Oral Fluid/Urine Proposed Mandatory Guidelines
Federal Register Notices:
Summary of Public Comments

Presented by
Charles LoDico, M.S., F-ABFT
Division of Workplace Programs

August 7, 2015
Drug Testing Advisory Board
Federal Register Notices

• HHS published two Federal Register Notices on May 15, 2015
  • Proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (URMG); 94 FR 28101
  • Proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG); 94 FR 28054
Public Comments

• HHS requested public comment on all aspects of the two Notices
• Public comments were accepted until July 14, 2015 (60 days) at http://www.regulations.gov
• HHS also specifically requested comment on certain items in the URMG and OFMG
HHS URMG Specific Comments

• Change cutoff for pH adulterated
  • \( \leq 4 \) and \( \geq 11 \)

• Requalification of MROs
  • Training and re-exam
  • 5 years after initial re-qualification
URMG Public Comments

- 123 commenters
- 427 comments
  - This includes comments relevant to urine that were submitted under the oral fluid FRN
URMG Commenters

- 123 URMG commenters
  - 104 Individuals
  - 9 Professional organizations
  - 2 HHS-certified laboratories
  - 1 Collection site
  - 2 Employers
  - 5 MROs and/or TPAs
Professional Organizations

• Airlines for America
• Air Line Pilots Association, International
• Association of Flight Attendants - CWA
• American College of Occupational & Environmental Medicine
• International Paruresis Association
• National Safety Council
• National School Transportation Association
• Substance Abuse Program Administrators Association
• Transportation Trades Department, AFL-CIO
Added Drugs

• 7 commenters agreed with the addition of oxycodone, oxymorphone, hydrocodone and hydromorphone
• 2 commenters disagreed
Added Drugs’ Cutoffs

• 3 commenters agreed with the proposed cutoffs
• 6 commenters disagreed with the initial or confirmatory test cutoffs for one or more drugs
Issue Oriented Comments

- 168 / 240 total commenters for both OF and UR (70 %)
- Comments:
  - Social anxiety disorder “paruresis”
  - Commenters signed “unknown”
  - Favors alternative specimen test
URMG Additional Comments

- 3 -- HHS costs and benefits analysis for the revisions to the URMG
- 6 -- Initial test analytical requirements
HHS OFMG Specific Comments

- IgG and albumin validity test
- Should HHS list FDA-cleared OF collection devices
- THCA-inclusion as test for marijuana use
- Lower THC cutoff (3 or 2 ng/mL initial screen and 1 ng/mL confirm)
- Lab’s ability to test/cost THCA (initial/confirm)
Oral Fluid Public Comments

- 117 commenters
- 373 comments
  - This includes comments relevant to urine that were submitted under the oral fluid FRN
OFMG Commenters

- 117 commenters
  - 85 Individuals
  - 11 Professional organizations
  - 5 HHS-certified laboratories
  - 7 Manufacturers
  - 6 MROs and/or TPAs
  - 1 Laboratory
  - 1 Employer
  - 1 Law firm
Professional Organizations

• Airlines for America
• Association of Flight Attendants - CWA
• American Trucking Association
• American College of Occupational & Environmental Medicine
• Commercial Vehicle Training Association
• Drug Alcohol Testing Industry Association
• Medical Review Officer Certification Council
• National Safety Council
• National School Transportation Association
• Owner-Operator Independent Drivers Association
• Substance Abuse Program Administrators Association
General Oral Fluid Comments

- 10 commenters agree with OF testing
- 3 commenters disagree with OF testing
Additional Oral Fluid Comments

• 19 -- OF specimen validity testing
• 39 -- Proposed initial and confirmatory test cutoffs
• 14 -- Marijuana analytes: THC and THCA
• 4 -- Other drug analytes
Additional Oral Fluid Comments

• 16 -- Collection device performance requirements
• 4 -- HHS costs and benefits analysis for oral fluid
• 9 -- Initial test analytical requirements
Comments on Both FRNs

• 16 -- MRO requalification/training
HHS Review/Decision Process

• All comments are discussed, reviewed, and presented to the following group:
  • DTAB
  • Federal partners
  • Office of General Council (OGC)
  • SAMHSA leadership

• Final decision based on concurrence from group