



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

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# 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

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- 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

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

# HHS OFMG Specific Comments

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- 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

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- 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

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- 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

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- 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

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- 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