solution.
- The first FDA- approved drug that contains a purified drug substance derived from marijuana -- CBD -- and the first treatment for Dravet syndrome.
- Scheduled V drug.
- All other CBD products remain Schedule I.

Emerging Issues/Synthetic Drugs

- DUID and Marijuana Laws
- CBD Studies continue
- Other potential problems with synthetic drugs are 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

<https://www.samhsa.gov/workplace>