

# Behavioral Health is Essential To Health



Prevention Works



Treatment is Effective



People Recover



# SAMHSA Federal Register Notices (FRN)

**Janine Denis Cook, Ph.D.**  
**Designated Federal Official**

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# Urine FRN

- The Federal Register Notice (FRN) announcing the HHS' proposal to revise the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines), 73 FR 71858 (November 25, 2008), for urine testing was published on May 15, 2015 (94 FR 28101)
  - Public comments will be accepted until July 14, 2015 (60 days) at <http://www.regulations.gov>

# Preamble requests

- The Department requested public comment on all aspects of the notice

# Specific Preamble requests

- In the preamble of the proposed urine Guidelines, comments on the following were specifically requested
  - Section 3.4 – proposed new analytes oxycodone, oxymorphone, hydrocodone, and hydromorphone and their cutoff concentrations

# Preamble requests, continued

- Section 13.1 - proposed requirements for MRO requalification training and reexamination on a regular basis (i.e., every five years) but does not require MROs to obtain continuing education units (CEUs) - comments on requiring MRO CEUs and on the optimum number of credits and the appropriate CEU accreditation bodies should CEUs be required

# Urine public comments

- To date (6.10.15), 7 comments have been received

# Urine comments

- 1 disagrees with urine testing unless the test is observed due to substitution
- 1 agrees with added drugs
- 1 agrees with Subpart M requiring MRO recertification every 5 years by authorized body
- 1 comment on Subpart M: The MRO should be required to contact the prescribing physician anytime a lab reports out a positive result for any Schedule II drug to verify with them that the donor is safe to perform their job duties
- 3 comments were inappropriate/not substantive (2 were OFMG comments)

# Oral fluid FRN

- The Federal Register Notice (FRN) announcing the HHS' proposal to establish scientific and technical guidelines for the inclusion of oral fluid specimens in the Mandatory Guidelines for Federal Workplace Drug Testing Programs was published on May 15, 2015 (94 FR 28054)
  - Public comments will be accepted until July 14, 2015 (60 days) at <http://www.regulations.gov>

# Preamble requests

- The Department requested public comment on all aspects of the notice

# Specific Preamble requests

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- In the preamble of the proposed oral fluid Guidelines, comments on the following were specifically requested
  - Section 3.1 – requirement for federal agencies to test all oral fluid specimens for either albumin or IgG to determine specimen validity
  - Section 3.4 - appropriateness of the proposed cutoff concentrations

# Preamble requests, continued

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- Section 3.4 - capability of laboratories to test THCA analyte using a cutoff of 50 pg/mL and the validity of whether THCA can be established as an accurate, sensitive and valid marker for oral fluid testing to detect marijuana use
- Section 3.4 - whether THCA should be used to extend the window of detection of marijuana use

# Preamble requests, continued

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- Section 3.4 - lowering the cutoff concentration for delta-9-tetrahydrocannabinol (THC) to either 2 or 3 ng/mL for the initial test cutoff concentration and to 1 ng/mL for the confirmatory cutoff concentration to extend the window of detection
- Section 7.3 - performance requirements for a collection device

# Preamble requests, continued

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- Section 13.5 - a concentration of 150 ng/mL morphine or codeine be used by the MRO to report a positive result in the absence of a legitimate medical explanation (i.e., prescription), without requiring clinical evidence of illegal opiate use, and to rule out the possibility of a positive result due to consumption of food products

# Oral fluid public comments

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- To date (6.10.15), 16 comments have been received
  - Two oral fluid comments were submitted under the urine FRN

# Oral fluid comments

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- 3 agree with the proposed OF Guidelines
  - 1 because it speeds up hiring
  - 1 because urine can be adulterated/substituted
- 1 disagrees with OF testing because of short detection times and believes hair is best matrix for drug testing

# Oral fluid comments, continued

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- 1 disagrees with the collection requirements
  - Disagrees with 10 minute wait time because it increases amount of time donor is detained, hinders the collector from doing other work while supervising the donor, and is more costly for employer and collector
  - Disagrees with requirement to contact DER for authorization to collect alternative specimen when sufficient OF is not provided
  - Disagrees with requiring tobacco users to rinse mouth because the majority of truck drivers smoke or chew tobacco and the collectors will have to find somewhere for them to spit out the liquid

# Oral fluid comments, continued

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- 1 commented on Subpart M saying that the MRO should be required to contact the prescribing physician anytime a lab reports out a positive result for any Schedule II drug to verify that the donor is safe to perform their job duties

# Oral fluid comments, continued

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- 1 commenter on multiple sections
  - Section 3.a - disagrees with requirement for albumin or IgG tests
    - No scientific basis, the collection is observed, unnecessary use of limited specimen volume

# Oral fluid comments, continued

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- Section 3.4: cutoffs
  - THC 4 ng/mL cutoff is appropriate but could be higher due to poor THC recovery of current collection devices and to avoid positives due to passive exposure
  - THCA testing should be mandatory to avoid positives due to passive exposure
  - AMP/MAMP cutoff should be 50 ng/mL to avoid increased confirmatory tests due to Vicks inhaler, phentermine, Adderall, and Vivanse

# Oral fluid comments, continued

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- Section 7.3.b.2: volume of diluent should be within +/- 5% of target volume and not specified volume of 0.05 mL of the diluent target volume due to the wide range of target diluent volumes in collection devices
- Section 7.3.d: recovery of all analytes should be >80% because THC is problematic and can't meet  $\geq 90\%$  requirement; should be >80% for THC; make same for all drugs

# Oral fluid comments, continued

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- Section 11.9: requests clarification on initial test requirements: is FDA clearance required for all initial test methods?
- Section 11.11: control requirements for initial test batches should be higher (i.e., 50% above and below cutoff controls instead of 25% above and below cutoff controls)
  - Current immunoassay technology for low cutoff assays are not able to perform robustly at those levels
    - FDA recognizes this and accepts +/-50% cutoff bracketing controls for low cutoff immunoassays.

# Oral fluid comments, continued

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- Other comments were inappropriate/not substantive

# Request for Information

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- The hair specimen RFI was published on May 29, 2015 (80 FR 30689)
  - Public comments will currently be accepted until June 29, 2015 (30 days) at <http://www.regulations.gov>

# RFI format

- The RFI questions were divided into the following topic areas:
  - Hair Specimen
  - Collection
  - Specimen Preparation
  - Analytes/Cutoffs
  - Specimen Validity
  - Testing

# RFI questions

- For each topic, specific questions were developed
  - Hair Specimen (4 questions)
  - Collection (4 questions)
  - Specimen Preparation (4 questions)
  - Analytes/Cutoffs (4 questions)
  - Specimen Validity (3 questions)
  - Testing (2 questions)

# RFI Public comments

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- To date (6.10.15), 11 comments have been received

# RFI comments

- 3 requested that comment period be extended another 30 days (through July 29)
- 2 comments of the reason for test
  - 1 agrees with pre-employment only
  - 1 agrees with pre-employment, follow-up (beginning and end of treatment), and when problems occur with urine (shy bladder, dilute, interfering substance)

# RFI comments, continued

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- 3 disagree with allowing hair testing
  - 1 believes urine is best matrix for DOT testing due to detection times when compared to hair and oral fluid
  - 1 believes oral fluid is best matrix for drug testing and doesn't believe a hair test is a viable option for the employer and public safety
  - 1 collector disagrees with hair testing
    - Difficult/impossible to collect hair from the crown of the head for men/women who wear their hair short, from men who have very little body hair (note collectors are limited to a dry shave using a disposable razor or attempting to cut very short hairs with scissors), and hair that is dry and fine
    - Would not recommend hair testing WITHOUT it being in conjunction with either urine or oral testing.
      - The reason being is that I have NEVER had a POS hair test alongside a POS urine test. It is either a POS hair test or POS urine test, but never both.

# RFI comments, continued

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- 1 recommends SAMHSA get additional information from the court system, Bureau of Justice Assistance standards for use of hair testing in drug courts, and Dr. Robert DuPont (Institute for Behavior and Health) who has published several articles about hair testing
- 2 comments were inappropriate/not substantive

# Plea!

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- Please submit your comments to the proposed urine and oral fluid Guidelines
  - Deadline: July 14, 2015
- Please submit your comments to the hair RFI
  - Deadline: June 29, 2015
- <http://www.regulations.gov>