Proposed Analyte Table Change Process
Workplace Drug Testing

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

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Ms. Lisa Davis, Senior Toxicologist Policy Advisor

DTAB Open Session

December 5, 2023

DTAB Members Discussion

SAMHSA
Substance Abuse and Mental Health Services Administration

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."*

- **Goal:** Comprehensive Review of the Federal Drug Testing Program and current state of the DFWP, examine the issues affecting the program, outline responses to these critical issues and look at initiatives to address the unanswered questions.

- **Future**: *Identify key policy and technical issues as well as the existing challenges* for Implementation of the Mandatory Guidelines using oral fluid and/or hair, look at ongoing studies for cannabis, and enhancements to the Federal Drug Testing Program.

Mandatory Guidelines Update

Urine

CURRENT Mandatory Guidelines for Federal Workplace Drug Testing using Urine effective February 1, 2024.

https://www.regulations.gov/document/HHS_FRDOC_0001-0914

Oral Fluid

CURRENT Mandatory Guidelines for Federal Workplace Drug Testing using Oral Fluid (OFMG) effective October 10, 2023.

https://www.regulations.gov/document/HHS_FRDOC_0001-0915

Hair

PROPOSED Mandatory Guidelines for Federal Workplace Drug Testing Programs using Hair in September 10, 2020 Federal Register for public comment.

https://www.govinfo.gov/content/pkg/FR-2020-09-10/pdf/2020-16432.pdf

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
   - Approve MRO certifying entities

*MROs review and report drug testing results.

Programs Outcomes:

- National drug testing standards
- Multiple specimen types (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 (TDPs) or safety-sensitive positions
4. **Policies/Legislation:** Evaluating impact of policies and legislation on the DFWP, e.g., Farm bill, state marijuana decriminalization.

Program Outcomes:

- Certified DFWP plans for all federal agencies
- DFWP policy and procedures for all federal agencies
- Policy Discussions with Office of National Drug Control Policy (ONDCP)
- Policy and Legislation Impact on the DFWP

The DWP Emerging Issues group addresses both components of science and policy.

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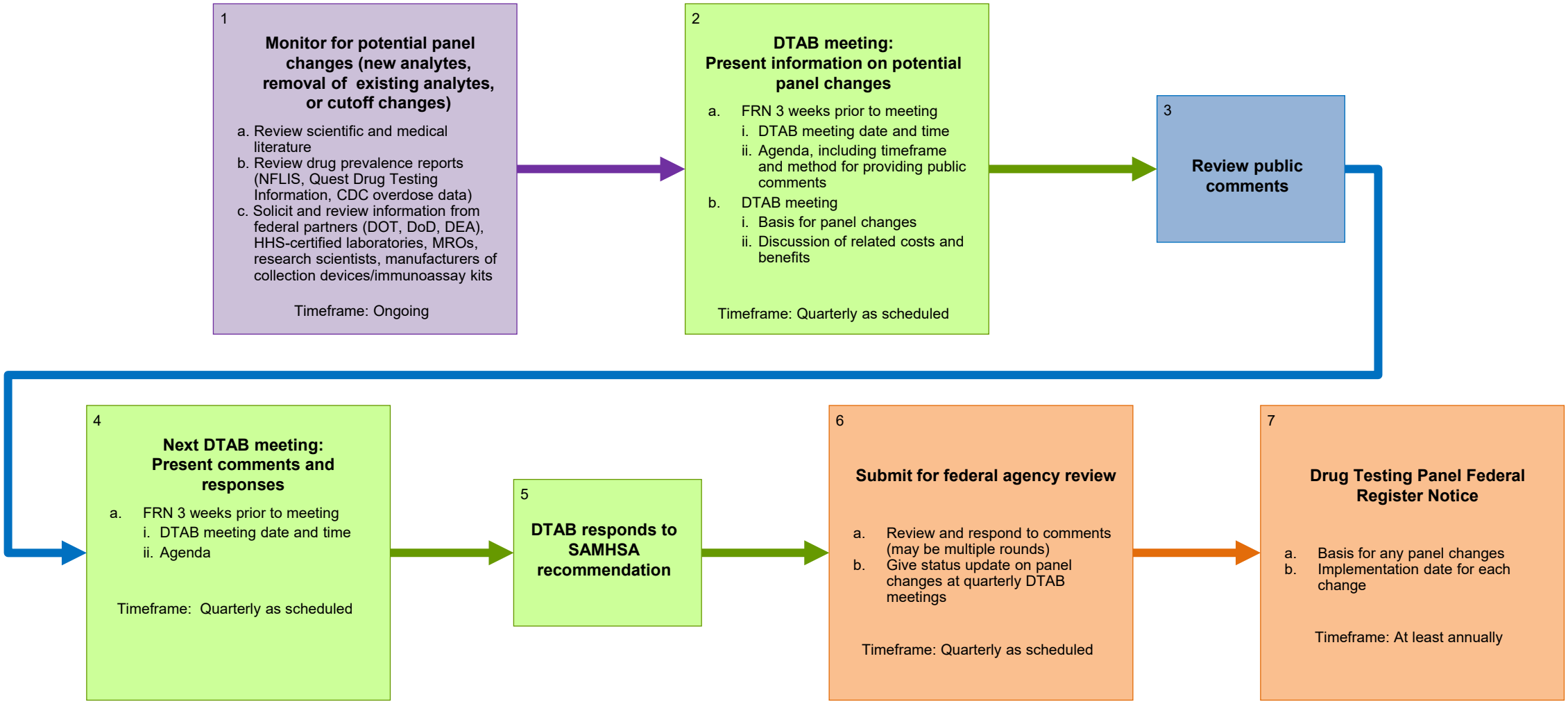
Proposed Process for Drug Testing Panel Changes



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Review Process: Urine and Oral Fluid Drug Testing Panels

1. Ongoing monitoring for potential panel changes
   a. Review scientific and medical literature
   b. Review drug prevalence reports (NFLIS, Quest Drug Testing Information, CDC overdose data)
   c. Solicit and review information from federal partners (DOT, DoD, DEA), HHS-certified laboratories, MROs, research scientists, manufacturers of collection devices/immunoassay kits

2. Quarterly DTAB meeting: present information on potential panel changes
   a. FRN 3 weeks prior to meeting
      i. DTAB meeting date and time
      ii. Agenda including timeframe and method for providing public comments
   b. DTAB meeting
      i. Basis for panel changes
      ii. Discussion of related costs and benefits

3. Review of public comments

Review Process: Urine and Oral Fluid Drug Testing Panels

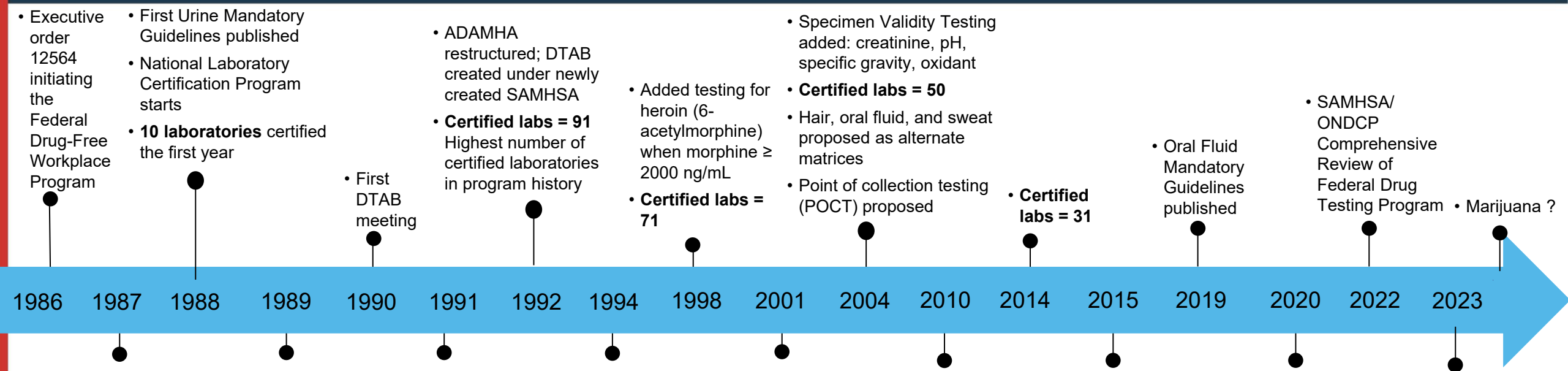
4. Next DTAB meeting: present comments and responses
    a. FRN 3 weeks prior to meeting
        i. DTAB meeting date and time
        ii. Agenda

5. DTAB responds to SAMHSA recommendation

6. Federal review process
    a. Review and respond to comments (may be multiple rounds)
    b. Give status updates on panel changes at quarterly DTAB meetings

7. Drug Testing Panel Federal Register Notice (at least annually)
    a. Basis for any panel changes
    b. Implementation date for each change

Federal Drug Free Workplace Program



*Alcohol, Drug Abuse and Mental Health Administration

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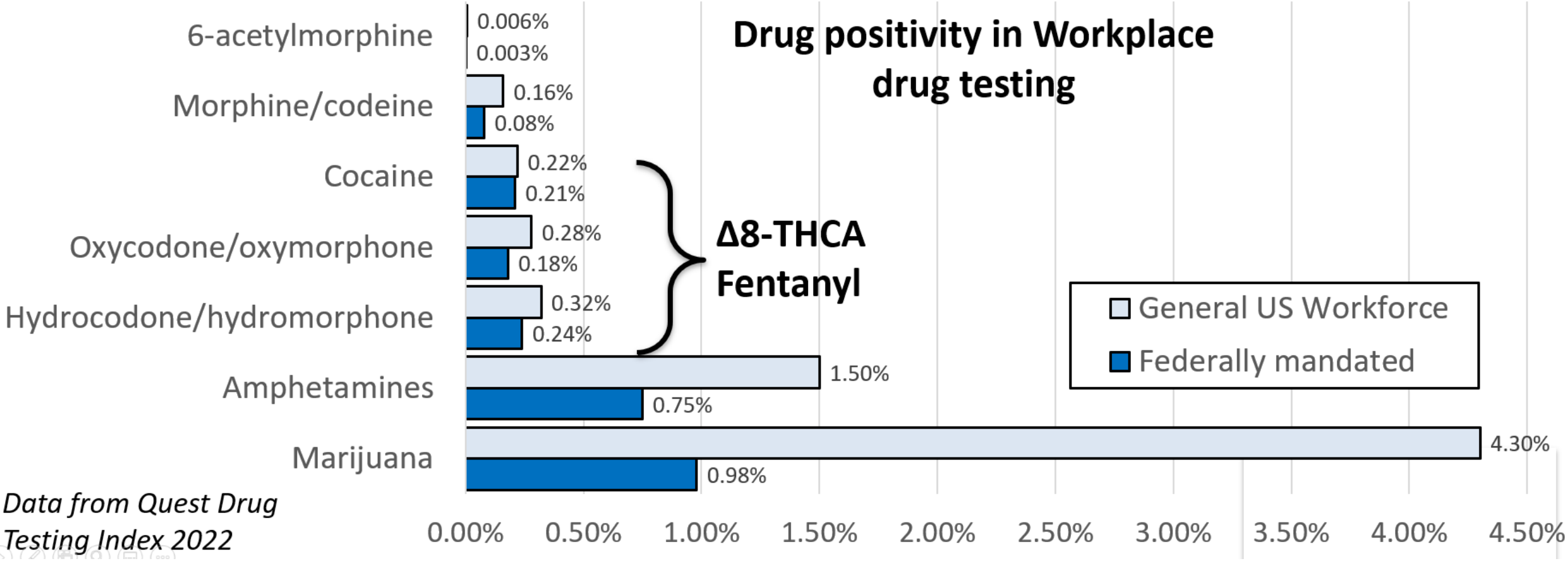
Estimated prevalence of Δ8-THCA and fentanyl

Δ8-THCA
Around 0.27%
(w/o marijuana ~0.1%)

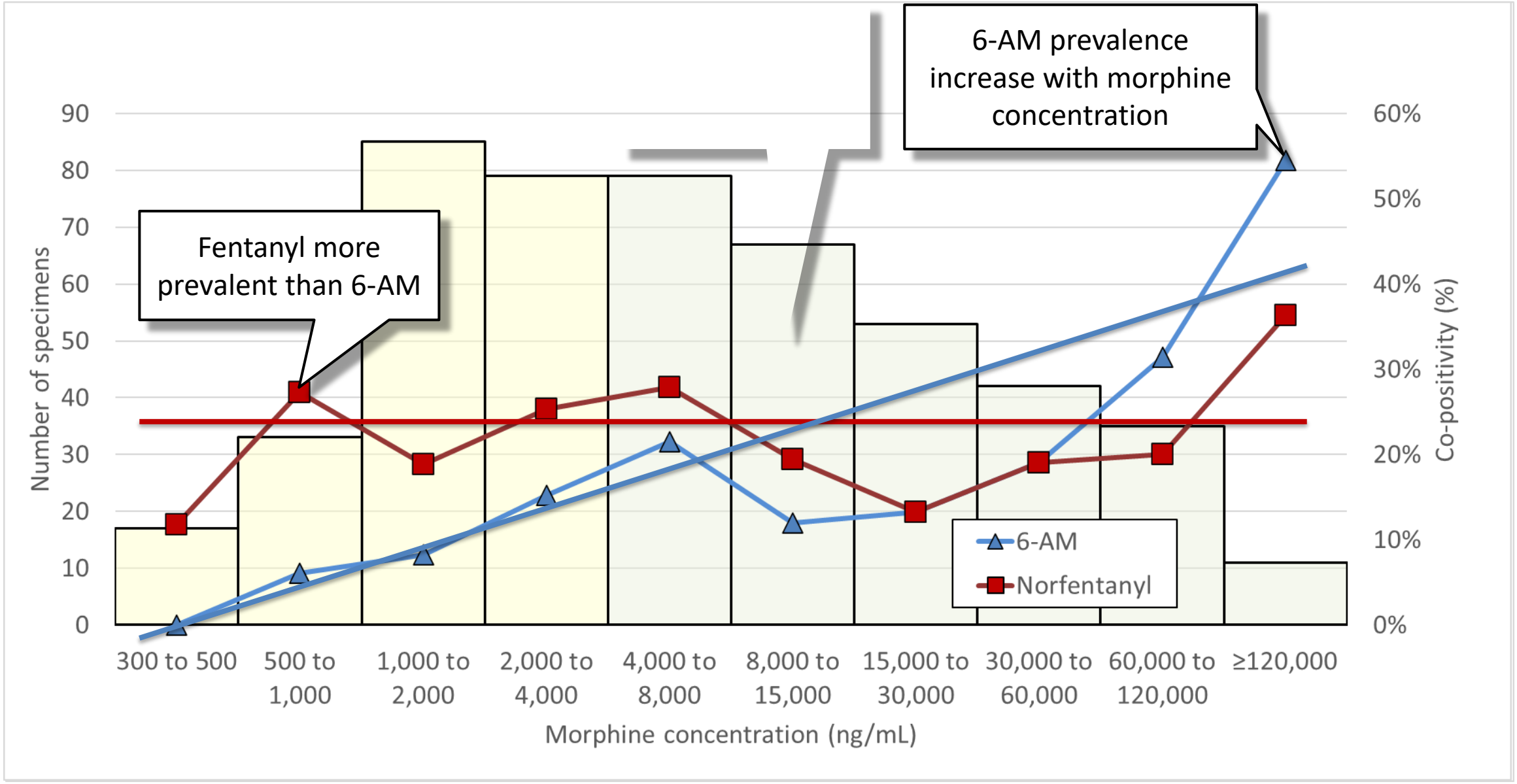
Both drugs among most prevalent in workplace drug testing

Fentanyl
Around 0.19%
(2017 and 2019 data)



Data from Quest Drug Testing Index 2022

Fentanyl more prevalent than 6-acetylmorphine (6-AM)



Analyte Table Update

Written comments regarding the addition of Fentanyl to the analyte table will be accepted for review for an additional 30 days no later than January 4th, 2024

Urine Analyte	Initial Test Cutoff	Confirmation Cutoff
Fentanyl	1 ng/mL	0.5 ng/mL
Norfentanyl	1 ng/mL	0.5 ng/mL

Oral Fluid Analyte	Initial Test Cutoff	Confirmation Cutoff
Fentanyl	1 ng/mL	0.5 ng/mL

Please submit those comments to: DFWP@samhsa.hhs.gov

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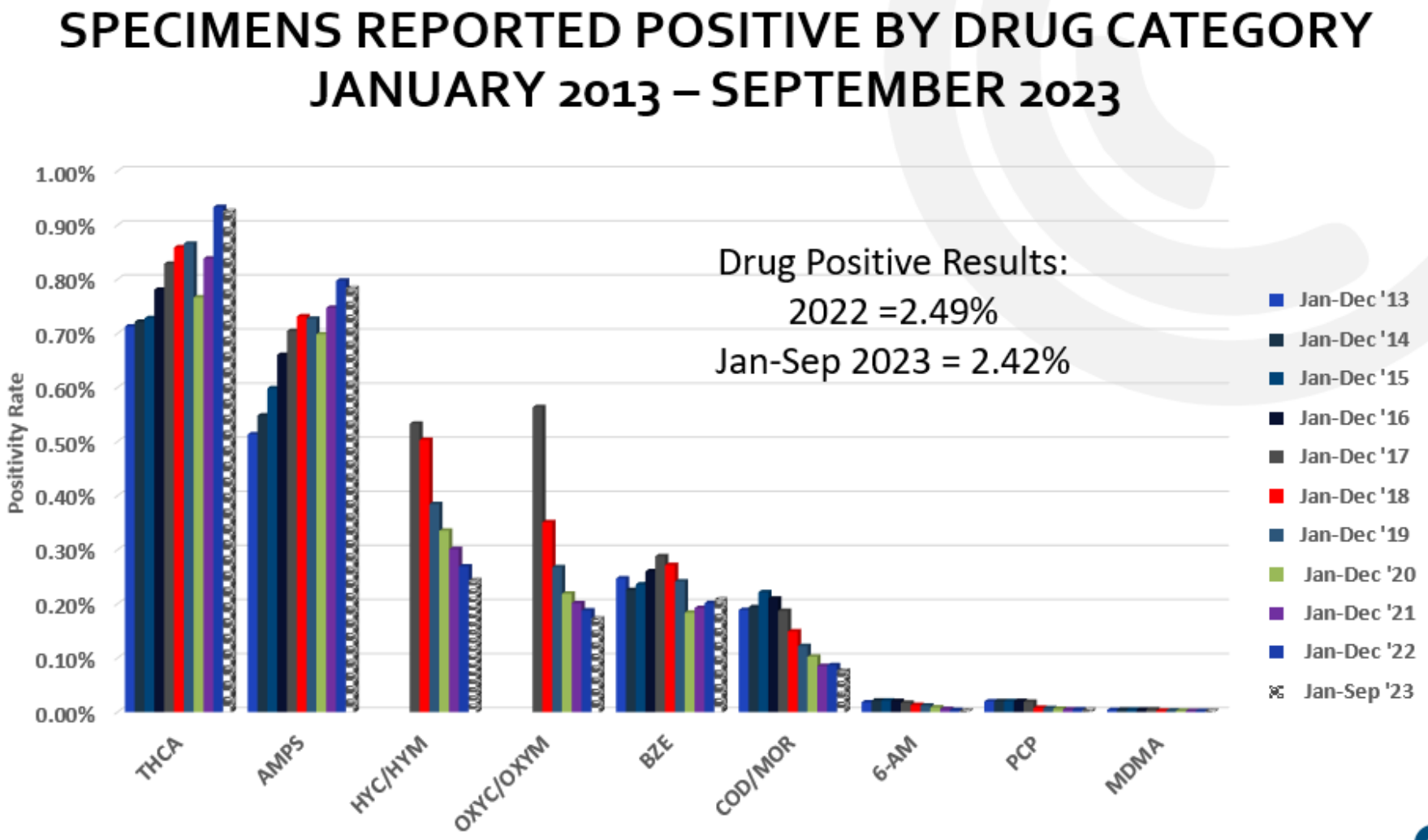
Drug Positivity Rates: Blind QC Included



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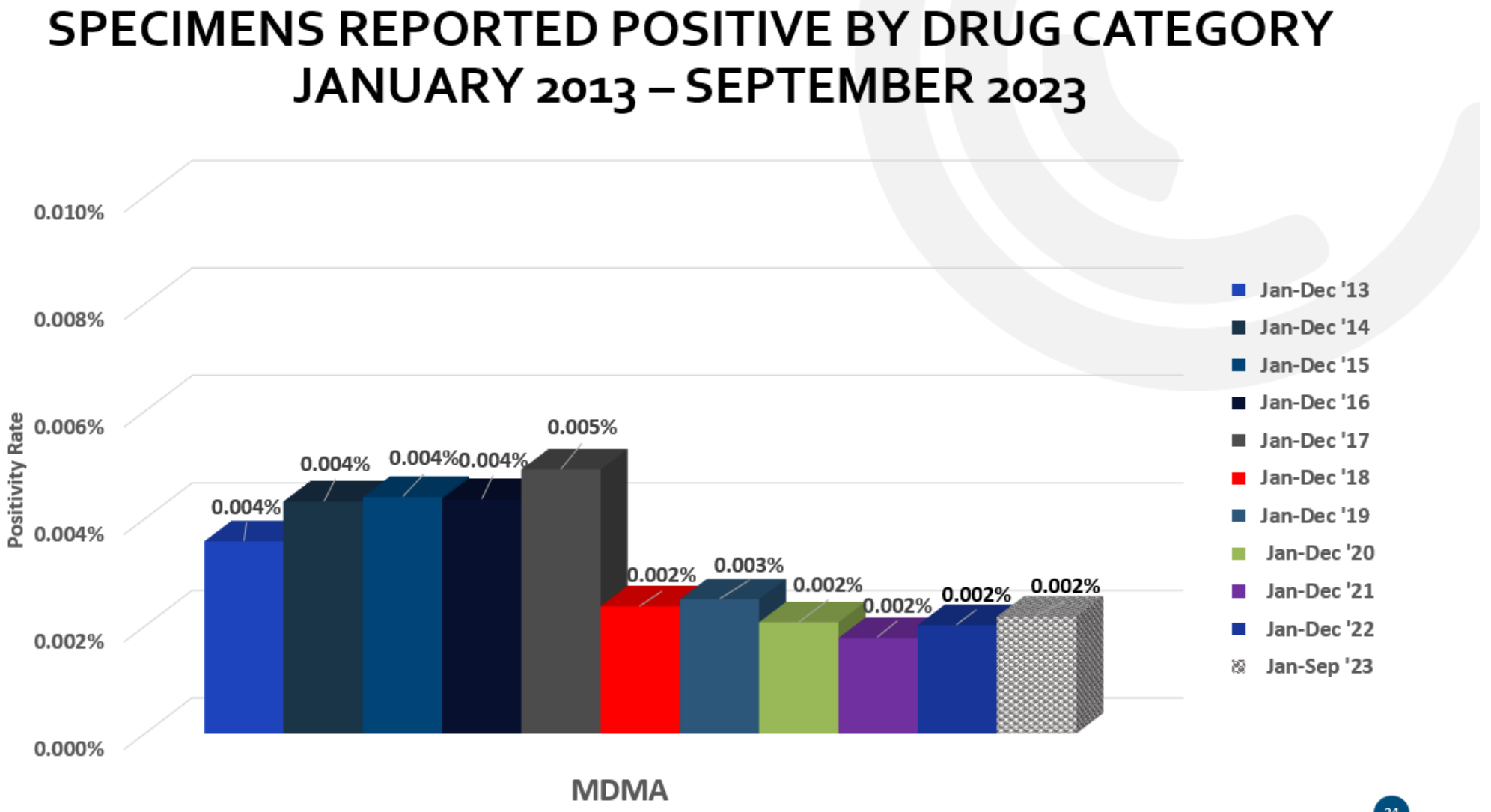
MDMA Positivity Rates: Blind QC Included



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MRO Guidance Manual and Case Studies

- Updates based on the 2023 UrMG and OFMG. Examples:
  - Revisions to MRO verification process
  - Annual Authorized Drug Testing Panels, Authorized Biomarker Testing Panels, and Required Nomenclature for MRO Reports
  - MRO semi-annual reports to SAMHSA
- Updates based on MRO-relevant information from SAMHSA. Examples:
  - NLCP Notices
  - DRAFT NLCP Manuals for Urine and Oral Fluid Laboratories
  - Guidance for Using the 2023 Federal CCF
  - DRAFT MRO Case Studies
- The 2023 MRO Guidance Manual and Case Studies will be posted on the SAMHSA website.

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Action Plans

Priority	#	Action	POC	Decision-maker	Actions/Steps
1	*1*	***Pursue emergency clearance strategy with FDA; alternatively, remove FDA clearance requirement and allow certified laboratory validation of IA kits***	***Lisa***	***FDA/ HHS***	• ***FDA Meeting*** • ***DTAB*** • ***Develop new process*** • ***Recommendations/Changes*** • ***Implement Guidelines changes***
1	2	Conduct quarterly ICGEC meetings; open some sessions to DPCs; create topic-focused groups of DPCs	Ron	Asst. Sec.	• Amplify message re: cannabis • OASH – presentation - Principals' meeting • Develop 15-minute summary of DWP data and implications
1	***3***	***Reduce length of time required to change the testing panel***	***Ron***	***Asst. Sec***	• ***DWP/SMEs/NLCP Meeting*** • ***Implement Surveillance Program*** • ***Develop Criteria for Adding Analytes*** • ***DTAB Presentations*** • ***Align New Process*** • ***Recommendations/Decision/Changes*** • ***Implement Guidelines changes***
1	*4*	*Align goals and timelines for SAMHSA/DWP and regulated agency partners*	*Ron*	*DWP*	• *Federal Partners Meeting* • *Align Goals / Regulations / MRO Verification Reporting* • *Develop Process/DTAB* • *Recommendations/Changes* • *Implement Regulatory Changes* • *Ongoing Dialogue*
1	*5*	*Develop and add surveillance program*	*Eugene*	*DWP/ NLCP*	• *DWP/SMEs/NLCP Meeting include DoD* • *Implement Surveillance Program: Drugs and SVT* • *Meets Criteria* • *Align New Process/Data* • *Recommendations/Decision/Changes* • *Implement Guidelines changes*

Action Plans

Priority	#	Action	POC	Decision-maker	Actions/Steps
1	***6***	***Identify and accomplish program process improvements that do not require a regulatory process***	***Ron***	***DWP/ NLCP***	• ***DWP/SMEs/NLCP Meeting*** • ***Program Focus/Fed Partners Meeting*** • ***DTAB Presentation*** • ***Align New Process/ OGC Review*** • ***Recommendations/Decision/Changes*** • ***Implement Guidelines changes if necessary***
2	7	*Review and streamline (where possible) Program requirements (Responsible Person, audits, initial testing, SVT)*	*Lisa/ Eugene*	*DWP/ NLCP*	• *DWP/NLCP Meeting* • *Program Focus* • *Align New Process/ OGC Review* • *Recommendations/Decision/Changes* • *Implement Guidelines changes if necessary*
2	8	*Improve program implementation by providing training on recovery-ready concepts, EAPs, Safe Harbor options, and test scheduling, completion, and reporting; incorporate in DPC Orientation content*	*Hyden*	*DWP/ ONDCP*	• *DWP/ONDCP Meeting* • *DWP / OPM Meeting* • *DTAB Presentation / DPCs* • *Align New Process/ SAMHSA Review* • *Recommendations/Decision/Changes*
3	9	*Identify and relieve (where possible) MRO burdens*	*Josh*	*DWP/ NLCP*	• *DWP/SMEs/NLCP Meeting* • *Program Focus/Fed Partners Meeting* • *DTAB Presentation / Discussion* • *Recommendations/Decision/Changes* • *Implement Guidelines changes if necessary*
3	**10**	***Leverage recovery-ready workplace initiatives to generate more top-down support for and commitment to the Program***	***Hyden***	***DWP/ NLCP***	• ***DWP/ONDCP Meeting*** • ***DWP / OPM Meeting*** • ***DTAB Presentation / DPCs*** • ***Align New Process/ SAMHSA Review***
3	11	*Utilize discussions around cannabis scheduling to focus attention on the Program and its strong rehabilitative intent*	*Ron*	*DWP/Asst Sec*	• *SME / DOJ / SAMHSA Meeting* • *Leg Affairs / OGC Meeting* • *DOJ / OGC Review* • *Recommendations/Decision/Changes*
4	12	*Re-evaluate criteria for dilute and pH invalid*	*Eugene*	*DWP/ NLCP*	• *DWP/ SMEs / NLCP Meeting* • *Program Focus* • *Align New Process/ OGC Review* • *Recommendations/Decision/Changes* • *Implement Guidelines changes if necessary*

Road Map and Action Plans

- Pursue clearance strategy with FDA
- Reduce the length of time required to change the testing panel
- Develop and add a pulse testing (emerging drugs, specimen validity issues)
- Review and streamline Program processes (inspections and audits)
- Align goals and timelines for SAMHSA/DWP and regulated agency partners

Analyte Table Update Issues

- Time required to respond to changes to authorized analytes, cutoffs and matrices
  - Time required for Mandatory Guideline revisions
  - Time for FDA Clearance of new assays and devices

Analyte Table Update Process

1. Drug Testing Advisory Board (DTAB) Presentation
    a. Board Discussion
    b. Public Comment
2. Review Public Comments
3. Review Public Comments at subsequent DTAB
4. Publish FRN

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Existing FDA Paradigm*

- Drugs of Abuse assays are reviewed and 510(k) cleared for detection of drugs around a specific cutoff

- Least burdensome principles:
  - the minimum amount of information
  - address a relevant regulatory question or issues
  - the most efficient manner
  - at the right time

*FDA Presentation DTAB June 2023

FDA Triage – Quick Review Program*

- FDA identifies complete submissions
  - 510(k) submission complete or “substantially equivalent”
  - Same characteristic as predicate
  - Different characteristics without new questions of public health

- FDA Review can be as short as a month

*FDA Presentation DTAB June 2023

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FDA Change Protocol*

- Make changes to a device to respond to an evolving need:
  - Change cutoff
  - Add a new analyte
- Can use the 510(k) substantial equivalence determination language
- Submit with initial application – validation protocol for change
- Do NOT have to return to FDA for a new 510(k) review
  - Do they need to contact FDA with the update?
  - Can they update their package inserts?

*FDA Presentation DTAB June 2023

Resources

- June DTAB Meeting link:

https://www.samhsa.gov/meetings/dtab-meeting-june-2023

- FDA link to request feedback to specific questions:

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program

- Joey Kotarek FDA Contact: Joseph.kotarek@fda.hhs.gov

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Thank You
Division of Workplace Programs

Please Visit our Website

https://workplace.samhsa.gov/

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