

correspondence related to this case. All comments received will be posted without change to <http://www.regulations.gov>, including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Michael O. Jackson, Procurement Analyst, at 202–208–4949, for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755. Please cite FAR Case 2016–005.

SUPPLEMENTARY INFORMATION:

I. Background

DoD, GSA, and NASA published a proposed rule in the **Federal Register** at 81 FR 85914, on November 29, 2016. The comment period is extended to provide additional time for interested parties to submit comments on the FAR case until March 2, 2017.

List of Subjects in 48 CFR Part 1

Government procurement.

Dated: January 17, 2017.

William F. Clark,

Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

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DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 40

[Docket DOT–OST–2016–0189]

RIN 2105–AE58

Procedures for Transportation Workplace Drug and Alcohol Testing Programs: Addition of Certain Schedule II Drugs to the Department of Transportation's Drug-Testing Panel and Certain Minor Amendments

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

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Transportation is proposing to amend its drug-testing program regulation to add four opioids (hydrocodone, hydromorphone, oxycodone, and oxycodone) to its drug-testing panel; add methylenedioxyamphetamine (MDA) as an initial test analyte; and remove methylenedioxyethylamphetamine, (MDEA) as a confirmatory test analyte.

The proposed revision of the drug-testing panel is intended to harmonize with the revised Mandatory Guidelines established by the U.S. Department of Health and Human Services for Federal drug-testing programs for urine testing. This proposal also adds clarification to certain drug-testing program provisions where necessary, removes outdated information in the regulations that is no longer needed, and proposes to remove the requirement for employers and Consortium/Third Party Administrators to submit blind specimens.

DATES: Comments to the notice of proposed rulemaking should be submitted by March 24, 2017. Late-filed comments will be considered to the extent practicable.

ADDRESSES: To ensure that you do not duplicate your docket submissions, please submit them by only one of the following means:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave. SE., West Building Ground Floor Room W12–140, Washington, DC 20590–0001.
- *Hand delivery:* West Building Ground Floor, Room W–12–140, 1200 New Jersey Ave. SE., between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

Instructions: To ensure proper docketing of your comment, please include the agency name and docket number DOT–OST–2016–0189 or the Regulatory Identification Number (RIN), 2105–AE58, for the rulemaking at the beginning of your comments. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Patrice M. Kelly, Acting Director, Office of Drug and Alcohol Policy and Compliance, 1200 New Jersey Avenue SE., Washington, DC 20590; telephone number 202–366–3784; ODAPCWebMail@dot.gov.

SUPPLEMENTARY INFORMATION:

I. Purpose

The Department of Transportation (DOT or the Department) is issuing this notice of proposed rulemaking (NPRM) to revise Part 40 of Title 49 of the Code of Federal Regulations to harmonize with the revised Department of Health and Human Services (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (HHS

Mandatory Guidelines) published on January 23, 2017, effective October 1, 2017. DOT currently requires urine testing for safety-sensitive transportation industry employees subject to drug testing under Part 40.

There are two changes to the HHS Mandatory Guidelines to which this notice proposes to harmonize Part 40. First, the revised HHS Mandatory Guidelines, in part, allow Federal agencies with drug-testing responsibilities to test for four additional Schedule II (of the Controlled Substances Act) prescription medications: Hydrocodone, hydromorphone, oxycodone, and oxycodone. Second, the HHS Mandatory Guidelines remove methylenedioxyethylamphetamine, (MDEA) as a confirmatory test analyte from the existing drug-testing panel and add methylenedioxyamphetamine (MDA) as an initial test analyte.

In addition to harmonizing with pertinent sections of the HHS Mandatory Guidelines for urine testing, we also propose in this NPRM to modify (for clarification) certain existing Part 40 provisions that cover the handling of urine specimens; to remove provisions that no longer are necessary (such as obsolete compliance dates); and to add clarifying language to other provisions (such as updated definitions and web links where necessary.) The Department also proposes to remove existing Part 40 requirements related to blind specimen testing.

II. Authority for This Rulemaking

This rulemaking is promulgated pursuant to the Omnibus Transportation Employee Testing Act (OTETA) of 1991 (Pub. L. 102–143, tit. V, 105 Stat. 952). OTETA sets forth DOT 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 engaged in such drug testing. While DOT 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 categories of drugs for which we will require testing.

III. Background

Relevant History of the DOT Drug-Testing Program Regulation

The Department first published its drug-testing program regulation (49 CFR part 40) on November 21, 1988 as an interim final rule (53 FR 47002). We based the rule on HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs (See 53 FR 11970), which, in part, required cocaine and marijuana to be screened by Federal agencies. HHS based this requirement on the incidence and prevalence of the abuse of these two substances in the general population and on the experiences, at the time, of the Departments of Defense and Transportation in screening their workforces (53 FR 11973–11974). Agencies also were authorized under the 1988 HHS Mandatory Guidelines to test for phencyclidine, amphetamines, and opiates. Among other provisions from those guidelines, DOT incorporated a 5-panel test to include all of the drugs HHS authorized and published a final rule on December 1, 1989 (54 FR 49854).

We made the last comprehensive revisions to Part 40, on August 16, 2010 (See 75 FR 49850). This 2010 revision once again harmonized our DOT drug-testing program, where necessary, with the HHS Mandatory Guidelines effective October 1, 2010 (See 73 FR 7185; 75 FR 22809). Specifically, to harmonize we required initial and confirmatory testing for methylenedioxymethamphetamine (MDMA); confirmatory testing for MDA and MDEA; and initial testing for 6-acetylmorphine (6-AM). We also lowered the initial and confirmatory test cutoff concentrations for amphetamines and cocaine.

Just as we have revised Part 40 in the past, we propose to revise Part 40 now to harmonize, in pertinent part, with the most recently revised HHS Mandatory Guidelines issued on January 23, 2017. HHS has set an effective date of October 1, 2017, for compliance with its final revision.

Relevant Changes to the HHS Mandatory Guidelines

HHS monitors drug abuse trends and reviews information on new drugs of abuse from sources such as Federal regulators, researchers, the drug-testing industry, and public and private sector employers. In its May 15, 2015 “Notice of Proposed Revisions” (See 80 FR 28103), HHS indicated that, since its original Guidelines were published in 1988, a number of recommendations have been made for additional drugs to be included in Federal workplace drug-

testing programs. According to HHS, recommendations for the four added semi-synthetic drugs were based on a review of scientific information and on input from the Drug Testing Advisory Board (DTAB)¹ on the methods necessary to detect the analytes of drugs and on drug abuse trends. With the DTAB recommendations, private sector experience findings, and analysis of current drug abuse trends, HHS concluded that the additional opioids, oxycodone, oxymorphone, hydrocodone, and hydromorphone, should be added in the Federal program.

In its “Final Notice of Revisions” HHS acknowledged that, while it had proposed MDA and MDEA as initial test analytes, three commenters disagreed with the addition of MDA and MDEA as target analytes. HHS indicated that the commenters stated that this change would require modification of current immunoassay reagents, laboratory processes, or both. The commenters noted that this imposes an unnecessary burden for compounds with such low incidence in workplace testing. HHS agreed and, based on comment, removed MDEA from its Mandatory Guidelines. HHS determined that the number of positive MDEA specimens reported by HHS-certified laboratories does not support testing all specimens for MDEA in Federal workplace drug testing programs. HHS indicated that it understands that MDA and some other analytes also have a low incidence, but believes that continued testing for these analytes is warranted in a deterrent program. In particular, inclusion of MDA as an initial and confirmatory test analyte is warranted according to HHS because, in addition to being a drug of abuse, it is a metabolite of MDEA and MDMA.

Harmonizing Changes to the DOT Drug-Testing Program Regulation

In keeping with our obligations under OTETA to follow the HHS Mandatory Guidelines for the drugs for which we test, we propose to add and remove the drugs adopted in the revised HHS Mandatory Guidelines for urine. Adding the four semi-synthetic opioids, which are already tested for in many transportation employers’ non-DOT testing programs, would allow the DOT to detect a broader range of potentially impairing drugs and thereby enhance

the safety of the transportation industry and the public they serve.

IV. Discussion of the Proposal

In this NPRM, in addition to proposing to add and remove drugs on the DOT drug-testing panel, we are using this opportunity to make some necessary modifications to Part 40. Specifically, we are proposing to amend certain provisions related to the testing of urine specimens. For example, we would add a new section to Part 40 to emphasize that only urine specimens screened and confirmed at HHS certified laboratories are currently authorized to be used for drug testing. We also have determined, based on a focused analysis of historical drug-testing program data, that the burdens associated with blind specimen testing may not be cost-beneficial. Therefore, in the interest of reducing burden on program participants who are affected by blind specimen testing requirements, we propose to remove this requirement from our program. We propose other, mainly editorial, revisions to improve the efficiency of our program, such as removing compliance dates that are no longer needed and updating program web links to reflect those currently being used on the DOT Web site.

Here is a more detailed summary of our specific proposals. We propose to:

1. Amend our drug-testing panel and Medical Review Officer (MRO) test result verification procedures to add hydrocodone, hydromorphone, oxycodone, and oxymorphone (and their corresponding test cutoff concentrations), add MDA as an initial test analyte, and remove MDEA.

2. Remove, modify, and add some definitions to further clarify our program and also to make certain definitions consistent with the revised HHS Mandatory Guidelines.

3. Modify three provisions related to urine specimens. We propose to: Add a new provision to indicate that only urine specimens are authorized to be used for drug testing under Part 40; revise an existing provision to describe the procedure for discarding an original urine specimen under certain circumstances; and align our regulations with the revised National Laboratory Certification Program (NLCP) manual by adding three new “fatal flaws” to the existing list of four “fatal flaws” currently found in Part 40.

4. Remove Part 40 provisions that reference blind specimen testing.

5. Add emphasis to an existing Part 40 provision that prohibits DNA testing of urine specimens.

6. Amend § 40.141, which refers to how an MRO obtains information for the

¹ The Drug Testing Advisory Board provides advice to HHS (the Administrator of SAMHSA) based on an ongoing review of the direction, scope, balance, and emphasis of the Agency’s drug-testing activities and the drug testing laboratory certification program. See <http://www.samhsa.gov/about-us/advisory-councils/drug-testing-advisory-board-dtab/board-charter>.

verification decision. We would amend this section to add a clarification that a “prescription” means a “valid prescription under the Controlled Substances Act,” which is language that already exists in Part 40 and add a new paragraph that would harmonize this section with Section 3.5 of the HHS Mandatory Guidelines, which allows MROs to request additional testing of a specimen in certain circumstances.

7. Modify §§ 40.137 and 40.139, the sections that address how the MRO must verify test results, by proposing to make minor modifications to the section headings and regulatory text to incorporate the addition of the four new semi-synthetic opioids.

8. Include a provision that would require collectors, Substance Abuse Professionals (SAPs), MROs, Screening Test Technicians (STTs), and Breath Alcohol Technicians (BATs) to subscribe to the DOT Office of Drug and Alcohol Policy and Compliance (ODAPC) list-serve.

9. Remove the list of SAP certification organizations from the list of qualifying SAP credentials in Part 40. Instead, we would maintain the list of certifying organizations on our Web site.

10. Provide a provision to prohibit program participants from using DOT- (or other Federal agency) branded items (such as logos, titles, emblems, etc.) on their Web sites, publications, etc.

11. Remove certain compliance dates that are now obsolete because they are more than 5 years old.

12. Correct two typos, in §§ 40.233(c)(4) and 40.162(c), that reference incorrect paragraph sections and make an editorial correction in § 40.67(n) that would delete erroneous wording.

13. Update the following appendices to Part 40: Appendices B and C, to add the four new drugs to the drugs listed and remove MDEA; Appendix D, to update a web link; and Appendix H, to remove the instruction sheet for the Management Information System Data Collection from our regulations and move it to our guidance material located on our Web site.

14. Update web links referenced in the current rule that have changed on our DOT Web site.

Detailed Discussion of the Proposals

1. *Modification of the Drug-Testing Panel*—We propose to modify the existing drug-testing panel in § 40.87(a) and the MRO test result verification procedures in §§ 40.137 and 40.139, to include hydrocodone, hydromorphone, oxycodone, and oxymorphone. We also propose to remove MDEA from § 40.87(a) and add MDA as an initial test

analyte as discussed previously in this document. As indicated above in the section of this preamble entitled “II. Authority for this Rulemaking,” OTETA mandates that the DOT drug-testing panel must correspond to HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs. As such, since the inception of our drug-testing program, the DOT has never deviated from HHS on the drugs for which we test, the type of specimens which we test, specimen testing validity values, or initial and confirmatory cutoff values. This proposal is no different. We propose to fully adhere to the revised HHS guidelines regarding the drugs for which we propose to require testing.

Currently, DOT regulations mandate urine testing under a five-panel test. We propose to maintain the current five-panel test, but would rename the existing opiates category in § 40.85 from “opiates” to “opioids” to include the new HHS-mandated drugs.

Opiates are derived from opium poppy plant alkaloid compounds, and include codeine and morphine. Heroin is produced by acetylation of morphine. Opioids is a broader term but, for purposes of Part 40, includes only opiate and semi-synthetic compounds (*i.e.*, hydrocodone, hydromorphone, oxycodone, and oxymorphone). Semi-synthetic opioids interact with the body’s chemical system in the same way as natural opiates (*e.g.* codeine, morphine, and heroin) and produce similar effects. Misuse, abuse, opioid use disorder (addiction), and overdose are potential dangers related to prescription opioids.

The following is a representative sampling of information provided by various organizations who have reported on prescription opioid use trends over the past few years:

- CDC data from 2012 indicates that 259 million prescriptions were written for prescription opioids, which is more than enough to give every American adult their own bottle of pills.²
- According to the SAMHSA National Survey on Drug Use and Health 2014 data, almost 2 million Americans misused or were dependent on prescription opioids.³
- As posted by the Office of National Drug Control Policy, according to the National Center for Health Statistics, the

² Centers for Disease Control and Prevention (2014). Opioid Painkiller and Prescribing. Where You Live Makes a Difference. Available at: <http://www.cdc.gov/vitalsigns/opioid-prescribing/>.

³ Substance Abuse and Mental Health Services Administration, National Survey on Drug Use and Health, 2014. Available at: <http://www.samhsa.gov/data/sites/default/files/NSDUH-FRR1-2014/NSDUH-FRR1-2014.pdf>.

number of overdose deaths involving opioids rose from 28,647 in 2014 to 33,091 in 2015.⁴

- National Center for Health Statistics⁵ data indicates that every year since 2002 more than 40 percent of the total number of overdose deaths in the United States have been related to prescription opioids.

In light of this compelling information regarding opioid use (and the national attention being focused on this issue), we propose to modify the DOT drug-testing regimen not only to meet our statutory obligation under OTETA to do so, but also to raise the level of safety for the transportation industry and the public.

2. *Definitions*—We propose to revise § 40.3 to make the following modifications:

- *Blind specimen or blind performance test specimen* would be removed. Because we are proposing to remove the requirement for blind specimen testing, we no longer would need to define this term in Part 40. In addition, Part 40 provisions do not refer to “blind performance test specimen,” so we propose to remove it as well.

- *DOT, the Department, DOT agency* would be revised to make a clarification with respect to the status of the U.S. Coast Guard. The Coast Guard transferred to the Department of Homeland Security (DHS) in 2003, and as such, is not part of the DOT. The Coast Guard, however, has continued to use Part 40 for most of its drug and alcohol testing procedures. This amendment would clarify that, when Part 40 mentions DOT agencies, the Coast Guard is included under that heading even though it resides in DHS.

- *Drugs* would be revised (for reasons discussed in detail earlier in this preamble) to reflect the addition of hydrocodone, hydromorphone, oxycodone, and oxymorphone to the existing DOT drug-testing panel. Specifically, we would expand the reference to “opiates” in the existing definition to “opioids.”

3. *Clarification/modifications related to urine specimens*—We propose the following three amendments relating to the testing of urine specimens:

- We propose to add a new § 40.210 entitled: “Are drug tests other than urine permitted under the regulations?” to indicate that *only* urine specimens are currently authorized for drug testing. Adding new § 40.210 would establish

⁴ <https://www.whitehouse.gov/the-press-office/2016/12/08/continued-rise-opioid-overdose-deaths-2015-shows-urgent-need-treatment>.

⁵ <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates>.

parity with an existing Part 40 alcohol testing section, § 40.277, entitled: “Are alcohol tests other than saliva or breath permitted under these regulations?” which indicates (for alcohol testing) that only saliva and breath are authorized.

- We propose to amend existing § 40.83 and § 40.199 to include revisions made to the “fatal flaws” listing found in the latest revision of the NLCP Manual which became effective September 21, 2016. Existing paragraph (b) of § 40.199 provides for four “fatal flaws” but would be amended to include three additional fatal flaws included in the revised NLCP Manual for a total of seven fatal flaws that MROs must consider during the review and verification process.

- We propose to amend paragraph § 40.193(b)(4) to address what a collector does when the employee provides a “questionable” specimen (due to signs of tampering or when the temperature is out of range), and then the employee does not provide a second sufficient specimen under direct observation even after being provided with a wait period of up to three hours.

Currently, Part 40 requires the collector to package and send the questionable specimen (*i.e.*, out of temperature range specimen or specimen with signs of tampering) to the laboratory along with a second sufficient specimen assuming a second specimen was collected (§§ 40.65(b)(7) & 40.65(c)(2), respectively). Part 40 does not, however, instruct the collector on what to do with the questionable specimen when the employee does not provide a sufficient specimen after a “shy bladder” wait period. The instructions in § 40.193(b)(1) direct the collector not to discard a questionable specimen; however, these instructions are rooted on the assumption that a second specimen will be collected. So absent a second sufficient specimen, § 40.193 does not tell the collector what to do with the questionable specimen.

Furthermore, we found the following inconsistencies in our guidance documents related to questionable specimens. In the July 2008 Q&A on § 40.193, the collector is instructed to “. . . discard any specimen the employee previously provided . . .” However, the Urine Specimen Collection Guidelines state that the collector is to send the questionable specimen to the laboratory and to immediately initiate another collection under direct observation.

If the employee did not provide a second specimen during the shy bladder period, and the collector sends the questionable specimen to the laboratory, the MRO must verify the employee’s

laboratory-reported questionable sample. The MRO would also conduct an evaluation to determine if a medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine.

The intent of the shy bladder evaluation is to provide the employee with an opportunity to provide an explanation for his/her inability to provide a sufficient specimen. This rationale becomes clouded when it’s coupled with a verified drug test result from the same collection event. If an employee provides a questionable specimen, the employee may have tampered with or substituted his/her specimen. Following this logic, the employee should be able to provide a sufficient specimen immediately after providing the questionable specimen. If the employee cannot provide a sufficient specimen, the employee would have the opportunity to provide an explanation for his/her shy bladder via an evaluation (§ 40.193(c)). Absent a supported medical condition, an employee’s inability to provide a sufficient specimen indicates that the employee chose not to provide a specimen in an effort to avoid a positive drug test result. As such, the MRO would report the result as a “refusal to test” to the employer, further ensuring the safety of the traveling public.

Therefore, we are proposing to require the collector to discard any specimen previously collected, thereby leaving the MRO to report only the outcome of the required evaluation. The Department seeks comment as to whether the proposed amendment to § 40.193 (b)(4) is a reasonable approach or whether there may be an alternate solution to the proposal.

4. Removal of blind specimen testing—We are proposing to remove existing Part 40 provisions (from §§ 40.3, 40.29, 40.103, 40.105, 40.123, 40.169, and 40.189) that reference blind specimen testing. We propose this as a burden-relieving measure for affected entities (*e.g.* employers, C/TPAs, etc.).

Existing Part 40 defines a blind specimen as “a specimen submitted to a laboratory for quality control testing purposes, with a fictitious identifier, so that the laboratory cannot distinguish it from an employee specimen.” Blind specimens are intended to test the accuracy and integrity of the laboratory testing system. As part of an overall quality control effort, employers have been required, since 1990 (54 FR 49857), to send blind urine specimens for drug testing to the laboratories they use. These samples are made to look like normal samples, are packaged in

the same manner, and arrive unannounced at the laboratory. Only the senders know if the results of the blind specimens are negative, positive, adulterated, or substituted.

Initially, in 1990 (54 FR 49854), the Department required three blind test specimens for each 100 employee test specimens. For employers with 2000 or more covered employees, approximately 80 percent of the samples were required to be negative, with the remaining samples positive for one or more of the drugs per sample in a distribution such that all the drugs to be tested were included in approximately equal frequencies of challenge. The positive samples were required to contain only those drugs for which the employer was testing.

DOT has always been concerned about the burdens associated with imposing blind specimen procedures in its drug-testing program and has attempted to reduce such burdens incrementally over time. For example, in an attempt to simplify the process and reduce burden, in 2001, (65 FR 79462; December 19, 2000), the Department revised Part 40 blind specimen requirements by reducing the number of quarterly blind specimens sent to a laboratory from three percent to one percent with a maximum number of 50 blinds per quarter.

In light of this rulemaking and the requirement in Executive Order 13563 to conduct retrospective analyses, we have once again reviewed the impact of blind specimen testing. Upon review, we found that, since the 2000 final rule, we did not identify any laboratory problems regarding false positives. Any discrepancies that have been brought to our attention were problems with the manufacturer of the blinds and not the laboratory testing procedures.

It is also important to remember that the laboratories are rigorously inspected through the HHS National Laboratory Certification Program (NLCP). After a thorough initial inspection, laboratories are inspected semi-annually and receive performance test “PT” samples every quarter. If there are any discrepancies, NLCP thoroughly investigates the matter that requires corrective action as necessary.

Finally, another important “check and balance” already in place is the employee’s split specimen or the “B” bottle. If the employee believes that the primary laboratory erred in reporting his/her result of the “A” bottle, the employee, via the MRO, can request to have his/her split (“B”) specimen sent to another laboratory.

Blind specimen testing requirements have been diligently followed over the

history of our program resulting in no cause for concern regarding laboratory accuracy. After 25 years, blind specimen testing has served its purpose and is now redundant in urine testing. Therefore, the Department seeks comment on any concerns, or unforeseen or unintended consequences, associated with our proposal to remove blind specimen requirements.

5. *DNA testing*—We propose to amend existing § 40.331 to add language that would further clarify that Deoxyribonucleic Acid (DNA) testing is not allowed for DOT-regulated urine specimens. To add further emphasis to this section, we would amend paragraph (f) to add the following sentence: *DNA testing or other types of identity testing are not authorized.* Identity testing, to include (DNA) testing, is prohibited in Section 3.3 of the HHS Mandatory Guidelines and in Part 40. The Department's main reason for imposing this prohibition (*See* 65 FR 79484, 79530) was to provide a safeguard against employees who would attempt to undermine the collection process by substituting a sample and, subsequently, request identity testing so that their sample would not be a match. If an employee believes there has been an error with his/her sample, the employee can request the Bottle B of the specimen to be drug tested (but not DNA tested) at a second HHS certified laboratory.

As the Court of Appeals recently validated in *Swaters v. Department of Transportation*, No. 14–1277 (D.C. Cir. June 24, 2016), the procedures described in the HHS Mandatory Guidelines and a properly completed Federal Drug Testing Custody and Control Form ensure that the specimen provided by the donor is the same specimen tested by a laboratory. Permitting DNA testing would undermine the integrity of the urine testing program because it would legitimize a donor's substitution of urine during an unobserved collection. The Court also indicated that “neither the DOT's general rule against releasing urine samples for DNA testing, nor its refusal to release the sample in this case, is arbitrary, capricious, or contrary to the Omnibus Transportation Employee Testing Act of 1991.”

6. *MRO Verification*—We propose to amend existing § 40.141 (b) to add a parenthetical “*i.e.*” that would indicate that “prescription” is intended to mean (as currently provided in § 40.135 (e)), “a legally valid prescription under the Controlled Substances Act (CSA).”

We understand that there may be various definitions for “prescription” under Federal law (*e.g.*, the Controlled Substances Act Pub. L. 91–513, tit. II, 84

Stat. 1242 (1970) and the Patient Protection and Affordable Care Act, Pub. L. 111–148, 124 Stat. 119 (2010)). As such, we propose to amend existing § 40.141 (b) to add language to indicate that, in the DOT drug-testing program, prescription means “a legally valid prescription under the Controlled Substances Act (CSA).” Doing so will clarify what prescription an MRO can accept when verifying an employee's claim that his/her use of a prescribed medication was the reason for the laboratory-confirmed positive drug result. This clarification does not create a new standard because this language is identical to the language used in § 40.135(e).

We also propose to modify § 40.141(b) to harmonize, in part, with Section 3.5 of the HHS Mandatory Guidelines. Specifically, we propose to allow MROs to conduct additional testing (*i.e.*, D, L stereoisomers and tetrahydrocannabinol (THC–V)) of a DOT urine specimen, if the MRO determines such testing is necessary for the purpose of verifying the drug test result. For example, the MRO could request a D, L stereoisomer test of a laboratory confirmed methamphetamine result to help rule out whether the result was possibly due to the use of an over-the-counter product. Another example would be for the MRO to request a THC–V test when verifying a positive marijuana test result after a dronabinol (Marinol)⁶ prescription is provided by the donor. THC–V testing provides useful information to the MRO when determining whether the laboratory-reported positive result for marijuana resulted from the employee's use of marijuana. As proposed, the MRO would not need to obtain DOT consent prior to requesting the D, L stereoisomer testing and/or the THC–V testing. Furthermore, the HHS-certified laboratory could only conduct these additional tests if its testing meets the appropriate validation and quality control requirements through the NLCP.

7. *Revision of certain Part 40 provisions to incorporate references to the new drugs*—We would revise the existing section headings and some regulatory text in §§ 40.137 and 40.139 to incorporate the proposed addition of the new opioids to the drug-testing panel. We would revise the section headings, and corresponding regulatory language where appropriate in these

⁶ Generically known as dronabinol, Marinol is a Schedule III drug product formulated in sesame oil in soft gelatin capsules, containing synthetic delta-9-THC. FDA has approved Marinol for the treatment of nausea and vomiting associated with cancer chemotherapy and for anorexia. (For further information see 81 FR 53691.)

sections, to clarify our intent regarding how the MRO must verify test results. We would revise the § 40.137 section heading to add the text “semi-synthetic opioids” and the § 40.139 section heading so that it would refer to “6-acetylmorphine, codeine, and morphine” specifically. The Department also proposes to clarify the example used in § 40.139(c)(3) regarding an employee's admission of an unauthorized use of a substance when use of that substance is not confirmed by their drug test.

8. *Subscription to ODAPC list-serve*—We would amend §§ 40.33, 40.121, 40.213, and 40.281 to require collectors, MROs, STTs and BATs, and SAPs to subscribe to the ODAPC list-serve, found on our Web site at <https://www.transportation.gov/odapc/get-odapc-email-updates>. The ODAPC list-serve provides an additional means for these individuals to meet existing requirements in the referenced sections to “be knowledgeable about” and to “keep current on any changes to” materials used in our program. In addition to all of the information (web links) available on the ODAPC Web site, the ODAPC list-serve is the vehicle that allows us to communicate all program matters of importance to our constituency in the most timely manner possible and, by extension, enables us to keep our program responsive. The list-serve is free of charge to list-serve subscribers.

9. *Nationally Recognized Training Organizations*—We propose to remove the list of approved certification organizations and their respective certified drug and alcohol counselors found in § 40.281, paragraph (a)(6) and to display that list on the ODAPC Web site. Currently, when a certification organization requests to be added to the list of acceptable credentials for a SAP, that organization needs to petition the DOT for inclusion. The DOT reviews the petition. If the DOT approves the petition, we must initiate a rulemaking process to add the SAP certification organization to Part 40. Each time a new certification organization is added, the DOT must initiate a separate rulemaking action. Because this is a time-consuming process, we are proposing to display the list on the ODAPC Web site and update it when necessary instead of including all qualified SAP certification organizations in the rule language. Any SAP certification organization seeking to be added to the web-based list would still need to petition the DOT and meet the criteria set forth in Appendix E of Part 40. Although this process would remove the public comment requirement of rulemaking, DOT would

fully vet the organization before deciding to add it to the list. Therefore, as a burden-relieving measure, the Department proposes to remove § 40.281 (a)(6) entirely and henceforth maintain the listing of nationally-recognized training or professional organizations in guidance material at <https://www.transportation.gov/odapc/sap>. In this manner, we would be able to maintain a more responsive list of organizations under which an individual may certify as a SAP and update it as needed without undertaking rulemaking action.

10. *Prohibition against use of federal branding*—We would amend § 40.365 to permit the public interest exclusion of a service agent for that agent's use of a DOT, or a DOT Agency's, logo on a Web site, in printed materials, or in any other manner that represents that the Department has approved, endorsed, or certified the service agent or its activities. The use of the DOT or DOT Agency's logo on materials generated by the DOT or the DOT Agency are permitted as long as the logo was on the original material being reprinted.

11. *Removal of Outdated Compliance Dates*—We would remove existing compliance dates from several Part 40 sections. Five Part 40 sections provide for training with compliance dates dating back to the early 2000s: § 40.33—A training schedule for collectors for qualification training and initial proficiency demonstration; § 40.121—a training schedule for MROs for qualification training; § 40.203—a specific timeframe relating to Federal Drug Testing Custody and Control Forms that has now expired; § 40.213—a training schedule for STTs and BATs for qualification training, initial proficiency training, and refresher training; § 40.281—a training schedule for qualification for SAPs. These compliance dates are no longer applicable, thus we propose to remove them from these sections where they occur.

12. *Editorial corrections*—Section 40.162 entitled “What must MROs do with multiple verified results for the same testing event?” contains an incorrect reference to § 40.159(f) in paragraph (c). Existing § 40.162(c) refers to how an MRO must handle multiple verified non-negative test results and is intended to conform to a § 40.159(g) provision that directs the MRO to act on the verified non-negative result and not report the invalid result unless the split specimen fails to reconfirm the results of the primary specimen. Section 40.162(c), however, inadvertently refers to § 40.159(f) rather than § 40.159(g) requirements because of a typographical

error. We would like this 40.162(c) provision to reference § 40.159(g) which is the correct reference.

Section 40.233 entitled “What are the requirements for proper use and care of EBTs?” contains an incorrect reference to § 40.333(a)(2) in paragraph (c)(4). Existing § 40.233(c)(4) refers to maintaining records of the inspection, maintenance, and calibration of Evidential Breath Testing devices and is intended to conform to a § 40.333(a)(3) provision related to the specific timeframe for keeping such records. Section 40.233(c)(4), however, inadvertently refers to § 40.333(a)(2) rather than § 40.333(a)(3) requirements because of a typographical error. We would like this § 40.233(c)(4) provision to reference § 40.333(a)(3) which is the correct reference.

Section 40.67 entitled “When and how is a directly observed collection conducted?” would be revised to remove the words “As the collector” to clarify that any service agent participating in the testing process (not just the collector) who discovers a direct observation should have taken place, but did not, would inform the employer.

13. *Appendix Items*—We propose amendments to four appendices. At Appendices B and C, we propose to add to the listing of the new drugs to conform with the revised drug testing list in proposed § 40.87 and also remove references to MDEA in those appendices. These revisions are needed to conform with the newly adopted HHS Guidelines that add these drugs. At Appendix D, we propose to modify existing web links from <http://www.dot.gov/ost/odapc> to <https://www.transportation.gov/odapc>. We propose to remove Appendix H in its entirety and relocate it to our Web page. This would remove the instruction sheet entitled “U.S. Department of Transportation Drug and Alcohol Testing MIS Data Collection Form Instruction Sheet” and the actual MIS Data Collection Form. With this change made, we would be able to keep the instruction sheet and MIS Data Collection Form updated as necessary without a rulemaking action.

14. *Web links/electronic submissions*—We would update references to web links that have been revised. Periodically our Departmental webmaster must update DOT Web sites for any number of reasons. The ODAPC Web site “<http://www.dot.gov/ost/odapc>” currently referenced in our regulation is now linked at “<https://www.transportation.gov/odapc>.” Therefore, we propose to update the regulation to replace <http://www.dot.gov/ost/odapc> with [https://](https://www.transportation.gov/odapc)

www.transportation.gov/odapc where the link occurs in the following sections: §§ 40.33, 40.45, 40.105, 40.121, 40.213, 40.225, and 40.401.

V. Regulatory Analyses and Notices

Changes to Federal regulations must undergo several analyses. First, Executive Orders 12866 and 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354), as codified in 5 U.S.C. 601 *et seq.*, requires agencies to analyze the economic impact of regulatory changes on small entities. The Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*) requires that DOT consider the impact of paperwork and other information collection burdens imposed on the public and, under the provisions of PRA section 3507(d), obtain approval from OMB for each collection of information it conducts, sponsors, or requires through regulations. Section (a)(5) of division H of the Fiscal Year 2005 Omnibus Appropriations Act, Public Law 108–447, 118 Stat. 3268 (Dec. 8, 2004) and section 208 of the E-Government Act of 2002, Public Law 107–347, 116 Stat. 2889 (Dec. 17, 2002) requires DOT to conduct a Privacy Impact Assessment (PIA) of a regulation that will affect the privacy of individuals. Finally, the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) requires DOT to analyze this action to determine whether it will have an effect on the quality of the environment. This portion of the preamble summarizes the DOT's analyses of these impacts with respect to this notice.

Executive Order 12866 and 13563 and DOT's Regulatory Policies and Procedures

This proposal is not a significant regulatory action under Executive Order 12866 and 13563, as well as the Department's Regulatory Policies and Procedures (44 FR 11034). It proposes to harmonize specific Part 40 procedures with recently mandated HHS Guidelines and, in the interest of improving efficiency, make certain program modifications. As such, this proposal would not impose any major policy changes and would not impose any significant new costs or burdens. Actually, DOT estimates a cost-savings of at least \$3.1 million per year for the proposed elimination of the requirement for employers to submit blind specimen testing to laboratories.

Costs

The HHS Mandatory Guidelines addressed the burdens associated with the addition of new drugs to the drug-testing panel. The cost impact of drug testing for oxycodone, oxymorphone, hydrocodone, and hydromorphone would be minimal because HHS has determined that all HHS laboratories testing specimens from Federal agencies are currently conducting tests for one or more of these analytes on non-regulated urine specimens. HHS further indicated in its analysis that laboratory personnel currently are trained to test for the additional drugs and test methods already have been implemented. Many HHS-certified laboratories conduct non-regulated tests for transportation employers who already include the four proposed drugs in their non-regulated testing programs. For those employers, therefore, shifting the four drugs from non-regulated tests to regulated tests would not increase testing costs.

HHS determined that the costs associated with implementation of testing for the four additional drugs would be approximately \$0.11–\$0.30 per test. Once the testing has been implemented, the cost per specimen for initial testing for the added analytes would range from \$.06 to \$0.20 due to reagent costs. Current costs for each confirmatory test range from \$5.00 to \$10.00 for each specimen reported as positive due to costs of sample preparation and analysis. HHS indicated that based on information from non-regulated workplace drug testing for these analytes in 2012 and testing performed on de-identified federally regulated specimens in 2011, approximately 1% of the submitted specimens is expected to be confirmed as positive for the added analytes. Therefore, HHS indicates that the added cost for confirmatory testing will be \$0.05 to \$0.10 per submitted specimen.

Approximately 6.3 million DOT-regulated tests occur per year. DOT considered the maximum ranges HHS provided in its analysis. Therefore, with the projected maximum implementation cost per specimen of \$0.30, the maximum cost per specimen of initial testing at \$0.20, and the maximum cost per specimen of confirmation testing at \$0.10, the additional cost per urine test would be an additional \$0.60. Under the new HHS Mandatory Guidelines, and based on an estimated 6.3 million DOT tests conducted annually, a cost of approximately \$3,800,000 would be realized by employers subject to DOT-regulated testing ($\$0.60 \times 6,300,000$ DOT tests annually = \$3,780,000).

HHS indicated that there will be minimal costs associated with adding MDA as an initial test analyte because the current immunoassays can be adapted to test for this analyte. According to HHS, before a lab is allowed to test regulated specimens for MDA, HHS must test three groups of performance test, or “PT” samples. HHS provides the PT samples at no cost to its certified laboratories but HHS estimates that the laboratory costs to conduct the PT testing would range from \$900 to \$1800 for each certified laboratory. There are approximately 27 HHS-certified laboratories who process DOT drug tests. With the maximum cost estimate of \$1800 for each certified laboratory, a cost of approximately \$48,600 would be realized for DOT ($\$1800 \times 27$ laboratories = \$48,600.)

Testing for additional drugs would result in MRO cost as MROs would have additional review and verification to conduct. Based on the positivity rates from non-regulated workplace drug testing and the additional review of specimens confirmed positive for prescription medications, HHS estimates that MRO costs would increase by approximately 3%. The additional costs for testing and MRO review would be incorporated into the overall cost for the Federal agency submitting the specimen to the laboratory. HHS bases the estimation of costs incurred on overall cost to the Federal agency affected because cost is usually based on all specimens submitted from an agency, rather than individual specimen testing costs or MRO review of positive specimens. Based on this analysis, therefore, DOT would project an additional MRO cost of \$189,000 (.03 projected increase \times 6,300,000 DOT tests annually).

Cost-Savings

DOT estimates a cost-savings of at least \$3.1 million per year from the proposed elimination of the requirement for employers to submit blind specimen testing to laboratories (estimated at approximately \$50 per test). This estimate of cost-savings is based on the regulatory analysis performed when DOT reduced blind specimen testing in 2000, [see 65 FR 79462, 79517 (Dec 19, 2000)] adjusted for inflation. Based on the blind specimen requirements made effective in 2000 for employers to submit 1% of 6,300,000 DOT tests for blind testing conducted annually at a cost of approximately \$50 per test yields a cost-savings of \$3,150,000 ($63,000 \times \50).

Net Economic Impact

The DOT believes the projected cost-savings realized would, for the most part, offset the projected cost to the DOT of implementing testing for the additional drugs being added to the drug-testing regimen. The projected \$3,848,600 for the four opioid drugs (and MDA) as well as the \$189,000 projected MRO costs would result in a total projected cost of \$4,037,600. The estimated cost impact of this proposal, therefore, would be negligible, an estimated \$887,600 ($\$4,037,600 - \$3,150,000$). If identifying illicit drug use by safety-sensitive transportation employees subjected to drug testing prevents a single serious accident, then the benefits of this proposal outweigh its minimal cost. This proposal would not have a major impact under Executive Order 12866 because it would not have an annual effect on the economy of \$100 million or more, nor would it adversely affect any sector of the economy.

Regulatory Flexibility Analysis

The Regulatory Flexibility Act of 1980 (Pub. L. 96–354, “RFA”), 5 U.S.C. 601 *et seq.*, establishes “as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration.” The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a proposed rule would have a significant economic impact on a substantial number of small entities. If the agency determines that it would, the agency must prepare a regulatory flexibility analysis. However, if an agency determines that it is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) provides that the head of the agency may so certify, and a regulatory flexibility analysis would not be required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

This rulemaking proposes to conform the existing DOT drug-testing panel to recently issued HHS Mandatory

Guidelines and, with certain minor amendments (mostly editorial), to improve the efficiency of the DOT drug-testing program. As noted above, any costs due to this rule are, for the most part, offset by the cost savings from the proposed elimination of the requirement for employers to submit blind specimen testing to laboratories. The net costs of this rule are negligible overall and would not constitute a significant burden to any entity, small or otherwise. Consequently, the DOT certifies, under the RFA, that this proposal would not have a significant economic impact on a substantial number of small entities.

Federalism

This proposal has been analyzed in accordance with the principles and criteria contained in Executive Order 13132 (“Federalism”). This proposal does not include requirements that (1) have substantial direct effects on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government, (2) impose substantial direct compliance costs on State and local governments, or (3) preempt State law. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

Paperwork Reduction Act/Privacy Act

The Paperwork Reduction Act requires that the DOT consider the impact of paperwork and other information collection burdens imposed on the public. Information collections for Part 40 currently are approved under OMB Control No. 2105–0529. The Privacy Act provides safeguards against invasion of personal privacy through the misuse of records by Federal Agencies. It establishes controls over what personal information is collected, maintained, used and disseminated by agencies in the executive branch of the Federal government. This proposal would not create any new paperwork or other information collection burdens needing approval, nor would it require any further protections under the Privacy Act.

National Environmental Policy Act

The Department has analyzed the environmental impacts of this proposed action pursuant to the National Environmental Policy Act of 1969 (NEPA) (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, Federal agencies also must consider whether extraordinary circumstances are present that would warrant the preparation of an EA or EIS. This proposal does not meet any of these criteria. Paragraph 3.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 Highway Administration’s implementing procedures, “[p]romulgation of rules, regulations, and directives.” 23 CFR 771.117(c)(20). The agency does not anticipate any environmental impacts, and there are no extraordinary circumstances present in connection with this rulemaking.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) does not require a written statement for this final rule because the rule does not include a Federal mandate that may result in the expenditure in any one year of \$155,000,000 or more by State, local, and tribal governments, or the private sector.

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.

The Proposal

For reasons discussed in the preamble, the Department of Transportation proposes to amend part 40 of Title 49 Code of Federal Regulations, as follows:

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

■ 1. The authority citation for 49 CFR part 40 continues to read as follows:

Authority: 40 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 54101 *et seq.*

■ 2. Amend § 40.3 as follows:

■ a. Remove the definition “*Blind specimen or blind performance test specimen*”; and

■ b. Revise and reorder (in correct alphabetical order) the definitions

“*DOT, the Department, DOT Agency*” and “*Drugs*” to read as follows:

§ 40.3 What do the terms used in this part mean?

* * * * *

DOT, The Department, DOT Agency. These terms encompass all DOT agencies, including, but not limited to the Federal Aviation Administration (FAA), the Federal Railroad Administration (FRA), the Federal Motor Carrier Safety Administration (FMCSA), the Federal Transit Administration (FTA), the National Highway Traffic Safety Administration (NHTSA), the Pipeline and Hazardous Materials Safety Administration (PHMSA), and the Office of the Secretary (OST). For purposes of this part, the United States Coast Guard (USCG), in the Department of Homeland Security, is considered to be a DOT agency. These terms include any designee of a DOT agency.

* * * * *

Drugs. The drugs for which tests are required under this part and DOT agency regulations are marijuana, cocaine, amphetamines, phencyclidine (PCP), and opioids.

* * * * *

■ 3. Revise § 40.26 to read as follows:

§ 40.26 What form must an employer use to report Management Information System 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 may view and download this form and its instructions on the Department’s Web site (<https://www.transportation.gov/odapc>). 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.

§ 40.29 [Amended]

■ 4. Amend § 40.29 by removing the entry “§§ 40.103–40.105—Blind specimen requirements.”

■ 5. Amend § 40.33 by revising paragraphs (a) and (d) to read as follows:

§ 40.33 What training requirements must a collector meet?

* * * * *

(a) *Basic information.* You must be knowledgeable about this part, the current “DOT Urine Specimen Collection Procedures Guidelines,” and DOT agency regulations applicable to the employers for whom you perform

collections. The DOT Urine Specimen Collection Procedures Guidelines document is available from ODAPC (Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590, 202-366-3784, or on the ODAPC Web site (<https://www.transportation.gov/odapc>). DOT agency regulations are available at each agency's Web site, on the DOT Web site (<http://www.transportation.dot.gov>), or at www.ecfr.gov. You must keep current on any changes to these materials. You must subscribe to the ODAPC list-serve (<https://www.transportation.gov/odapc/get-odapc-email-updates>).

(d) You must meet the requirements of paragraphs (b) and (c) of this section before you begin to perform collector functions.

■ 6. Amend § 40.67 by revising paragraph (n) to read as follows:

§ 40.67 When and how is a directly observed collection conducted?

(n) As a service agent, when you learn that a directly observed collection

should have been collected but was not, you must inform the employer that it must direct the employee to have an immediate recollection under observation.

■ 7. Amend § 40.83 by revising paragraph (c) to read as follows:

§ 40.83 How do laboratories process incoming specimens?

(c) You must inspect each specimen and CCF for the following "fatal flaws:"

- (1) There is no CCF;
- (2) There is no specimen submitted with the CCF;
- (3) There is no printed collector's name and no collector's signature;
- (4) Two separate collections are performed using one CCF;
- (5) The specimen ID numbers on the specimen bottle and the CCF do not match;
- (6) The specimen bottle seal is broken or shows evidence of tampering, unless a split specimen can be redesignated (see paragraph (h) of this section);
- (7) There is an insufficient amount of urine in the primary bottle for analysis, unless the specimens can be

redesignated (see paragraph (h) of this section).

■ 8. Revise § 40.85 to read as follows:

§ 40.85 What drugs do laboratories test for?

As a laboratory, you must test for the following five drugs or classes of drugs in a DOT drug test. You must not test "DOT specimens" for any other drugs.

- (a) Marijuana metabolites.
- (b) Cocaine metabolites.
- (c) Amphetamines.
- (d) Opioids.
- (e) Phencyclidine (PCP).

■ 9. Amend § 40.87 by revising paragraph (a) to read as follows:

§ 40.87 What are the cutoff concentrations for drug tests?

(a) As a laboratory, you must use the cutoff concentrations displayed in the following table for initial and confirmatory drug tests. All cutoff concentrations are expressed in nanograms per milliliter (ng/mL). The table follows:

Initial test analyte	Initial test cutoff ¹	Confirmatory test analyte	Confirmatory test cutoff concentration
Marijuana metabolites (THCA) ²	50 ng/mL ³	THCA	15 ng/mL.
Cocaine metabolite (Benzoyllecgonine)	150 ng/mL ³	Benzoyllecgonine	100 ng/mL.
Codeine/Morphine	2000 ng/mL	Codeine	2000 ng/mL.
		Morphine	2000 ng/mL.
Hydrocodone/Hydromorphone	300 ng/mL	Hydrocodone	100 ng/mL.
		Hydromorphone	100 ng/mL.
Oxycodone/Oxymorphone	100 ng/mL	Oxycodone	100 ng/mL.
		Oxymorphone	100 ng/mL.
6-Acetylmorphine	10 ng/mL	6-Acetylmorphine	10 ng/mL.
Phencyclidine	25 ng/mL	Phencyclidine	25 ng/mL.
Amphetamine/Methamphetamine	500 ng/mL	Amphetamine	250 ng/mL.
		Methamphetamine	250 ng/mL.
MDMA ⁴ /MDA ⁵	500 ng/mL	MDMA	250 ng/mL.
		MDA	250 ng/mL.

¹ For grouped analytes (i.e., two or more analytes that are in the same drug class and have the same initial test cutoff): *Immunoassay:* The test must be calibrated with one analyte from the group identified as the target analyte. The cross-reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.

Alternate technology: Either one analyte or all analytes from the group must be used for calibration, depending on the technology. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present (i.e., equal to or greater than the laboratory's validated limit of quantification) must be equal to or greater than the initial test cutoff.

² An immunoassay must be calibrated with the target analyte, Δ-9-tetrahydrocannabinol-9-carboxylic acid (THCA).

³ *Alternate technology (THCA and benzoyllecgonine):* When using alternate technology to test for THCA and Benzoyllecgonine, the screening and confirmatory test cutoff concentrations must be the same respectively (i.e., 15 ng/mL for THCA and 100 ng/mL for Benzoyllecgonine)."

⁴ Methylendioxyamphetamine (MDMA).

⁵ Methylendioxyamphetamine (MDA).

§ 40.103 [Removed]

■ 10. Remove § 40.103.

■ 11. Remove § 40.105.

■ 12. Amend § 40.121 by revising paragraphs (b)(3) and (c)(3), and the paragraph (d) introductory text to read as follows:

§ 40.121 Who is qualified to act as an MRO?

(b) * * *

(3) You must be knowledgeable about this part, the DOT MRO Guidelines, and the DOT agency regulations applicable to the employers for whom you evaluate drug test results, and you must keep

current on any changes to these materials. You must subscribe to the ODAPC list-serve at <https://www.transportation.gov/odapc/get-odapc-email-updates>. DOT agency regulations, DOT MRO Guidelines, and other materials are available from ODAPC (Department of Transportation, 1200 New Jersey Avenue SE.,

Washington, DC 20590, 202-366-3784, or on the ODAPC Web site (<http://www.transportation.gov/odapc>).

(c) * * *

(3) You must meet the requirements of paragraphs (a), (b), and (c) of this section before you begin to perform MRO functions.

(d) *Requalification training.* During each five-year period from the date on which you satisfactorily completed the examination under paragraph (c) (2) of this section or have successfully completed the required continuing education requirements, you must complete requalification training.

* * * * *

■ 13. Amend § 40.123 by revising paragraph (e) to read as follows:

§ 40.123 What are the MRO's responsibilities in the DOT drug testing program?

* * * * *

(e) You must act to investigate and correct problems where possible and notify appropriate parties (e.g., HHS, DOT, employers, service agents) where assistance is needed (e.g., cancelled or problematic tests, incorrect results).

* * * * *

■ 14. Amend § 40.137 by revising the section heading and paragraph (a) to read as follows:

§ 40.137 On what basis does the MRO verify test results involving marijuana, cocaine, amphetamines, semi-synthetic opioids, or PCP?

(a) As the MRO, you must verify a confirmed positive test result for marijuana, cocaine, amphetamines, semi-synthetic opioids (i.e., hydrocodone, hydromorphone, oxycodone, and oxymorphone), and/or PCP unless the employee presents a legitimate medical explanation for the presence of the drug(s)/metabolite(s) in his or her system.

* * * * *

■ 15. Amend § 40.139 by revising the section heading and paragraphs (c) introductory text and (c)(3) to read as follows:

§ 40.139 On what basis does the MRO verify test results involving 6-acetylmorphine, codeine, and morphine?

* * * * *

(c) For all other codeine and morphine positive results, you must verify a confirmed positive test result only if you determine that there is clinical evidence, in addition to the urine test, of unauthorized use of any opium, opiate, or opium derivative (i.e., morphine, codeine, or heroin).

(1) * * *

(2) * * *

(3) To be the basis of a verified positive result for codeine or morphine, the clinical evidence you find must concern a drug that the laboratory found in the specimen. (For example, if the test confirmed the presence of codeine, and the employee admits to unauthorized use of hydrocodone, you must verify the test positive for codeine. The admission must be for the substance that was found through the actual drug test).

* * * * *

■ 16. Amend § 40.141 by revising paragraph (b) to read as follows:

§ 40.141 How does the MRO obtain information for the verification decision?

* * * * *

(b) If the employee asserts that the presence of a drug or drug metabolite in his or her specimen results from taking prescription medication (i.e., a legally valid prescription under the Controlled Substances Act), you must review and take all reasonable and necessary steps to verify the authenticity of all medical records the employee provides. You may contact the employee's physician or other relevant medical personnel for further information. You may request an HHS-certified laboratory with validated protocols (see § 40.81(c)) to conduct D, Lstereoisomer testing or tetrahydrocannabivarin (THC-V) testing when verifying lab results, as you determine necessary.

■ 17. Amend § 40.162 by revising paragraph (c) to read as follows:

§ 40.162 What must MROs do with multiple verified results for the same testing event?

* * * * *

(c) As an exception to paragraphs (a) and (b) of this section, as the MRO, you must follow procedures at § 40.159(g) when any verified non-negative result is also invalid.

§ 40.169 [Amended]

■ 18. Amend § 40.169 by removing the entry “§ 40.105—Notification of discrepancies in blind specimen results.”

§ 40.189 [Amended]

■ 19. Amend § 40.189 by removing the entry “§ 40.103—Blind split specimens.”

■ 20. Amend § 40.193 by revising paragraph (b)(4) to read as follows:

§ 40.193 What happens when an employee does not provide a sufficient amount of urine for a drug test?

* * * * *

(b) * * *

(4) If the employee has not provided a sufficient specimen within three hours of the first unsuccessful attempt to

provide the specimen, you must discontinue the collection, note the fact on the “Remarks” line of the CCF (Step 2), and immediately notify the DER. You must also discard any specimen the employee previously provided to include any specimen that is ‘out of temperature range’ or shows signs of tampering. In the remarks section of the CCF that you will distribute to the MRO and DER, you must note the fact that the employee provided an ‘out of temperature range specimen’ or ‘specimen that shows signs of tampering’ and that it was discarded because the employee did not provide a second sufficient specimen.

* * * * *

■ 21. Amend § 40.199 by revising paragraph (b) to read as follows:

§ 40.199 What problems always cause a drug test to be cancelled?

(a) * * *

(b) The following are “fatal flaws”:

(1) There is no CCF;

(2) There is no specimen submitted with the CCF;

(3) There is no printed collector's name and no collector's signature;

(4) Two separate collections are performed using one CCF;

(5) The specimen ID numbers on the specimen bottle and the CCF do not match;

(6) The specimen bottle seal is broken or shows evidence of tampering (and a split specimen cannot be re-designated, see § 40.83(h)); and

(7) Because of leakage or other causes, there is an insufficient amount of urine in the primary specimen bottle for analysis and the specimens cannot be re-designated (see § 40.83(h)).

* * * * *

§ 40.203 What problems cause a drug test to be cancelled unless they are corrected?

(d) * * *

(3) The collector uses a non-Federal form or an expired CCF for the test. This flaw may be corrected through the procedure set forth in § 40.205(b)(2), provided that the collection testing process has been conducted in accordance with the procedures in this part in an HHS-certified laboratory.

■ 23. Add § 40.210 in subpart I to read as follows:

§ 40.210 Are drug tests other than urine permitted under the regulations?

No. Drug tests other than on urine specimens are not authorized for testing under this part. Only urine specimens screened and confirmed at HHS

certified laboratories (see § 40.81) are allowed for drug testing under this part. Point-of-collection urine testing or instant tests are not authorized.

■ 24. Amend § 40.213 by revising paragraphs (a), (d), and (e) to read as follows:

§ 40.213 What training requirements must STTs and BATs meet?

* * * * *

(a) You must be knowledgeable about the alcohol testing procedures in this part and the current DOT guidance. Procedures and guidance are available from ODAPC (Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590, 202-366-3784, or on the ODAPC Web site, <https://www.transportation.gov/odapc>). You must keep current on any changes to these materials. You must subscribe to the ODAPC list-serve at (<https://www.transportation.gov/odapc/get-odapc-email-updates>).

* * * * *

(d) You must meet the requirements of paragraphs (b) and (c) of this section before you begin to perform STT or BAT functions.

(e) *Refresher training.* No less frequently than every five years from the date on which you satisfactorily complete the requirements of paragraphs (b) and (c) of this section, you must complete refresher training that meets all the requirements of paragraphs (b) and (c) of this section.

* * * * *

■ 25. Amend § 40.233 by revising paragraph (c)(4) to read as follows:

§ 40.233 What are the requirements for proper use and care of EBTs?

* * * * *

(c) * * *

(4) You must maintain records of the inspection, maintenance, and calibration of EBTs as provided in § 40.333(a)(3).

* * * * *

■ 26. Amend § 40.281 by revising paragraphs (a)(6), (b)(3), and (c)(3) to read as follows:

§ 40.281 Who is qualified to act as a SAP?

* * * * *

(a) * * *

(6) You are a drug and alcohol counselor certified by an organization listed at <https://www.transportation.gov/odapc/sap>.

(b) * * *

(3) You must be knowledgeable about this part, the DOT agency regulations applicable to the employers for whom you evaluate employees, and the DOT SAP Guidelines. You must keep current on any changes to these materials. You

must subscribe to the ODAPC list-serve at <https://www.transportation.gov/odapc/get-odapc-email-updates>. DOT agency regulations, DOT SAP Guidelines, and other materials are available from ODAPC (Department of Transportation, 1200 New Jersey Avenue SE., Washington DC, 20590 (202-366-3784), or on the ODAPC Web site (<http://www.transportation.gov/odapc>).

(c) * * *

(3) You must meet the requirements of paragraphs (a), (b), and (c) of this section before you begin to perform SAP functions.

* * * * *

■ 27. Amend § 40.331 by revising paragraph (f) to read as follows:

§ 40.331 To what additional parties must employers and service agents release information?

* * * * *

(f) Except as otherwise provided in this part, as a laboratory you must not release or provide a specimen or a part of a specimen to a requesting party, without first obtaining written consent from ODAPC. DNA testing and other types of identity testing are not authorized and ODAPC will not give permission for such testing. If a party seeks a court order directing you to release a specimen or part of a specimen contrary to any provision of this part, you must take necessary legal steps to contest the issuance of the order (*e.g.*, seek to quash a subpoena, citing the requirements of § 40.13). This part does not require you to disobey a court order, however.

* * * * *

■ 28. Amend § 40.365 by revising paragraph (b)(10) to read as follows:

§ 40.365 What is the Department's policy concerning starting a PIE proceeding?

* * * * *

(b) * * *

(10) For any service agent, representing falsely that the service agent or its activities is approved or certified by the Department or a DOT agency (such representation includes, but is not limited to, the use of a Department or DOT agency logo, title, or emblem).

* * * * *

■ 29. Revise appendix B to part 40 to read as follows:

Appendix B to Part 40—DOT Drug-Testing Semi-Annual Laboratory Report to Employers

The following items are required on each laboratory report:

Reporting Period: (inclusive dates)
Laboratory Identification: (name and address)

Employer Identification: (name; may include Billing Code or ID code)

C/TPA Identification: (where applicable; name and address)

Specimen Results Reported (total number)
By Test Reason

- (a) Pre-employment (number)
- (b) Post-Accident (number)
- (c) Random (number)
- (d) Reasonable Suspicion/Cause (number)
- (e) Return-to-Duty (number)
- (f) Follow-up (number)
- (g) Type of Test Not Noted on CCF (number)

2. Specimens Reported

- (a) Negative (number)
- (b) Negative and Dilute (number)

3. Specimens Reported as Rejected for Testing (total number)

By Reason

- (a) Fatal flaw (number)
- (b) Uncorrected Flaw (number)

4. Specimens Reported as Positive (total number) By Drug

- (a) Marijuana Metabolite (number)
- (b) Cocaine Metabolite (number)
- (c) Opioids (number)
 - (1) Codeine (number)
 - (2) Morphine (number)
 - (3) 6-AM (number)
 - (4) Hydrocodone (number)
 - (5) Hydromorphone (number)
 - (6) Oxycodone (number)
 - (7) Oxymorphone (number)
 - (d) Phencyclidine (number)
 - (e) Amphetamines (number)
 - (1) Amphetamine (number)
 - (2) Methamphetamine (number)
 - (3) MDMA (number)
 - (4) MDA (number)
- 5. Adulterated (number)
- 6. Substituted (number)
- 7. Invalid Result (number)

■ 30. Revise appendix C to part 40 to read as follows:

Appendix C to Part 40—DOT Drug-Testing Semi-Annual Laboratory Report to DOT

Mail, fax, or email to:

U.S. Department of Transportation, Office of Drug and Alcohol Policy and Compliance, W62-300, 1200 New Jersey Avenue SE., Washington, DC 20590, Fax: (202) 366-3897, Email: ODAPCWebMail@dot.gov.

The following items are required on each report:

Reporting Period: (inclusive dates)
Laboratory Identification: (name and address)
DOT Specimen Results Reported (total number)

2. Negative Results Reported (total number)

- Negative (number)
- Negative-Dilute (number)

3. Rejected for Testing Results Reported (total number)

By Reason

- (a) Fatal flaw (number)
- (b) Uncorrected Flaw (number)

4. Positive Results Reported (total number)

By Drug

- (a) Marijuana Metabolite (number)
- (b) Cocaine Metabolite (number)
- (c) Opioids (number)

- (1) Codeine (number)
 - (2) Morphine (number)
 - (3) 6-AM (number)
 - (4) Hydrocodone (number)
 - (5) Hydromorphone (number)
 - (6) Oxycodone (number)
 - (7) Oxymorphone (number)
 - (d) Phencyclidine (number)
 - (e) Amphetamines (number)
 - (1) Amphetamine (number)
 - (2) Methamphetamine (number)
 - (3) MDMA (number)
 - (4) MDA (number)
5. Adulterated Results Reported (total number)
By Reason (number)
6. Substituted Results Reported (total number)
7. Invalid Results Reported (total number)
By Reason (number)
- 31. Revise appendix D to part 40 to read as follows:

Appendix D to Part 40—Report Format: Split Specimen Failure To Reconfirm

Mail, fax, or submit electronically to: U.S. Department of Transportation, Office of Drug and Alcohol Policy and Compliance, W62-300, 1200 New Jersey Avenue SE., Washington, DC 20590, *Fax:* (202) 366-3897.

Submit Electronically: <https://www.transportation.gov/content/split-specimen-cancellation-notification-49-cfr-part-40187-appendix-d>

The following items are required on each report:

- 1. MRO name, address, phone number, and fax number.
- 2. Collection site name, address, and phone number.
- 3. Date of collection.
- 4. Specimen I.D. number.
- 5. Laboratory accession number.
- 6. Primary specimen laboratory name, address, and phone number.
- 7. Date result reported or certified by primary laboratory.
- 8. Split specimen laboratory name, address, and phone number.

- 9. Date split specimen result reported or certified by split specimen laboratory.
- 10. Primary specimen results (*e.g.*, name of drug, adulterant) in the primary specimen.
- 11. Reason for split specimen failure-to-reconfirm result (*e.g.*, drug or adulterant not present, specimen invalid, split not collected, insufficient volume).
- 12. Actions taken by the MRO (*e.g.*, notified employer of failure to reconfirm and requirement for recollection).
- 13. Additional information explaining the reason for cancellation.
- 14. Name of individual submitting the report (if not the MRO).

Appendix H to Part 40 [Removed]

- 32. Remove appendix H to part 40.

Dated: January 12, 2017.

Anthony R. Foxx,

Secretary of Transportation.

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