

Submitted via Federal eRulemaking Portal: Regulations.gov

October 16, 2025

Dockets Operations
U.S. Department of Transportation
1200 New Jersey Ave. SE
West Building, Ground Floor
Washington, DC 20590–0001

RE: Docket DOT-OST-2025-0049 - Procedures for Transportation Workplace Drug and Alcohol Testing Programs: Addition of Fentanyl to the Department of Transportation's DrugT esting Panel; Harmonization With Certain Items in the HHS Mandatory Guidelines for Urine and Oral Fluid; and Technical Amendments

Dear Madam or Sir:

The American College of Occupational and Environmental Medicine (ACOEM) welcomes the opportunity to provide comments to the Department of Transportation (DOT) regarding its Notice of Proposed Rulemaking (NPRM) concerning the addition of fentanyl to the Department of Transportation's drug testing panel, harmonization with certain items in the Department of Health and Human Services (HHS) Mandatory Guidelines for Urine and Oral Fluid, and technical amendments. As our organization's membership consists of many physicians who are medical review officers (MROs), we are keenly aware of the issues that have been brought forth in this NPRM.

We wish to reinforce our support for the addition of oral fluid testing to the federal repertoire within 49 CFR Part 40 and would make similar comments as we did with the HHS rulemaking process in this regard. Clearly, harmonizing DOT rules with HHS rules is a necessary step. As you may be aware, we have been following the science of oral fluid testing keenly over the last several years and agree with the Department that oral fluid testing is now at the level of scientific validity and specificity on par with urine testing. We

have long advocated for measures that increase stakeholder ease of implementation of drug testing processes to comply with the purpose of transportation industry drug testing.

We do have one major concern with one specific aspect of the NPRM.

40.137 (c) 4-5 states:

"When verifying codeine or morphine results in oral fluid, you must verify a result between 15 ng/mL and 150 ng/mL as "negative" when the employee claims ingestion of poppy seed products, unless the employee admits to unauthorized use. (5) For all other results, you must verify the result as 'positive' unless the employee presents a legitimate medical explanation for the presence of the drug/metabolite in his or her system."

This process and protocol seem inconsistent with the HHS rules. As MROs, we fail to understand the need to include this special requirement for results between 15 ng/mL and 150 ng/mL and instead recommend removing it to be similar to the movement to the bright line cutoff for urine testing, which is proposed to be moved to 4000 ng/mL. In other words, we believe that instructions to the MRO for oral fluid interpretation of morphine should simply state that if the level is less than 150 ng/mL that it should be reported as negative, without any requirement from the MRO to make a value judgement during the interview of whether they heard the donor claim poppy seed ingestion or not.

To be clear, we would use the HHS language, which is as follows:

- "(i) For codeine and/or morphine less than 150 ng/mL, the MRO must report the result as negative to the agency, unless the donor admits unauthorized use of the drug(s) that caused the positive result as described in Section 13.5(c)(1).
- (ii) For codeine and/or morphine equal to or greater than 150 ng/mL and no legitimate medical explanation, the MRO shall report a positive result to the agency. Consumption of food products must not be considered a legitimate medical explanation for the donor having morphine or codeine at or above this concentration."

ACOEM is supportive of the other proposed changes, including the addition of fentanyl to the drug testing panel, addition of biomarkers for both urine and oral fluid testing, and other definitional and technical amendments.

We would like to make a point of emphasis regarding MRO training. ACOEM has long been a trusted source and subject matter expert in the arena of MRO continuing medical education (CME), including courses that qualify and re-qualify physicians to be MRO certified so that they may function in the federal systems. ACOEM has been and will continue to include comprehensive training for all MROs who have taken or will take our courses in the future concerning the changes that this NPRM reflects.

Thank you for the opportunity to comment. We are available to discuss the issues further at your request.

For more information about ACOEM, please visit acoem.org or contact Craig Sondalle, CEO at craig@acoem.org.

Sincerely,

Laura G. Gillis, MD, MPH, FACOEM

President, American College of Occupational and Environmental Medicine