



DTAB Future Direction

SAMHSA's
Center for Substance Abuse Prevention
Drug Testing Advisory Board

Ron Flegel, B.S., MT(ASCP), M.S.
Chair DTAB

August 6-7, 2015



Drug Testing Advisory Board

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- Discussion Points
 - Goals
 - Milestones
 - Objectives
 - Updates

Division of Workplace Programs

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- Director: Ron Flegel, B.S., MT(ASCP), M.S.
- CDR Sean Belouin, Pharm.D.
- Janine Denis Cook, Ph.D., DABCC, FACB
- CAPT Jennifer Fan, Pharm.D., J.D.
- Deborah Galvin, Ph.D.
- Eugene D. Hayes, Ph.D., M.B.A.
- Charles LoDico, M.S., F-ABFT
- Coleen Sanderson
- Hyden Shen, J.D.
- Program Assistant: Giselle Hersh

DTAB Goals

- To assist SAMHSA in:
 - Implementation of Mandatory Guidelines for Urine (URMG)
 - Implementation of Mandatory Guidelines for Oral Fluid (OFMG)
 - Evaluation of hair as an alternate specimen

Publications

Publications:

- Cone, E.J., Heltsley, Black, D.L., Mitchell, J.M., LoDico, C.P., and Flegel, R.R. Prescription Opioids. I. Metabolism and Excretion Patterns of Oxycodone in Urine Following Controlled Single Dose Administration. *J. Anal. Toxicol.* 37: 255-264, 2013.
- Cone, E.J., Heltsley, Black, D.L., Mitchell, J.M., LoDico, C.P., and Flegel, R.R. Prescription Opioids. II. Metabolism and Excretion Patterns of Hydrocodone in Urine Following Controlled Single Dose Administration. *J. Anal. Toxicol.* 37: 486-494, 2013.
- Cone, E.J., Bigelow, G.E., Herrmann, E.S., Mitchell, J.M., LoDico, C., Flegel, R., and Vandrey, R., Non-Smoker Exposure to Secondhand Cannabis Smoke. I. Urine Screening and Confirmation Results. *J. Anal. Toxicol.* 39: 1-12, 2015.
- Cone, E.J., DePriest, A.Z., Heltsley, R., Black, D.L., Mitchell, J.M., LoDico, C., and Flegel, R. Prescription Opioids. III. Disposition of Oxycodone in Oral Fluid and Blood following Controlled Single Dose Administration. *J. Anal. Toxicol.* 39: 192-202, 2015.
- Cone, E.J., DePriest, A.Z., Heltsley, R., Black, D.L., Mitchell, J.M., LoDico, C., and Flegel, R. Prescription Opioids. IV. Disposition of Hydrocodone in Oral Fluid and Blood following Single Dose Administration. *J. Anal. Toxicol.*, 2015.
Herrmann, E.S., Cone, E.J., Mitchell, J.M., Bigelow, G.E., LoDico, C., Flegel, R., and Vandrey, R., Non-Smoker Exposure to Secondhand Cannabis Smoke. II. Effect of Room Ventilation on the Physiological, Subjective, and Behavioral/Cognitive Effects. *Drug and Alcohol Dependence* 151:194-202, 2015.
- Cone, E.J., Bigelow, G.E., Herrmann, E.S., Mitchell, J.M., LoDico, C., Flegel, R., and Vandrey, R. Non-Smoker Exposure to Secondhand Cannabis Smoke. III. Oral Fluid and Blood Drug Concentrations and Corresponding Subjective Effects. *J. Anal. Toxicol.*, 2015.

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- Cone, E.J., Heltsley, Black, D.L., Mitchell, J.M., LoDico, C.P., and Flegel, R.R. Prescription Opioids. II. Metabolism and Excretion Patterns of Hydrocodone in Urine Following Controlled Single Dose Administration. *J. Anal. Toxicol.* 37: 486-494, 2013.
- Cone, E.J., Bigelow, G.E., Herrmann, E.S., Mitchell, J.M., LoDico, C., Flegel, R., and Vandrey, R., Non-Smoker Exposure to Secondhand Cannabis Smoke. I. Urine Screening and Confirmation Results. *J. Anal. Toxicol.* 39: 1-12, 2015.
- Cone, E.J., DePriest, A.Z., Heltsley, R., Black, D.L., Mitchell, J.M., LoDico, C., and Flegel, R. Prescription Opioids. III. Disposition of Oxycodone in Oral Fluid and Blood following Controlled Single Dose Administration. *J. Anal. Toxicol.* 39: 192-202, 2015.

Publications

Publications:

- Herrmann, E.S., Cone, E.J., Mitchell, J.M., Bigelow, G.E., LoDico, C., Flegel, R., and Vandrey, R. Non-Smoker Exposure to Secondhand Cannabis Smoke. II. Effect of Room Ventilation on the Physiological, Subjective, and Behavioral/Cognitive Effects. *Drug and Alcohol Dependence* 151:194-202, 2015.
- Cone, E.J., Bigelow, G.E., Herrmann, E.S., Mitchell, J.M., LoDico, C., Flegel, R., and Vandrey, R., Non-Smoker Exposure to Secondhand Cannabis Smoke. III. Oral Fluid and Blood Drug Concentrations and Corresponding Subjective Effects. *J. Anal. Toxicol.*, 2015.

Publications in submission or preparation:

- DePriest, A.Z., Heltsley, R., Black, D.L., Mitchell, J.M., LoDico, C., Flegel, R. and Cone, E.J., Prescription Opioids. V. Metabolism and Excretion Patterns of Oxymorphone in Urine Following Controlled Single Dose Administration. *J. Anal. Toxicol.*, 2015.

Presentations

Presentations:

- Edward J. Cone, George E. Bigelow, Evan S. Herrmann, John M. Mitchell, Charles LoDico, Ronald Flegel and Ryan Vandrey, Passive Inhalation of Cannabis Smoke is Drug Administration, TIAFT 2015, Florence, Italy, August 30 – September 4, 2015.
- Ron R. Flegel, Oral Fluid Testing, Basic Science and Practical Applications, Oral Fluid Testing Workshop, SOFT 2014, October 14, 2014.
- Edward J. Cone, Introduction to Oral Fluid and Drug Disposition, Oral Fluid Testing Workshop, SOFT 2014, October 14, 2014.
- Edward J. Cone, Rebecca Heltsley, David L. Black, Ronald R. Flegel, Charles P. LoDico, and John M. Mitchell, Oxycodone and Hydrocodone: Kinetic Relationships of Whole Blood to Oral Fluid. SOFT 2013, October 28 – November 1, 2013, Orlando, FL.
- Ronald R. Flegel, Charles P. LoDico, Rebecca Heltsley, David L. Black, John M. Mitchell, and Edward J. Cone, Prescription Opioid Abuse. I. Profiling Oxycodone and Metabolites in Urine. SOFT 2013, October 28 – November 1, 2013, Orlando, FL.
- Charles P. LoDico, Ronald R. Flegel, Rebecca Heltsley, David L. Black, John M. Mitchell, and Edward J. Cone, Prescription Opioid Abuse. II. Profiling Hydrocodone and Metabolites in Urine. SOFT 2013, October 28 – November 1, 2013, Orlando, FL.

Presentations

Presentations:

- Rebecca Heltsley, David L. Black, John M. Mitchell, Charles P. LoDico, Ronald R. Flegel, and Edward J. Cone, Disposition of Oxycodone and Hydrocodone in Oral Fluid. SOFT 2013, October 28 – November 1, 2013, Orlando, FL.
- Brandi L. Puet, Julie Knight, Anne DePriest, Rebecca Heltsley, David L. Black, Timothy Robert, Yale H. Caplan, and Edward J. Cone, Disposition of Oxycodone and Hydrocodone in Oral Fluid. SOFT 2013, October 28 – November 1, 2013, Orlando, FL.
- Cone, E.J. Introduction to Oral Fluid and Drug Disposition, SOFT 2014, October 20-24, 2014, Grand Rapids, MI.
- Cone, E.J., Vandrey, R., Bigelow, G., Mitchell, J.M., LoDico, C., and Flegel, R., Updated Results from the Marijuana Smoke Exposure Study, NLCP meeting, October 19, 2014, SOFT 2014, October 20-24, 2014, Grand Rapids, MI.
- Cone, E.J., Bigelow, G., Herrmann, E.S., Mitchell, J.M., LoDico, C., Flegel, R., and Vandrey, R., Passive Inhalation of Cannabis Smoke is Drug Administration. TIAFT meeting, October 30, 2015, Florence, Italy.
- Cone, E.J., Mitchell, J.M., Flegel, R., LoDico, C., Herrmann, E.S., Bigelow, G., and Vandrey, R., Passive Exposure to Secondhand Cannabis Smoke. I. Disposition in Urine, Oral fluid and Blood, SOFT meeting, October 18-23, 2015.

Presentations

Presentations:

- Flegel, R. Cone, E.J., Logan, B., and Faybusovich, M., Weed and Your Workforce: What You Need to Know. National Safety Council Congress and Expo in Atlanta, GA, September 26-30, 2015.
- Cone, E.J., Mitchell, J.M., Flegel, R., LoDico, C., Herrmann, E.S., Bigelow, G., and Vandrey, R., Passive Exposure to Secondhand Cannabis Smoke. II. Passive Exposure to Secondhand Cannabis Smoke. II. Dose, Response, and Implications, SOFT meeting, October 18-23, 2015.
- Flegel, R., SAMHSA's Role in Establishing Drug Testing Standards for Contemporary Drugs, SOFT meeting, October 18-23, 2015.
- Mitchell, J.M., Cone, E.J., Flegel, R., LoDico, C., Herrmann, E.S., Bigelow, G., and Vandrey, R., Oral Administration of Cannabis in Brownies, SOFT meeting, October 18-23, 2015.
- Vandrey, R., Cone, E.J., Herrmann, E.S., Mitchell, J.M., Flegel, R., LoDico, C. and Bigelow, G., The Pharmacodynamic Dose Effects of Oral Cannabis Administration, SOFT meeting, October 18-23, 2015.
- Vandrey, R., Cone, E.J., Herrmann, E.S., Mitchell, J.M., Flegel, R., LoDico, C. and Bigelow, G., The Pharmacodynamic effects of Passive Exposure to Secondhand Cannabis Smoke, SOFT meeting, October 18-23, 2015.

Special Studies

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- **Cannabis vaporization** followed by inhalation
 - NIDA/SAMHSA collaboration
 - This study evaluated cannabis pharmacodynamics and pharmacokinetics in occasional and frequent smokers after vaporized administration (eCigarettes)
 - Occasional and frequent cannabis smokers were in a double blind, randomized, crossover, placebo-controlled design where participants consumed smoked vaporized cannabis (6.9% Δ 9-tetrahydrocannabinol [THC])
 - Whole blood, oral fluid, urine, dried blood spots, and breath are collected throughout the study

Special Studies, cont'd

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- **Pharmacokinetic and pharmacodynamic effects of oral cannabis**
 - 3 doses
 - 10 mg, 25 mg, or 50 mg THC doses of orally consumed intact cannabis (e.g., cannabis-containing brownies)
 - Collected oral fluid, plasma, hair and urine for up to 9 days post consumption
 - Conducted subjective, behavioral, and cognitive performance assessments to evaluate the time course of the consequences of oral cannabis ingestion among study participants

Publications

- Smith, M.L., Nichols, D.C., Underwood, P., Fuller, Z., Moser, M.A., Flegel, R.R., Gorelick, D.A., Newmeyer, M.N., Concheiro, M., Huestis, M.A. (2014) **Methamphetamine and amphetamine isomer concentrations in human urine following controlled Vicks VapoInhaler administration.** *Journal of Analytical Toxicology*, **38**, 524-7.
- Smith, M.L., Nichols, D.C., Underwood, P., Fuller, Z., Moser, M.A., LoDico, C.P., Gorelick, D.A., Newmeyer, M.N., Concheiro, M., Huestis, M.A. (2014) **Morphine and codeine concentrations in human urine following controlled poppy seeds administration of known opiate content.** *Forensic Science International*, **241**, 87-90.

Submitted for Publication

14

- Cone, E.J., Bigelow, G.E., Herrmann, E.S., Mitchell, J.M., LoDico, C.P., Flegel, R and Vandrey, R. **Non-smoker exposure to secondhand cannabis smoke. I. Urine screening and confirmation results.**
- Herrmann, E.S., Cone, E.J., Mitchell, J.M., Bigelow, G.E., LoDico, C., Flegel, R. and Vandrey, R. **Non-smoker exposure to secondhand cannabis smoke. II: Effect of room ventilation on the physiological, subjective, and behavioral/cognitive effects.**

Submitted for Publication

15

- Newmeyer, M.N., Concheiro, M., Luiz da Costa, J., LoDico, C.P., Gorelick, D.A., Huestis, M.A. **Simultaneous plasma and oral fluid morphine and codeine concentrations after controlled administration of poppy seeds with known opiate content.**
- Cone, E.J., DePriest, A.Z., Heltsley, R., Black, D.L., Mitchell, J.M., LoDico, C.P., Flegel, R. **Prescription Opioids. III. Disposition of oxycodone in oral fluid and blood following controlled single dose administration.**

DTAB Hair Testing Milestones

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- Milestones
 - Two year review of technical and scientific issues
 - Hair testing industry input
 - Review of public comments in response to Request for Information (RFI)

MRO Manual Update

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- Subject Matter Expert (SME): Dr. Richard Hilderbrand
 - Spearheading the Medical Review Officer (MRO) Manual revisions
 - Consistency with the proposed revisions for Urine Mandatory Guidelines
 - Place holder for proposed Oral Fluid Mandatory Guidelines

MRO Manual Update

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- MRO Manual Working Group
 - 12 Members
 - Sean Belouin, Rich Hilderbrand, Yale Caplan, Donna Smith, Lawrence Brown, Ted Shults, Jim Ferguson, Susan Crumpton, Robert Swotinsky, David Kuntz, David Nahin, Nicholas Lomangino
 - DWP staff

MRO Manual Update

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- Major issues
 - Addressing the addition of prescription opioid drugs to drug testing panel:
 - Oxycodone, oxymorphone, hydrocodone, hydromorphone
 - Hydrocodone combination drugs rescheduled to Schedule II
 - “What is considered a valid prescription under the Drug-Free Workplace Programs (DFWP) and how will it be interpreted by the MRO?”

MRO Manual Update

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- Major Issues continued . . .
 - Addition of the electronic Federal Custody and Control Form (eCCF)
 - Mandatory Guidelines allow “transmitting a scanned image of the completed MRO copy of the Federal CCF”
 - Addressing when lab reports “insufficient volume” to the MRO
 - Case notes
 - Whether to be included or kept separate from MRO Manual

DTAB Objectives

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- Objectives
 - URMG - public comments
 - OFMG - public comments
 - Preparation of the final UrMG and OFMG
 - Evaluation of the scientific supportability of hair
 - Implementation of MRO Manual

DTAB Short Term Objectives

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- Short Term Objectives
 - Review RFI Comments for Hair (August)
 - Review URMG public comments (August)
 - Review OFMG public comments (August)
 - Review URMG changes to proposed URMG (October)
 - Review OFMG changes to proposed OFMG (October)

Future Goals

- Development of a DFWP database
 - SAMHSA working with the a federal agency / contractor to create a real-time database for federally regulated drug tests
 - Federal agency and federally regulated drug tests (DOT and NRC) – Phase II
 - Data contained in the database: specimen number, federal agency, type of test, collection site, drug test result, quantitative data, demographic information by zip code, reason for test, reporting reason, etc.

Database Goals

- Generate reports that:
 - Provide data for federal agencies to incorporate into their annual survey report (ASR)
 - Provide true total and non-negative data for individual and combined federal agencies
 - Provide geographical distributions of dilute and non-negative specimens for individual and combined federal agencies

Database Advantages

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- The advantages of establishing a regulated drug testing database for participating federal agencies
 - Increased data reporting accuracy through federal agency collaboration
 - Near real-time reporting
 - Consolidation of drug testing result data
 - Potential 80% reduction in agency burden when generating the ASR

Long Term Database Goals

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Potential long range opportunities

- eCCF transmission of data
- Standard variables across laboratory reporting
- Replacement of the non-negative specimen list
- Other federal agency participation (DOT/NRC)
- Real time data – within hours to days
- Detect federal agency trends – drug test results
- **Single reporting method for laboratories**

Other Program Goals

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- Complete the training course modules for inspectors/lab responsible persons and staff
- Continue to research alternative specimens for inclusion in the MG
- Develop supporting guidance documents for alternative matrices in the MG
- Revise the current urine MG to include the DTAB recommendation

Time Line: Step 1

- Timeline for the publication of final revisions to the Mandatory Guidelines to include Schedule II drugs in urine and oral fluids as an alternate specimen

Step 1	Tentative Date	Urine	Oral fluids	Hair
Writing of the proposed rule with the preamble	-	6 months	6 months	-
Review by DTAB	-	30 days	30 days	-
SAMHSA routing and review	-	30 days	30 days	-
Submission to SAMHSA Clearance Officer and OPPI Clearance	-	15 days	15 days	-
Submit to Exec Sec for Administrator's signature	-	30 days	30 days	-
Submission to HHS for review	-	90 days	90 days	-
Submission to OMB for review	-	90 days	90 days	-
Circulation by OMB to federal stakeholders	-	60-90 days	60-90 days	-
Review by SAMHSA of the federal comments	-	30 days	30 days	-
Writing of the final rule with the preamble to incorporate the federal comments	-	30 days	30 days	-
HHS and OMB final approval	-	30 days	30 days	-
Publication in the FR	-	15 days	15 days	-
60-90 day public comment period	-	60 days	60 days	-
Drafting of responses to public comments	August 10, 2015	90 days	90 days	-
Review by DTAB (optional)	October 15, 2015	30 days	30 days	-
Total Time	-	26.5-30.5 months	26.5-30.5 months	-

Time Line: Step 2

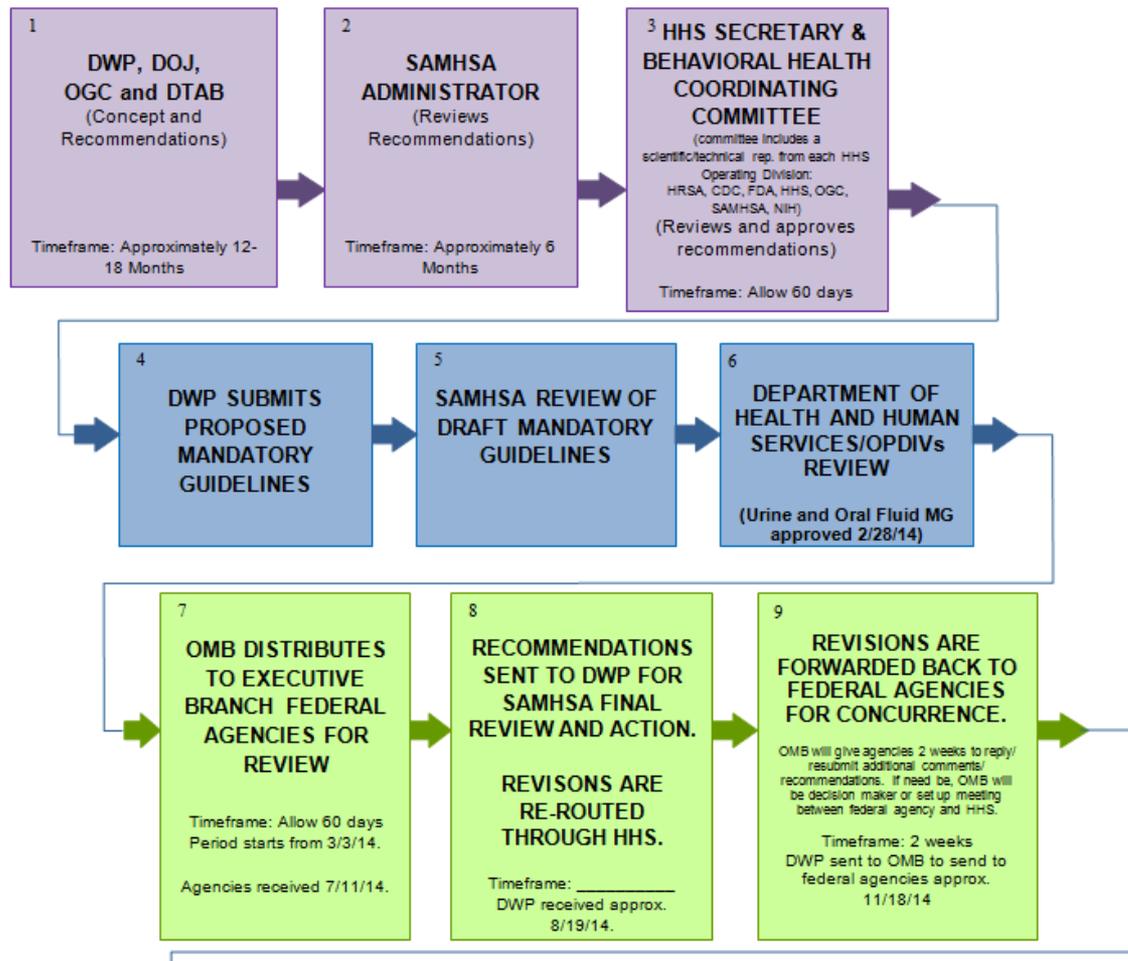
- Timeline for the publication of final revisions to the Mandatory Guidelines to include Schedule II drugs in urine and oral fluids as an alternate specimen

Step 2 Schedule II Drugs	Tentative Date	Urine	Oral fluids	Hair
SAMHSA routing and review	October 27, 2015	30 days	30 days	-
Submission to SAMHSA Clearance Officer and OPPI Clearance	-	15 days	15 days	-
Submit to Exec Sec for Administrator's signature	-	30 days	30 days	-
Submission to HHS for review	-	30 days	30 days	-
Submission to OMB for review	-	30 days	30 days	-
HHS and OMB final approval	-	30 days	30 days	-
Publication in the FR	-	30 days	30 days	-
Implementation date after FRN publication date	-	6 months	12-24 months	-
Total Time	-	6.5-12.5 months	6.5-30.5 months	-

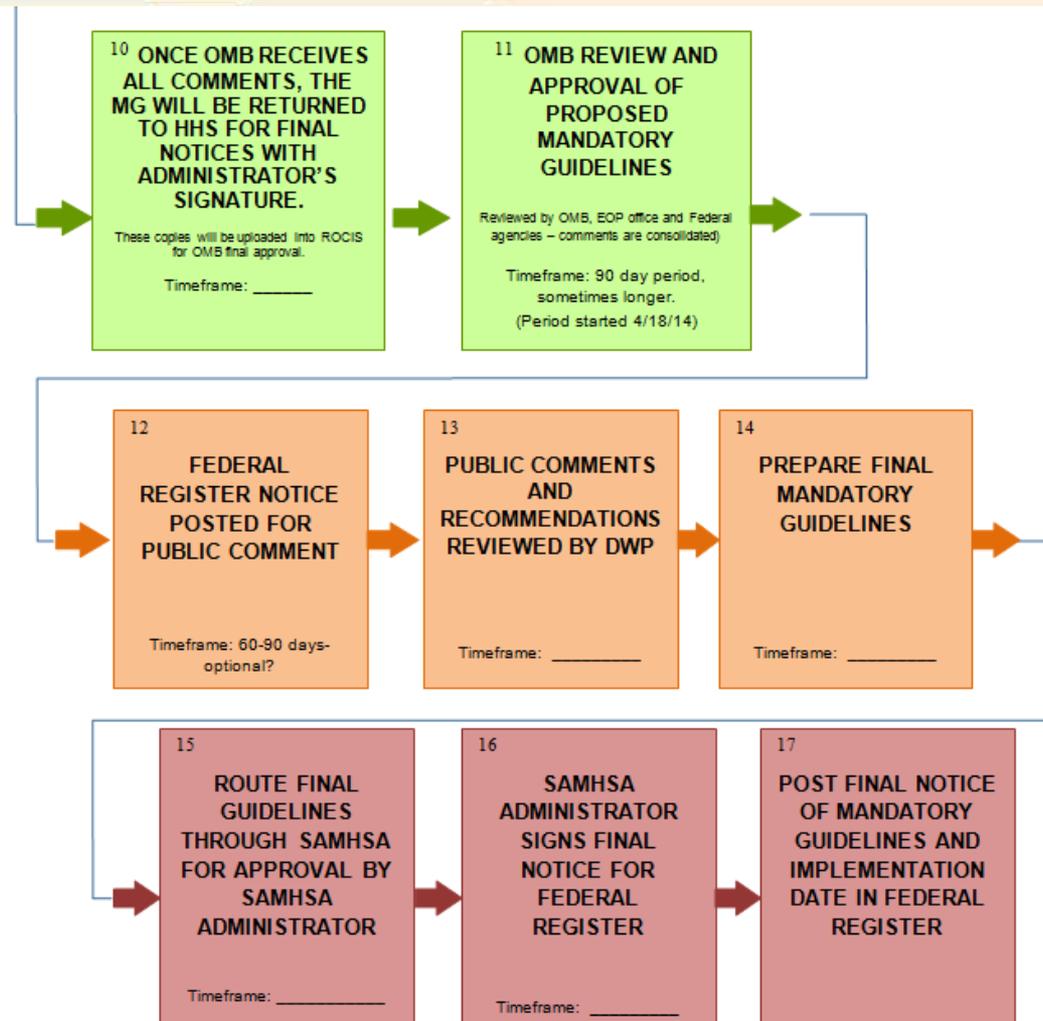
Routing Process

Mandatory Guidelines Routing Process

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Routing Process



Summary

- Continue to partner with DOT and NRC to harmonize the MG for urine and oral fluid
- Communicate with the laboratories on program issues
- Continue to advance the technology and science in the Program
- Address emerging drug testing issues and trends
- Program oversight and review
- Studies / tasks regarding alternate matrices
- Marijuana issues/reclassification/rescheduling
- Synthetic opiates / prescription drug use

Thank You
Division of Workplace Programs