



DEPARTMENT OF TRANSPORTATION

Billing Code 4910-9X

Federal Aviation Administration

14 CFR Part 120

Office of the Secretary of Transportation

49 CFR Parts 40

Pipeline and Hazardous Materials Safety Administration

49 CFR Part 199

Federal Transit Administration

49 CFR Part 655

RIN 2105-AE78

Conforming Amendments and Technical Corrections to Department Rules

Implementing the Transportation Industry Drug Testing Program

AGENCY: Office of the Secretary of Transportation (OST), Federal Aviation Administration (FAA), Federal Transit Administration (FTA), and Pipeline and Hazardous Materials Safety Administration (PHMSA); U.S. Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule makes minor technical corrections to the OST, FAA, FTA, and PHMSA regulations governing drug testing for safety-sensitive employees to ensure consistency with the recent amendments made to the Department of Transportation's regulation, "Procedures for Transportation Workplace Drug and Alcohol Testing Programs," which added requirements to test for oxycodone, oxymorphone, hydrocodone, and hydromorphone to DOT-regulated drug testing programs. The changes to the Department's regulation make it necessary to refer to these substances, as well as

the previously covered drugs morphine, 6-acetylmorphine, and codeine, by the more inclusive term “opioids,” rather than “opiates.” This rule amends the term in the FAA, FTA, and PHMSA regulations to ensure that all DOT drug testing rules are consistent with one another and with the Mandatory Guidelines for Federal Workplace Drug Testing Programs. In addition, this rule makes a conforming amendment to include the term “opioids” in the wording of the Department’s annual information collection requirement and clarifications to section 40.26 and Appendix H regarding the requirement for employers to follow the Department’s instructions for the annual information collection.

DATES: This rule is effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: For OST, Patrice M. Kelly, Director, Office of Drug and Alcohol Policy and Compliance, 1200 New Jersey Avenue, SE., Washington DC 20590 (telephone: 202-366-3784; email: ODAPCwebmail@dot.gov). For FTA, for program issues, contact Iyon Rosario, Office of Transit Safety and Oversight (TSO), FTA, 1200 New Jersey Avenue, SE., Washington, DC 20590-0001 (telephone: 202-366-2010; email: Iyon.Rosario@dot.gov). For legal issues, contact Bruce Walker, Office of Chief Counsel (TCC), FTA, 1200 New Jersey Avenue, SE., Washington, DC 20590-0001 (telephone: 202-366-9109; email: Bruce.Walker@dot.gov). For FAA, Rafael Ramos, Office of Aerospace Medicine, Drug Abatement Division, AAM-800, FAA, 800 Independence Avenue SW., Washington, DC 20591 (telephone 202-267-8442; facsimile 202-267-5200; email: drugabatement@faa.gov). For PHMSA, Wayne Lemoi, Drug and Alcohol Program Manager, PHMSA Office of Pipeline Safety (telephone 909-937-7232, email wayne.lemoi@dot.gov).

SUPPLEMENTARY INFORMATION:

Background

On January 23, 2017, the Department of Health and Human Services (HHS) published its final version of its Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (HHS Mandatory Guidelines) (82 FR 7920). In that final rule, HHS added four semi-synthetic opioid substances (hydrocodone, hydromorphone, oxycodone, and oxymorphone) to the drugs for which laboratories test under the HHS Mandatory Guidelines. That rule became effective October 1, 2017.

By statute, the Department of Transportation is required to follow the HHS Mandatory Guidelines for the drugs for which it tests in the transportation industry drug testing program. Consequently, the Department issued a notice of proposed rulemaking (NPRM) on January 23, 2017 (82 FR 7771). In that NPRM, the Department proposed to revise 49 CFR part 40 (part 40) to harmonize with certain parts of the revised HHS Mandatory Guidelines. The Department received 69 comments on the NPRM from various stakeholders, which were addressed in the final rule published on November 13, 2017.

The Department's final rule, among other things, added the four semi-synthetic opioid substances (hydrocodone, hydromorphone, oxycodone, and oxymorphone) to the

Department's drug testing program (82 FR 52229). The Department's final rule became effective on January 1, 2018. These testing requirements are now codified at 49 CFR 40.85(d) and 40.87.

Before the 2017 HHS and DOT rulemakings, laboratories under the HHS Mandatory Guidelines and Part 40 tested for codeine, 6-acetylmorphine, and morphine, properly referred to as "opiates." The four substances added in the DOT 2017 final rule are semi-synthetic substances, closely related to opiates but chemically distinct. For this reason, it is more accurate to refer to all six substances under the more inclusive term "opioids."

DOT Management Information System Form

The 2017 DOT final rule changed the terminology from "opiates" to "opioids" throughout part 40, with one minor exception in the DOT's Management Information System (MIS) Form. Specifically, we did not change the term "opiates" to "opioids" within the MIS Form in order to avoid any confusion on what employers were to report for the 2017 calendar year MIS reporting period. Since testing for the semi-synthetic opioids began in calendar year 2018, employers would not need to report that data until after January 1, 2019. Therefore, we are now updating the MIS Form to be consistent with the rest of part 40. The costs for the additional opioid testing were addressed in the final rule dated November 13, 2017.

In addition, in our November 13, 2017, final rule (82 FR 52243), we moved the instructions to the MIS data collection form from Appendix H to our web site. We did so

to provide greater flexibility to make changes and/or updates to the MIS instructions. We did not intend for this to suggest that employers were no longer required to use the MIS instructions as they have been required to do by part 40 and the respective DOT Agency regulations since 2003. Therefore, we are making a technical amendment to § 40.26 and Appendix H to part 40 to clarify the requirement for employers to use the MIS instructions.

Discussion

The Department's 2017 final rule was promulgated under the authority of the Omnibus Transportation Employee Testing Act (OTETA) of 1991 (Pub. L. 102–143, Title V, 105 Stat. 952). The OTETA sets the requirements for DOT's reliance on the HHS Mandatory Guidelines for scientific testing issues. Section 503 of the Supplemental Appropriations Act, 1987 (Pub. L. 100–71, 101 Stat 391, 468), 5 U.S.C. 7301, and Executive Order 12564 establish HHS as the agency that directs scientific and technical guidelines for Federal workplace drug-testing programs and standards for certification of laboratories' regulated programs. While the Department has discretion concerning many aspects of the regulations governing testing in the transportation industries' regulated programs, we must follow the HHS Mandatory Guidelines for the drugs for which we require testing.

The final rule follows that same mandate with respect to 49 CFR part 40 (OST), 14 CFR part 120 (FAA), and 49 CFR part 655 (FTA), all of which are directly subject to the OTETA mandate to conform to the HHS Mandatory Guidelines. Although PHMSA is not one of the agencies mentioned in OTETA, PHMSA's drug testing rule (49 CFR part

199) has always incorporated part 40 procedures, and it is important for all DOT drug testing regulations, and their terminology, to remain consistent. For this reason, we are changing the definition of “prohibited drug” in part 199 to directly reference part 40 and not the Controlled Substances Act.

In the OST rule, in Appendix H, the MIS form, in Section III, “Drug Testing Data,” the word “opiates” in Column 7 is being changed to “opioids.”

In the FAA rule, the FAA is revising the definition of “prohibited drug” in § 120.7(m) to mean any of the drugs specified in part 40. The FAA is also revising §§ 120.107 and 120.109 to replace the list of drugs and drug metabolites with the term “prohibited drug.” These changes will harmonize part 120, in pertinent part, with part 40. In § 120.109(c) the words “can not” are being corrected to “cannot.”

In the FTA rule, the FTA is replacing the term “opiates” with “opioids” in 49 CFR 655.21(b)(3).

In the PHMSA rule, 49 CFR 199.5, pipeline operators are required to conduct their anti-drug programs according to the requirements of part 199 and the DOT Procedures in part 40. Moreover, the regulations explain that the terms and concepts used in part 199 have the same meaning as in the DOT Procedures in part 40. The ODAPC final rule, dated November 13, 2017, changed the definition of “drug” in 49 CFR 40.3 to: “The drugs for which tests are required under this part and DOT Agency regulations are marijuana,

cocaine, amphetamines, phencyclidine (PCP), and opioids.” As a conforming amendment, PHMSA is changing the definition of “prohibited drug” in part 199 to align it with the recently changed definition of “drugs” in part 40. Instead of referencing the Controlled Substances Act, the definition of “prohibited drug” will now reference part 40. This change will also conform with the requirement under part 40 that the drug test panel includes the four semi-synthetic opioids (i.e. hydrocodone, oxycodone, hydromorphone, oxymorphone) in addition to the three natural opiates (i.e. heroin, morphine, codeine) previously included in DOT drug tests.

REGULATORY ANALYSES AND NOTICES

Good Cause for Immediate Adoption Without Prior Notice and Comment

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 et seq.) authorizes agencies to dispense with prior notice and comment for rules when the agency for “good cause” finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under this section, an agency, upon finding good cause, may issue a final rule without seeking comment prior to the rulemaking.

As discussed above, this final rule revises the terminology in the respective OST, FAA, FTA, and PHMSA drug testing rules to conform to the Department of Transportation’s final rule requiring testing for semi-synthetic opioids. Also, as discussed above, OST, FAA, and FTA are statutorily required to incorporate the Department of Health and Human Services (HHS) scientific and technical guidelines, including mandatory guidelines establishing the list of controlled substances which individually may be tested.

While PHMSA is not subject to the OTETA mandate to follow the HHS Mandatory Guidelines, the PHMSA rule already required compliance with part 40. The terminological changes involved will not make substantive changes in the obligations of regulated parties but clarify those parties' obligations. For these reasons, we find that it is unnecessary to seek public comment before issuing this final rule.

There will be no additional costs associated with any of these changes, which are all administrative. Each of these changes removes inconsistencies and harmonizes with changes made to the HHS Mandatory Guidelines in January of 2017 that were incorporated into 49 CFR part 40 on November 13, 2017. Any costs associated with the substantive rulemaking changes to add the semi-synthetic opioids were accounted for in the final rule dated November 13, 2017 (82 FR 52229).

Similarly, section 553(d)(3) of the APA requires that agencies publish a rule not less than 30 days before its effective date, except as otherwise provided by the agency for good cause found and published with the rule. DOT finds that, for the same reasons stated above, there is good cause to make these amendments effective immediately.

Executive Order 12866 and 13563

Executive Order 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563

emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule implements changes that are administrative in nature. All agencies involved have determined that this action is not a significant regulatory action under section 3(f) of Executive Order 12866, nor is it significant within the meaning of Department of Transportation regulatory policies and procedures.

This rule provides technical corrections to the cited regulations harmonizing them with part 40. The only entities affected by this rule are those aviation, transit, and pipeline entities already subject to DOT drug testing rules and the changes made to part 40 by the final rule dated November 13, 2017. This rule does not require any additional costs associated with compliance. Accordingly, it has not been reviewed by the Office of Management and Budget.

This rule is not expected to impose any new compliance costs, and would not adversely affect, in any material way, any sector of the economy. There are no significant changes to the existing program with the publication of this rulemaking. Additionally, this rule does not interfere with any action planned by another agency and does not materially alter the budgetary impact of any entitlements, grants, user fees, or loan programs.

Consequently, a full regulatory evaluation is not required.

Executive Order 13771

This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

Regulatory Flexibility Act

The requirements of the Regulatory Flexibility Act (RFA) do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because this rule adopts Departmental regulatory requirements pursuant to part 40, the involved agencies have determined that there is good cause to adopt the rule as a final rule; therefore, RFA analysis is not required. Additionally, this administrative action will result in no significant economic impact nor impose any additional cost to small entities that are subject to alcohol misuse and controlled substance testing requirements of the cited regulations.

Paperwork Reduction Act

This rule does not provide a new collection of information that is subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). Under the provisions of the Paperwork Reduction Act, the affected agencies may not conduct or sponsor, and a person is not required to respond to or may not be penalized for failing to comply with, a collection of information unless it displays a currently valid OMB control number.

Executive Order 13132, Federalism

Executive Order 13132 sets forth principles and criteria that agencies must adhere to in formulating and implementing policies that have Federalism implications. That is,

regulations that have substantial direct effects on the States, or on the distribution of power and responsibilities among the various levels of government. Federal agencies must closely examine the statutory authority supporting any action that would limit the policymaking discretion of the States, and to the extent practicable, must consult with State and local officials before implementing any such action.

The agencies involved have reviewed this rule under the threshold criteria of Executive Order 13132 on Federalism and certify that the rule would not have Federalism implications as defined by the Executive Order. The rule would not significantly affect the rights, roles, and responsibilities of States, and would not involve preemption of State law, nor would it limit State policymaking discretion.

Unfunded Mandates Reform Act

This rule is not an unfunded Federal mandate within the meaning of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4, March 22, 1995, 109 Stat. 48). This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$148.1 million or more in any one year (2 U.S.C. 1532).

Executive Order 13175 (Tribal Consultation)

The agencies involved have analyzed this action under Executive Order 13175, and determined that this rule would not have substantial direct effects on one or more Indian Tribes; would not impose substantial direct compliance costs on Indian Tribal governments; and would not preempt Tribal law.

National Environmental Policy Act

The Department has analyzed the environmental impacts of this action pursuant to the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.) and has determined that it is categorically excluded pursuant to DOT Order 5610.1C, Procedures for Considering Environmental Impacts (44 FR 56420, Oct. 1, 1979). Categorical exclusions are actions identified in an agency's NEPA implementing procedures that do not normally have a significant impact on the environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS). See 40 CFR 1508.4. In analyzing the applicability of a categorical exclusion, the agency must also consider whether extraordinary circumstances are present that would warrant the preparation of an EA or EIS. Id. Paragraph 4(c)(5) of DOT Order 5610.1C incorporates by reference the categorical exclusions for all DOT Operating Administrations. This action is covered by the categorical exclusion listed in the Federal Transit Administration's implementing procedures, "[p]lanning and administrative activities that do not involve or lead directly to construction, such as: . . . promulgation of rules, regulations, directives..." 23 CFR 771.118(c)(4). The purpose of this rulemaking is to make minor technical corrections to the Department's drug-testing regulations. The Department does not anticipate any environmental impacts and there are no extraordinary circumstances present in connection with this rulemaking.

International Compatibility and Cooperation

In keeping with U.S. obligations under the Convention on International Civil Aviation (ICAO), it is FAA policy to conform to ICAO Standards and Recommended Practices to

the maximum extent practicable. The FAA has determined that its portion of this final rule does not conflict with any international agreement of the United States.

List of Subjects

14 CFR Part 120

Air carriers, Alcoholism, Alcohol abuse, Aviation safety, Drug abuse, Drug testing, Operators, Reporting and recordkeeping requirements, Safety, Safety-sensitive, Transportation.

49 CFR Part 40

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

49 CFR Part 655

Mass transportation, Alcohol testing, Drug testing, Reporting and recordkeeping requirements, Safety, Transportation.

49 CFR Part 199

Alcohol testing, Drug testing, Pipeline safety, Reporting and recordkeeping requirements, Safety, Transportation.

In consideration of the foregoing, the Department of Transportation and its agencies amend their regulations as follows:

Title 14—Aeronautics and Space

PART 120-- DRUG AND ALCOHOL TESTING PROGRAM

1. The authority citation for part 120 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40101-40103, 40113, 40120, 41706, 41721, 44106, 44701, 44702, 44703, 44709, 44710, 44711, 45101-45105, 46105, 46306.

2. In § 120.7, revise paragraph (m) to read as follows:

§ 120.7 Definitions.

* * * * *

(m) *Prohibited drug* means any of the drugs specified in 49 CFR part 40.

* * * * *

3. Revise § 120.107 to read as follows:

§ 120.107 Substances for which testing must be conducted.

Each employer shall test each employee who performs a safety-sensitive function for evidence of a prohibited drug during each test required by § 120.109.

4. In § 120.109, revise paragraphs (a)(5) and (c) to read as follows:

§ 120.109 Types of drug testing required.

* * * * *

(a) * * *

(5) Before hiring or transferring an individual to a safety-sensitive function, the employer must advise each individual that the individual will be required to undergo pre-employment testing in accordance with this subpart, to determine the presence of a prohibited drug in the individual's system. The employer shall provide this same notification to each individual required by the employer to undergo pre-employment testing under paragraph (a)(4) of this section.

* * * * *

(c) *Post-accident drug testing.* Each employer shall test each employee who performs a safety-sensitive function for the presence of a prohibited drug in the employee's system if that employee's performance either contributed to an accident or cannot be completely discounted as a contributing factor to the accident. The employee shall be tested as soon as possible but not later than 32 hours after the accident. The decision not to administer a test under this section must be based on a determination, using the best information available at the time of the determination, that the employee's performance could not have contributed to the accident. The employee shall submit to post-accident testing under this section.

* * * * *

Title 49—Transportation

PART 40—PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG AND ALCOHOL TESTING PROGRAMS

5. The authority citation for part 40 continues to read as follows:

AUTHORITY: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 54101 *et seq.*

6. Revise § 40.26 to read as follows:

§ 40.26 What form must an employer use to report Management Information System (MIS) data to a DOT agency?

As an employer, when you are required to report MIS data to a DOT agency, you must use the U.S. Department of Transportation Drug and Alcohol Testing MIS Data Collection Form to report that data. You must use the form and instructions referenced at Appendix H to part 40. You must submit the MIS report in accordance with rule requirements (e.g., dates for submission; selection of companies required to submit, and method of reporting) established by the DOT agency regulating your operation.

7. Revise Appendix H to part 40 to read as follows:

Appendix H to Part 40 - DOT Drug and Alcohol Testing Management Information System (MIS) Data Collection Form

The following form is the MIS Data Collection form required for use to report calendar year MIS data. The instructions for this form are found at <https://www.transportation.gov/odapc>.

U.S. DEPARTMENT OF TRANSPORTATION DRUG AND ALCOHOL TESTING MIS DATA COLLECTION FORM

Calendar Year Covered by this Report: _____

OMB No. 2105-0529

Form DOT F 1385 (Rev. 4/2019)

I. Employer:

Company Name: _____

Doing Business As (DBA) Name (if applicable): _____

Address: _____ E-mail: _____

Name of Certifying Official: _____ Signature: _____

Telephone: (____) _____ Date Certified: _____

Prepared by (if different): _____ Telephone: (____) _____

C/TPA Name and Telephone (if applicable): _____ (____) _____

Check the DOT agency for which you are reporting MIS data; and complete the information on that same line as appropriate:

___ FMCSA – Motor Carrier: DOT #: _____ Owner-operator: (circle one) YES or NO Exempt (Circle One) YES or NO

___ FAA – Aviation: Certificate # (if applicable): _____ Plan / Registration # (if applicable): _____

___ PHMSA – Pipeline: (Check) Gas Gathering ___ Gas Transmission ___ Gas Distribution ___ Transport Hazardous Liquids ___ Transport Carbon Dioxide

___ FRA – Railroad: Total Number of observed/documentated Part 219 “Rule G” Observations for covered employees: _____

___ USCG – Maritime: Vessel ID # (USCG- or State-Issued): _____ (If more than one vessel, list separately.)

___ FTA – Transit

II. Covered Employees: (A) Enter Total Number Safety-Sensitive Employees In All Employee Categories:

(B) Enter Total Number of Employee Categories:

Employee Category	Total Number of Employees in this Category

If you have multiple employee categories, complete Sections I and II (A) & (B). Take that filled-in form and make one copy for each employee category and complete Sections II (C), III, and IV for each separate employee category.

III. Drug Testing Data

Type of Test	1 Total Number Of Test Results [Should equal the sum of Columns 2, 3, 9, 10, 11, and 12]	2 Verified Negative Results	3 Verified Positive Results ~ For One Or More Drugs	4 Positive For Marijuana	5 Positive For Cocaine	6 Positive For PCP	7 Positive For Opioids	8 Positive For Amphetamines	Refusal Results					13 Cancelled Results
									9 Adulterated	10 Substituted	11 “Shy Bladder” ~ With No Medical Explanation	12 Other Refusals To Submit To Testing		
Pre-Employment														
Random														
Post-Accident														
Reasonable Susp./Cause														
Return-to-Duty														
Follow-Up														
TOTAL														

IV. Alcohol Testing Data:

Type of Test	1 Total Number Of Screening Test Results [Should equal the sum of Columns 2, 3, 7, and 8]	2 Screening Tests With Results Below 0.02	3 Screening Tests With Results 0.02 Or Greater	4 Number Of Confirmation Tests Results	5 Confirmation Tests With Results 0.02 Through 0.039	6 Confirmation Tests With Results 0.04 Or Greater	Refusal Results		
							7 “Shy Lung” ~ With No Medical Explanation	8 Other Refusals To Submit To Testing	9 Cancelled Results
Pre-Employment									
Random									
Post-Accident									
Reasonable Susp./Cause									
Return-to-Duty									
Follow-Up									
TOTAL									

PAPERWORK REDUCTION ACT NOTICE (as required by 5 CFR 1320.21)

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2105-0529. Public reporting for this collection of information is estimated to be approximately 90 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, U.S. Department of Transportation, Office of Drug and Alcohol Policy and Compliance, 1200 New Jersey Avenue, SE, Suite W62-300, Washington, D.C. 20590.

Title 18, USC Section 1001, makes it a criminal offense subject to a maximum fine of \$10,000, or imprisonment for not more than 5 years, or both, to knowingly and willfully make or cause to be made any false or fraudulent statements of representations in any matter within the jurisdiction of any agency of the United States.

PART 199 – DRUG AND ALCOHOL TESTING

8. The authority citation for part 199 continues to read as follows:

AUTHORITY: 49 U.S.C. 5103, 60102, 60104, 60108, 60117, and 60118; 49 CFR 1.53.

9. In § 199.3, revise the definition of “*Prohibited drug*” to read as follows:

§ 199.3 Definitions.

* * * * *

Prohibited drug means any of the substances specified in 49 CFR part 40.

* * * * *

**PART 655 - PREVENTION OF ALCOHOL MISUSE AND PROHIBITED DRUG
USE IN TRANSIT OPERATIONS**

10. The authority citation for part 655 continues to read as follows:

Authority: 49 U.S.C. 5331; 49 CFR 1.91.

11. Amend § 655.21 by revising paragraph (b)(3) to read as follows:

§ 655.21 Drug testing.

* * * * *

(b) * * *

(3) Opioids;

* * * * *

Issued in Washington, DC on Tuesday, March 19, 2019.

Elaine L. Chao,

Secretary of Transportation.

Daniel K. Elwell,

Acting Administrator,

Federal Aviation Administration.

