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DEPARTMENT OF TRANSPORTATION **4910-9X**

Office of the Secretary

49 CFR Part 40

[Docket DOT-OST-2010-0026]

RIN 2105-AE14

Procedures for Transportation Workplace Drug and Alcohol Testing Programs: 6-acetylmorphine (6-AM) Testing

AGENCY: Office of the Secretary, U.S. Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This rule adopts as final, without change, a May 4, 2012, interim final rule (IFR) which no longer requires laboratories and Medical Review Officers (MRO) to consult with one another regarding the testing for the presence of morphine when the laboratory confirms the presence of 6-acetuylmorphine (6-AM). Also, laboratories and MROs will no longer need to report 6-AM results to the Office of Drug and Alcohol Policy and Compliance (ODAPC). This rule also responds to comments on the IFR.

DATES: The rule is effective **[INSERT date of publication]**.

FOR FURTHER INFORMATION CONTACT: Bohdan Baczara, U.S. Department of Transportation, Office of Drug and Alcohol Policy and Compliance, 1200 New Jersey Avenue, SE, Washington, DC 20590; 202-366-3784 (voice), 202-366-3897 (fax), or bohdan.baczara@dot.gov (email).

SUPPLEMENTARY INFORMATION:

Background and Purpose

On August 16, 2010, [75 FR 49850] the Department published its final rule to harmonize with many aspects of the revised Department of Health and Human Services (HHS) Mandatory Guidelines [73 FR 71858]. One item with which the DOT harmonized was the laboratory testing for 6-acetylmorphine (6-AM) without a morphine marker. 6-AM is a unique metabolite produced when a person uses the illicit drug heroin. Prior to the October 1, 2010, rulemaking, both the HHS and Department of Transportation (DOT) regulations required the laboratory to first test for morphine, and if it detected morphine at the HHS / DOT cutoff of 2000ng/mL, the lab would then test for 6-AM.

For the reasons discussed in the DOT final rule [75 FR 49850], we decided that, until more experience was gained with the new testing procedures for 6-AM, we would place additional requirements on laboratories and MROs. Specifically, when there was a 6-AM positive result and morphine was not detected by a laboratory at the 2000ng/mL cutoff, we added a requirement for the laboratory and MRO to determine whether morphine was detected at the laboratory's level of detection (LOD). If morphine was not detected at the laboratory's LOD, the laboratory and MRO were to report that result to DOT's Office of Drug and Alcohol Policy and Compliance (ODAPC). After consulting with ODAPC, the MRO would make a verified result determination, keeping in mind that there is no legitimate explanation for 6-AM in the employee's specimen [see § 40.151(g)]. The Department would track these results and discuss them with HHS.

On May 4, 2012, the Department issued an IFR [77 FR 26471] and effective July 3, 2012, related to 6-AM testing. For reasons stated in that IFR, we removed the requirement for

laboratories and MROs to consult with one another regarding the testing for the presence of 6-AM. The IFR also streamlined the laboratory analysis and MRO reporting of 6-AM results by not having either the laboratory or MRO report the 6-AM information to ODAPC. The IFR also sought comments to the IFR which were to be submitted by June 4, 2012. There were two such comments.

Discussion of Comments to the Docket

There were two comments to the docket representing three organizations. One comment was submitted by a large organization which represents physicians who are MROs. The other comment was submitted by a large medical review officer service and consortium which provide drug and alcohol testing services primarily to the pipeline industry.

Each of the commentors fully supported the Department's position on amending the requirements for testing and reporting 6-AM test results. Their support of the IFR further reinforces that there are no legitimate medical explanations for the confirmation of 6-AM on a DOT drug test and that the MRO must make positive results determinations in these cases.

One commenter asked whether we had noted a spike followed by a decline in the 6-AM results during the first year of testing, as they did. They wondered whether our commissioned study was designed to shed light on their observation.

We would note that over time, the Department has indeed seen an increase of laboratory-reported 6-AM test results. However, we found that the largest semi-annual period rise of 6-AM results, by number and percentage increase, came even before the October 2010 effective date of the new rules. This larger rise was noted when we compared the July-December 2009 period with the January-June 2010 period. Also, it is important to note that the number of total drug tests reported by laboratories has risen during each 6-month period, starting with the July-

December 2009 period, and the number of 6-AM positive results has steadily risen each period since July-December 2008.

The following table displays the laboratory data for 6-AM before, during transition, and after full implementation of the new testing protocols:

Semi - Annual Period	2008 July-Dec	2009 Jan-June	2009 July-Dec	2010 Jan-June	2010* July-Dec	2011 Jan-June	2011 July-Dec
Total Laboratory Test Results	2.85 million	2.59 million	2.57 million	2.69 million	2.77 million	2.82 million	2.87 million
6-AM Laboratory Positives	121	158	173	281	298	371	429

* The new requirement for 6-AM testing was in effect for the last 3 months of the period.

Our commissioned study was not designed to evaluate the pattern of 6-AM test results over time. Its scope was "…to verify the atypical results obtained by the laboratories, to determine if other drug or metabolites present in the specimens could explain the absence of morphine, and to determine if something other than heroin use could explain the presence of 6-AM." [77 FR 26472] The study's findings were presented and discussed in the IFR. [77 FR 26472] We would note that the rise in 6-AM positives was predicted, and a rise seems to have become the trend over time.

For the reasons discussed above and outlined in the IFR, we are adopting the rule text in the IFR as final.

Regulatory Analyses and Notices

Authority

The statutory authority for this rule derives from the Omnibus Transportation Employee Testing Act of 1991 (49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 54101 *et seq.*) and the Department of Transportation Act (49 U.S.C. 322).

Executive Order 12866 and Regulatory Flexibility Act

This Final Rule is not significant for purposes of Executive Order 12866 or the DOT's regulatory policies and procedures. It finalizes modifications, already in effect, to our procedures that do not increase costs on regulated parties. The rule will impose no new burdens on any parties, and will actually decrease the burden upon the laboratories and the MROs. I hereby certify, under the Regulatory Flexibility Act, that this rule does not have a significant economic impact on a substantial number of small entities.

List of Subjects in 49 CFR Part 40

Administrative practice and procedures, Alcohol abuse, Alcohol testing, Drug abuse, Drug testing, Laboratories, Reporting and recordkeeping requirements, Safety, Transportation.

Accordingly, the Interim Final Rule amending 49 CFR Part 40 which was published at 77 FR 26471 on May 4, 2012 is adopted as a final rule without change.

ISSUED on September 20th, 2012, at Washington D.C.

Ray LaHood,

Secretary of Transportation

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