DEPARTM **de: 4910-9X**

Office of the Secretary

49 CFR Part 40

[Docket DOT-OST-2025-0049]

RIN 2105-AF26

Procedures for Transportation Workplace Drug and Alcohol Testing Programs: Addition of Fentanyl to the Department of Transportation's Drug-Testing Panel; Harmonization with Certain Items in the HHS Mandatory Guidelines for Urine and Oral Fluid; and Technical Amendments

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

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The U.S. Department of Transportation (Department or DOT) proposes to amend its drug-testing program regulation, 49 CFR part 40 (part 40), to add fentanyl (a synthetic opioid) and norfentanyl (a metabolite of fentanyl) to its drug testing panels. The proposed rulemaking would harmonize part 40 with the U.S. Department of Health and Human Services (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines), which DOT must follow for the minimum list of drugs for which DOT requires testing, and the comprehensive standards for laboratory drug testing per the Omnibus Employee Testing Act of 1991. Adding fentanyl and norfentanyl is also in the interest of transportation safety, given compelling information regarding the number of overdose deaths in the United States involving fentanyl. The Department also proposes to amend certain provisions of part 40 to harmonize, as appropriate, with the current HHS Mandatory Guidelines using urine (UrMG) and oral fluid

(OFMG). This NPRM also proposes to clarify certain existing part 40 drug testing program provisions and to make technical amendments.

DATES: Comments to this notice of proposed rulemaking should be submitted by [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Late-filed comments will be considered to the extent possible.

FOR FURTHER INFORMATION CONTACT: Bohdan Baczara, Deputy Director, Office of Drug and Alcohol Policy and Compliance, 1200 New Jersey Avenue, S.E., Washington, D.C. 20590; telephone number 202-366-3784; ODAPCWebMail@dot.gov.

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:* Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Ave. S.E., West Building, Ground Floor, Washington, D.C. 20590–0001;
- *Hand Delivery:* West Building, Ground Floor, 1200 New Jersey Ave. S.E., between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329;
- *Instructions:* You must include the agency name and docket number DOT-OST-2025-0049 or the Regulatory Identification Number (2105-AF26) 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.

SUPPLEMENTARY INFORMATION:

I. Purpose

DOT requires urine drug testing and authorizes oral fluid drug testing as an alternative methodology to urine drug testing of safety-sensitive transportation industry employees subject to drug testing under part 40 of Title 49 of the Code of Federal Regulations (part 40). DOT's

part 40 regulations are in turn incorporated by reference in the drug and alcohol testing requirements of each of its operating administrations such that updates to part 40 automatically update the pertinent requirements of DOT's operating administrations.[1]

DOT is issuing this NPRM to harmonize part 40, as appropriate, with the revised HHS UrMG published on October 12, 2023 (88 FR 70768), the HHS OFMG published on October 12, 2023 (88 FR 70814), and the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs–Authorized Testing Panels published on January 16, 2025 (90 FR 4662). The Department proposes to harmonize with these HHS Mandatory Guidelines because the Omnibus Transportation Employee Testing Act (OTETA) of 1991 requires DOT to incorporate the HHS scientific and technical guidelines that establish comprehensive standards for all aspects of laboratory testing of controlled substances to ensure full reliability and accuracy in testing. DOT also proposes to clarify certain existing part 40 drug testing program provisions and to make technical amendments.

II. Authority for This Rulemaking

This NPRM is issued pursuant to OTETA of 1991 (Pub. L. 102–143, Tit. V, 105 Stat. 952). While DOT has discretion concerning many aspects of the regulations governing testing in the transportation industries' regulated programs, the Department must follow the HHS Mandatory Guidelines for the minimum list of drugs for which DOT requires testing and the standards for laboratory drug testing. 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 establishes scientific and technical guidelines for Federal workplace drug-testing programs and standards for certification of laboratories engaged in such drug testing.

III. Background

Relevant History of the DOT Drug Testing Program Regulation

[1] *See* § 40.3 (defining "DOT, The Department, DOT Agency" to include each of the DOT operating administrations).

DOT first published its drug-testing program regulation, part 40, on November 21, 1988, as an interim final rule (53 FR 47002). The Department based the rule on HHS's April 11, 1988, Mandatory Guidelines for Federal Workplace Drug Testing Programs (See 53 FR 11970), which, in part, required Federal agencies to test employees for cocaine and marijuana. 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 (See 53 FR 11970). Agencies also were authorized under the 1988 HHS Mandatory Guidelines to test for phencyclidine, amphetamines, and opiates. Among other provisions from those guidelines, DOT published a final rule on December 1, 1989 (54 FR 49854) that incorporated a 5-panel test with all of the drugs HHS authorized for testing.

The Department made comprehensive revisions to part 40 on several occasions and harmonized with the HHS Mandatory Guidelines where necessary. For example, on August 16, 2010 (See 75 FR 49850), DOT harmonized with the HHS Mandatory Guidelines effective October 1, 2010 (See 73 FR 71858; 75 FR 22809). Specifically, the Department required initial and confirmatory testing for methylenedioxymethamphetamine (MDMA), confirmatory testing for methylenedioxyamphetamine (MDA) and methylenedioxymethamphetamine (MDEA); and initial testing for 6-acetylmorphine (6-AM). The Department also lowered the initial and confirmatory test cutoff concentrations for amphetamines and cocaine to conform with HHS changes. On November 13, 2017 (See 82 FR 52229), DOT harmonized with HHS Mandatory Guidelines effective October 1, 2017 (See 82 FR 7920). Specifically, the Department required the initial and confirmatory testing for four additional Controlled Substances Act (CSA) Schedule II prescription opioid medications: hydrocodone, hydromorphone, oxycodone, and oxymorphone. DOT also removed MDEA as a confirmatory test analyte and added MDA as an initial test analyte from the existing drug-testing panel. On May 2, 2023 (See 88 FR 27596), the Department harmonized with the HHS OFMG effective January 1, 2020 (See 88 FR 57554). Specifically, DOT amended part 40 to authorize oral fluid drug testing in the DOT drug testing

program. This additional methodology for drug testing gives employers a choice that will help combat employee cheating on urine drug tests as oral fluid tests are inherently directly observed. Oral fluids testing provides a less intrusive means of achieving the safety goals of the program.

Relevant Changes to the HHS Mandatory Guidelines

After declaring the opioid crisis a public health emergency in 2017, the President signed the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) into law on October 24, 2018. Section 8105 of the Fighting Opioid Abuse in Transportation Act, included in the SUPPORT Act, required the Secretary of HHS to determine whether it is justified, based on the reliability and cost-effectiveness of testing, to revise the Mandatory Guidelines to include fentanyl.[2] In addition, Section 8105 required the Secretary of HHS to consider whether to include any other drugs or other substances listed in Schedule I and II of section 202 of the Controlled Substances Act (CSA) (21 U.S.C. 812).[3]

Historically, when adding or removing drugs/analytes from the authorized drug testing panel, which was included in the HHS Mandatory Guidelines, HHS would publish "proposed revised Mandatory Guidelines" and after reviewing public comment and consulting with its Drug Testing Advisory Board (DTAB), publish "revised Mandatory Guidelines." On April 7, 2022 HHS proposed (87 FR 20560; 87 FR 20522), and then revised on October 12, 2023, its UrMG (88 FR 70768) and OFMG (88 FR 70814), establish a new process for adding and removing drugs/analytes from its drug testing panel that would be more responsive to drug use trends, as well as provide flexibility based on the state of the science (e.g., new technologies and research including dosing studies). Using this new process, HHS would conduct a thorough review of the

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[2] Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act or the SUPPORT for Patients and Communities Act, Public Law No. 115–271, 132 Stat. 3895 (Oct. 24, 2018).

[3] Schedules of Controlled Substances, 21 CFR part 1308. https://www.ecfr.gov/current/title-21/chapter-II/part-1308?toc=1.

scientific and medical literature, solicit input from subject matter experts including DTAB, and provide an opportunity for public comment. Rather than publish the updated drug testing panels (i.e., drugs, analytes, and cutoffs) in the HHS Mandatory Guidelines, HHS would publish them annually or as necessary, in the Federal Register and post them on the HHS website. The drug testing panels are still part of the HHS Mandatory Guidelines by reference in Section 3.4 in both the UrMG and OFMG.

Utilizing the new process described above, HHS issued a notice in the Federal Register on October 17, 2023 announcing a December 5, 2023 DTAB meeting and agenda, which included a proposal to update the HHS drug testing panels to include fentanyl and norfentanyl (88 FR 71582). On November 17, 2023, HHS published a notice of correction to the October 17, 2023 notice stating that the DTAB Board would discuss the Mandatory Guidelines and the proposed revisions to the drug testing panels to (1) add fentanyl for urine and oral fluid and norfentanyl for urine, (2) remove MDMA and MDA, and (3) ask for public comment on its recommended changes to the authorized drug testing panels (88 FR 80323). In both notices, HHS listed the proposed initial and confirmation cutoffs for fentanyl and norfentanyl in urine, listed the proposed initial and confirmation cutoffs for fentanyl in oral fluid, and asked for public comment on the proposed cutoffs.

HHS said:

> Fentanyl accounts for a large proportion of overdose deaths in the United States and is therefore an important public safety concern. Furthermore, fentanyl is increasingly used as a stand-alone substance of abuse, not in conjunction with heroin and other substances as was common in the past. According to the National Forensic Laboratory Information System (NFLIS) 2021 report, fentanyl was the 4th most frequently identified drug and accounted for 11.61% of all drugs reported by forensic laboratories. Norfentanyl is an important component of identifying fentanyl users when urine is the specimen matrix. Fentanyl has been detected in oral fluid in pain management patients, overdose cases, and

driving under the influence of drugs (DUID) cases. Information provided by HHS-certified laboratories in 2023 indicated that a majority (84%) of the laboratories have previously analyzed non-regulated workplace specimens for fentanyl and/or norfentanyl and that all had the ability to analyze urine specimens for fentanyl with sufficiently sensitive detection limits using commercially available immunoassay kits and confirmatory test instrumentation commonly used in HHS-certified laboratories.[4]

On November 1, 2023, DOT sent out a listserv notice[5] informing employers, employees, and testing service providers involved in the DOT drug testing program of the upcoming DTAB meeting, and that the meeting agenda included a discussion regarding a possible update to the HHS analyte table to include fentanyl. DOT reminded the readers that it must follow the HHS scientific guidelines for DOT-regulated drug testing laboratory procedures, and that any change to the HHS analyte table may affect the DOT testing program under part 40, but only after DOT conducts its own conforming rulemaking. The listserv notice also stated that HHS was requesting public comment on the recommendation to add fentanyl and norfentanyl (along with their proposed testing cutoffs) to the analyte table and that comments could be submitted (1) prior to the DTAB meeting, (2) during the DTAB meeting, (3) up to 30 days after the DTAB meeting, but no later than January 4, 2024, or (4) via email to HHS.

On February 9, 2024, HHS published a notice announcing a March 5, 2024 open-session DTAB meeting (89 FR 9166) with presentations regarding the proposed changes to the analyte table, fentanyl prevalence, fentanyl immunoassay updates, cost and benefits analysis, and a summary of public comments received regarding the proposed changes to the HHS drug testing panels. As with the other DTAB-related notices discussed earlier, this notice discussed the reasons for adding fentanyl/norfentanyl and removing MDA and MDMA from the panel and

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[4] 88 FR 71582, HHS Substance Abuse and Mental Health Services Administration (SAMSHA) Notice of Meeting (Oct. 17, 2023), https://www.govinfo.gov/content/pkg/FR-2023-10-17/pdf/2023-22797.pdf (footnote omitted).

[5] U.S. DOT, The Substance Abuse and Mental Health Services Administration Requests Public Comment on the Possible Addition of Fentanyl to the Urine and Oral Fluid Analyte Table (Nov. 1, 2023), https://content.govdelivery.com/accounts/USDOT/bulletins/378c63a.

requested public comment on the proposed changes. At the March 5, 2024 open-session DTAB meeting, there were presentations on (1) the prevalence of fentanyl and norfentanyl in non-regulated specimens, (2) the availability of fentanyl and norfentanyl assays, (3) the costs of testing for fentanyl and norfentanyl, and (4) a summary of the public comments received regarding the proposed panel changes (i.e., addition of fentanyl and norfentanyl and removal of MDMA and MDA from the panel).[6] There were 118 commenters and 176 comments received.[7] The commenters included substance abuse professionals (SAPs), designated employer representatives (DERs), medical review officers (MROs), laboratory responsible persons, employer safety directors/managers, truck drivers, consortium/third-party administrators (C/TPAs), nurses, school district transportation services managers, and national drug testing associations and transportation industry associations.[8]

In a January 16, 2025 Federal Register notice (90 FR 4662), HHS added fentanyl (for urine and oral fluid) and norfentanyl (for urine only) to the authorized drug testing panels after (1) conducting studies to determine the prevalence of fentanyl in drug testing specimens, (2) examining the current state of the technology available to HHS-certified laboratories for initial and confirmatory testing for fentanyl and norfentanyl, (3) identifying and analyzing peer-reviewed publications that reported concentrations of fentanyl and/or norfentanyl in urine and oral fluid to help identify the appropriate testing cutoff concentrations,
(4) requesting, receiving, and reviewing public comment, (5) conducting a cost analysis, and (6) considering input from DTAB.

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[6] Substance Abuse and Mental Health Services Administration, DTAB Meeting March 2024, https://www.samhsa.gov/meetings/dtab-meeting-march-2024.

[7] Substance Abuse and Mental Health Services Administration, DTAB Meeting Open Session Transcript, at 47 (Mar. 5, 2024), https://www.samhsa.gov/sites/default/files/meeting/transcripts/dtab-meeting-transcript-03052024.pdf.

[8] Substance Abuse and Mental Health Services Administration, DTAB Meeting March 2024, Public Comments to Analyte Table Change, https://www.samhsa.gov/sites/default/files/meeting/documents/adding-fentanyl-drug-testing-panel.pdf.

HHS also said that though they had proposed to remove MDMA and MDA from the drug testing panels due to the significantly low laboratory positivity rates, retain MDMA and MDA on the testing panels. This decision was based on HHS's review of all the comments to the docket. HHS said that removing MDMA and MDA from the testing panels was not warranted at this time, but that it will continue to monitor MDMA and MDA prevalence, assess the costs and benefits of removing one or both analytes in the future, and engage with DTAB on the issue.

In the same Federal Register notice, HHS included separate tables with abbreviations for the drug analytes and required HHS laboratories and MROs to report results using this nomenclature. This was done for consistency and to avoid misinterpretations of test results. Specific to marijuana, the drug testing panels include revised abbreviations for the marijuana test analytes to be consistent with current scientific nomenclature. In the urine drug test panel, both the initial and confirmatory test analytes for marijuana were changed from THCA to Δ9THCC. In the oral fluid drug testing panel, both the initial and confirmatory test analytes for marijuana were changed from THC to Δ9THC. HHS also edited Footnote 1 in both drug testing panels to include more specific and updated criteria for alternate technology initial drug tests.

In the latest revisions to the UrMG (effective February 1, 2024) and the OFMG (effective October 10, 2023), HHS also authorized laboratories to conduct biomarker testing in urine and oral fluid specimens after HHS approval and made edits to reflect this change (e.g., adding and defining the terms "biomarker," "biomarker testing panel," and "drug testing panel," and revising the existing definition of "substituted" to address the change to report specimens as substituted based on biomarker testing). Once a biomarker test has been added to the HHS-authorized biomarker testing panel, HHS-certified laboratories may routinely conduct the test without requiring an MRO request, and only require a signed MRO request for case-by-case biomarker testing (in accordance with OFMG section 3.5). HHS continued to require the National Laboratory Certification Program (NLCP) to review biomarker assay validation records

before allowing a laboratory to use the test for federally regulated workplace specimens.[9] HHS will review and approve biomarkers based on submitted laboratory data and support from the scientific and medical literature, then will add approved biomarkers to the biomarker testing panel in a subsequent Federal Register notice. At the time of this NPRM, no biomarkers have been approved for Federal workplace drug testing.

HHS also made other revisions to the UrMG[10] and OFMG,[11] including (1) revising the urine confirmatory test cutoff for morphine, (2) removing the additional decision point of 15,000ng/mL for codeine and morphine in urine, (3) removing the MRO requirement to determine clinical evidence of illegal opioid use to support a positive codeine or morphine result in urine and oral fluid drug testing, and (4) revising the definitions of "adulterated specimen," "cutoff," "initial specimen validity test," "negative result," "substituted specimen," and "positive result."

IV. Discussion of the Proposals

Summary of Proposed Changes to the DOT Drug-Testing Program Regulation

In keeping with the Department's statutory obligation under OTETA of 1991 to incorporate the HHS Mandatory Guidelines specifically for the minimum list of drugs for which DOT requires testing, and for the scientific and technical guidelines related to laboratory testing procedures, the Department proposes to amend part 40 to (1) add the drugs fentanyl and norfentanyl and their respective cutoffs for initial and confirmatory testing (as listed in the HHS urine and oral fluid drug testing panels published in the Federal Register on January 16, 2025, (90 FR 4662)) to the DOT drug testing panels (fentanyl would be added to both the urine and oral fluid testing panels, and norfentanyl to the urine testing panel); (2) adjust the laboratory confirmatory test cutoff for morphine in urine drug testing; (3) remove the MRO requirement to

[9] 87 FR 20560, Mandatory Guidelines for Federal Workplace Drug Testing Programs (Apr. 7, 2022), https://www.govinfo.gov/content/pkg/FR-2022-04-07/pdf/2022-06886.pdf.

[10] https://www.govinfo.gov/content/pkg/FR-2023-10-12/pdf/2023-21734.pdf.

[11] https://www.govinfo.gov/content/pkg/FR-2023-10-12/pdf/2023-21735.pdf.

determine clinical evidence of illegal opioid use to support a positive codeine or morphine result in urine and oral fluid drug testing; (4) add and define the term "biomarker" and revise the definitions of "adulterated specimen," "cutoff," "initial specimen validity test," "negative result," "positive result," and "substituted specimen" for clarity and consistency with HHS; (5) authorize laboratories to conduct biomarker testing once HHS approves laboratory biomarker testing; (6) amend the analyte nomenclature for marijuana in both drug testing panels; and (7) revise the footnotes in both drug testing panels to include more specific and updated criteria for alternate technology initial drug tests. The Department will also provide clarification for certain existing drug testing program provisions and make certain technical amendments.

Proposal to Add Fentanyl and Norfentanyl to DOT Drug Testing Panels.

There are two types of fentanyl: pharmaceutical fentanyl and illicitly manufactured fentanyl. Both are considered synthetic opioids. Pharmaceutical fentanyl is prescribed by doctors to treat severe pain, especially after surgery and for advanced-stage cancer. Most cases of fentanyl-related overdose are linked to illicitly manufactured fentanyl,[12] which is distributed through illegal drug markets for its heroin-like effect. It is often added to other illicit drugs because of its extreme potency, which makes those drugs cheaper, more powerful, more addictive, and more dangerous. Fentanyl is up to 50 times stronger than heroin and 100 times stronger than morphine. It is a major contributor to fatal and nonfatal overdoses in the U.S.[13] Even in small doses, it can be deadly. Over 150 people die in the U.S. every day from overdoses related to synthetic opioids, primarily fentanyl.[14]

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[12] United States Drug Enforcement Administration, Facts about Fentanyl, https://www.dea.gov/resources/facts-about-fentanyl; National Institute of Drug Abuse, Drug Overdose Deaths: Facts and Figures (Aug. 2024), https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates#Fig2.

[13] Wilson N, Kariisa M, Seth P, Smith H IV, Davis NL. Drug and Opioid-Involved Overdose Deaths — United States, 2017–2018. *MMWR Morb Mortal Wkly Rep* 2020; 69:290–297.
DOI: http://dx.doi.org/10.15585/mmwr.mm6911a4.

[14] NCHS, National Vital Statistics System. Estimates for 2020 are based on provisional data. Estimates for 2015-2019 are based on final data (available from: https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm).

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

- Drug overdose death rates involving fentanyl increased by 279 percent from 5.7 per 100,000 in 2016 to 21.6 in 2021, according to new data from the CDC's National Center for Health Statistics (NCHS).[15]
- In 2022, the CDC's NCHS reported and predicted that the number of drug overdose deaths involving synthetic opioids (including fentanyl but excluding methadone) and psychostimulants with abuse potential (such as methamphetamine) continue to increase compared to the previous year.[16]
- According to the State Health Access Data Assistance Center (SHADAC), "Not only has fentanyl become the dominant substance driving today's crisis of drug overdose deaths, but it also has become the center of gravity around which other drugs orbit."[17]
- According to the DEA, "While recent data shows progress in reducing overdose deaths from record highs, nearly half of teens still don't know that counterfeit prescription pills often contain lethal amounts of fentanyl. This lack of knowledge is leading to tragic consequences—young people are dying simply because they didn't know the pill they took was fake. That's why we need to turn awareness into action."[18]
- "While provisional data from the CDC indicates a 25.5% decrease in overdose deaths in the 12 months ending October 2024 compared with the same period in 2023,

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[15] Spencer, M.R., Warner, M., Cisewski, J.A., Miniño, A., Dodds, D., Perera, J., & Ahmad, F.B. (May 2023). Estimates of Drug Overdose Deaths Involving Fentanyl, Methamphetamine, Cocaine, Heroin, and Oxycodone: United States, 2021 (NVSS Rapid Release Report No.27), National Center for Health Statistics (NCHS), https://www.cdc.gov/nchs/data/vsrr/vsrr027.pdf.

[16] NCHS, National Vital Statistics System. Estimates for 2022 are based on provisional data (May 18, 2023) (available from: https://blogs.cdc.gov/nchs/2023/05/18/7365/).

[17] Planalp, C, & Stewart, A (Nov. 2023). The Opioid Crisis in the Pandemic Era. State Health Access Data Assistance Center (SHADAC) (available from: https://www.shadac.org/sites/default/files/publications/Opioid_Crisis/Opioid%20Crisis%20Pandemic-2023%20Brief.pdf).

[18] DEA, April 29, 2025 National Fentanyl Awareness Day, https://fentanylawarenessday.org/.

approximately 150 Americans die every day from overdose involving illegal, synthetic opioids such as illegally made fentanyl. Overdose remains the leading cause of death among Americans aged 18–44. The Administration and HHS remain committed to preventing substance use initiation, reducing the number of lives lost to overdose, and helping Americans to overcome substance use disorders, achieve recovery, and live healthy lives."[19]

- "Approximately 70% of U.S. overdose deaths in 2023 were estimated to involve illegally manufactured fentanyls (IMFs). Local reports indicate reemergence of carfentanil, a fentanyl analog."[20]

In light of this compelling information regarding fentanyl use (and the national attention on this issue), and consistent with the action taken by HHS, the Department proposes to amend the DOT drug testing panels to meet our statutory obligation under OTETA of 1991, and to raise the level of safety for the transportation industry and the transported public. Specifically, the Department proposes to amend the drug-testing panels in sections 40.85(a) and 40.91(a) to include fentanyl in the urine and oral fluid testing panel and norfentanyl to the urine testing panel (along with their corresponding test cutoff concentrations), amend the MRO verification process to include these drugs, and amend Appendices D and E of part 40 to add fentanyl and norfentanyl to the drugs listed on the laboratory reports to employers and DOT.

Recognizing that the term "opioid" is used in a broad context to include various natural, synthetic, and semi-synthetic opioids, the Department proposes to modify its definition of "opioid" in section 40.137 to remove the specific semi-synthetic compounds (i.e., hydrocodone, hydromorphone, oxycodone, and oxymorphone) and use the term "opioids" when referring to the opiates, synthetic opioids, and semi-synthetic opioid test results that an MRO may review and

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[19] Secretary Kennedy Renews Public Health Emergency Declaration to Address National Opioid Crisis, https://www.hhs.gov/press-room/secretary-kennedy-opiod-crisis-emergency-declaration.html.

[20] Detection of Illegally Manufactured Fentanyls and Carfentanil in Drug Overdose Deaths — United States, 2021–2024, https://www.cdc.gov/mmwr/volumes/73/wr/mm7348a2.htm.

verify.

For Urine Drug Testing – Proposal to Adjust the Laboratory Morphine Confirmatory Cutoff and Remove the Additional Requirement for MROs to Look for Clinical Evidence of Illegal Opioid Use

Currently, for a laboratory to report a positive codeine/morphine[21] result for a urine specimen, the laboratory-confirmed result must be greater than or equal to 2,000 ng/mL.[22] In our December 19, 2000 final rule (65 FR 79462), the Department established a process to address a laboratory-reported positive result, which depends on the laboratory-reported codeine/morphine level. If the morphine level is between 2,000 and 15,000 the burden of proof is on the MRO, if the level is above 15,000 the burden of proof is on the employee. This process was established, in part, to address positive laboratory-reported codeine/morphine results that may be due to poppy seed ingestion. Specifically, if the laboratory-reported codeine or morphine concentration for a urine specimen is greater than 2,000 ng/mL and less than 15,000 ng/mL, the MRO is required to examine the employee for clinical signs of unauthorized use or refer the employee to another physician for this purpose. In conducting the examination of the employee, the MRO or physician may consider such factors as needle tracks, behavioral or psychological signs of acute addiction, clinical history of unauthorized use including admissions by employees, or use of foreign opiate medication without substantiation that the medication was obtained and used legally.[23] The MRO is to use his/her best professional and ethical judgment on a case-by-case basis. If the MRO finds clinical evidence, then the result is verified as "positive." If the MRO does not establish that there is clinical evidence of unauthorized use of an opiate, then the result is verified as "negative." If the laboratory-reported codeine/morphine concentration is 15,000 ng/mL or greater, then the burden of proof falls on the employee to provide a legitimate medical

[21] Codeine and morphine are both metabolites of heroin. Heroin occurs naturally in the poppy seed plant.

[22] 49 CFR 40.85(a).

[23] 49 CFR § 40.139.

explanation, which the employee may meet by showing that she or he had used a legally prescribed medication. When an employee cannot establish a legitimate medical explanation for codeine/morphine at or above 15,000 ng/mL, then the MRO verifies the test as positive.

On April 7, 2022, HHS proposed revisions to its UrMG to (1) raise the confirmatory test cutoff for morphine in urine from 2,000 ng/mL to 4,000 ng/mL and (2) remove the additional requirement for clinical evidence of illegal opioid use to verify laboratory-reported positive codeine/morphine results less than 15,000 ng/mL as positive (87 FR 20560). Regarding morphine cutoff levels, HHS stated that it had reviewed several studies and concluded that those studies "…confirm that urine morphine concentrations exceeding 4,000 ng/mL would be very rare, transient, and a consequence of unrealistic and extreme poppy seed exposure (i.e., ingesting barely tolerable amounts of raw and/or unwashed poppy seeds)." HHS also cited the DEA's 2019 warning about unwashed poppy seeds from online retailers, which stated "… their use and misuse may result in unpredictable outcomes including death when used alone or in combination with other drugs. DEA reiterated that morphine and codeine, if present as contaminants on poppy seed material, are not exempted from Controlled Substances Act (CSA) control." HHS concluded that "…the Department is not aware of any evidence that reasonable or realistic consumption of poppy seed-containing food products would cause a positive drug test using the codeine and morphine cutoffs specified by these Guidelines. Only purposeful consumption of large amounts (*e.g.,* 15 g or more) of raw and/or unwashed poppy seeds has been shown to result in codeine at or above 600 ng/mL or in morphine exceeding 4,000 ng/mL, and the extreme amounts of poppy seeds in these studies, described by subjects as intolerable or barely tolerable, do not represent a real-world situation for donors in a Federal agency testing program." Based on its review of existing research, which did not show that reasonable or realistic consumption of poppy seed-containing products would cause a positive urine drug test result for codeine at the established cutoff of 2,000 ng/mL, HHS did not propose to adjust the cutoff level for codeine in urine.

As mentioned above, the requirement to look for clinical evidence of illegal opioid use to verify laboratory-reported positive codeine/morphine results of less than 15,000 ng/mL (for urine) was established to address positive laboratory-reported codeine/morphine results that may be due to poppy seed ingestion. Because HHS has now identified a morphine cutoff level at which reasonable or realistic consumption of poppy seed-containing products would not trigger a positive urine drug test result, and because the existing codeine cutoff level would also not trigger a positive urine drug test result, HHS has removed the requirement for MROs to look for clinical evidence of illicit opiate use as a decision point on whether to report a urine codeine/morphine result as negative or positive due to poppy seed ingestion.

In its October 2023 revised UrMG effective February 1, 2024, HHS adjusted only the confirmatory test cutoff for morphine from 2,000 ng/mL to 4,000 ng/mL and removed the requirement for clinical evidence of illegal opioid use to verify laboratory-reported positive urine codeine/morphine results less than 15,000 ng/mL as positive as proposed. HHS said that it had received one comment agreeing with the proposed change. HHS made these changes following a notice and opportunity for public comment.

Because DOT's laboratory drug testing procedures must remain consistent with the HHS UrMG as required by OTETA of 1991, the Department proposes to amend the urine drug testing panel in section 40.85 by adjusting the morphine confirmation cutoff from 2,000 ng/mL to 4,000 ng/mL and propose to remove the word "concentrations" from the header in the table to be consistent with the terminology in the HHS urine drug testing panel. Because the proposed morphine cutoff is at a level at which reasonable or realistic consumption of poppy seed-containing products would not trigger a positive urine drug test result, and because the existing codeine cutoff level would also not trigger a positive urine drug test result, there is no need for an additional decision point (i.e., clinical evidence of illegal opioid use). Therefore, the Department proposes to remove the additional requirement in section 40.139 for a clinical exam to identify evidence of illicit opiate use as a decision point on whether to report a

codeine/morphine result as negative or positive due to poppy seed ingestion. Instead, DOT proposes that MROs follow the existing verification process outlined in section 40.137. Accordingly, the Department proposes to modify section 40.137 to include the verification of opiates (6-AM, codeine, and morphine) previously found in section 40.139.

In further support of this proposal, the Department has heard from MROs anecdotally that they have difficulty finding a physician to complete the required clinical examination and that a majority of those examinations result in the MRO verifying the result as "negative." Based on calendar year 2023 data from four HHS-certified laboratories (which conduct approximately 44 percent of the annual DOT tests), approximately 1,782 of the 6.8 million drug tests administered in the DOT program were reported with morphine results between 2,000 ng/mL and 15,000 ng/mL (899 tests were between 2,000–4,000 ng/mL, and 883 tests were between 4,000–15,000 ng/mL). By adjusting the urine morphine confirmation cutoff in part 40, and by removing the requirement for clinical evidence of illegal opioid use for laboratory-reported positive codeine/morphine results less than 15,000 ng/mL, the Department expects that MROs will be better able to verify laboratory-reported urine codeine/morphine results.

For Oral Fluid Drug Testing – Proposal to Remove Additional Requirement for MROs to Look for Clinical Evidence of Illegal Opioid Use

In the OFMG effective January 1, 2020, HHS established a confirmatory cutoff of 15 ng/mL for both codeine and morphine for laboratories to report a laboratory-confirmed positive result and a codeine/morphine level of 150 ng/mL (10 times that of the confirmatory test cutoff) as a conservative decision point for MROs to rule out the possibility of a positive result due to poppy seed consumption. HHS noted that "the 150 ng/mL concentration is higher than the highest concentration seen in study subjects at one hour and later after consumption of raw poppy seeds and products containing poppy seeds."[24] In its OFMG effective October 10, 2023,

[24] https://www.govinfo.gov/content/pkg/FR-2019-10-25/pdf/2019-22684.pdf (pg. 57559).

HHS maintained the confirmatory cutoff of 15 ng/mL for both codeine and morphine for laboratories to report a laboratory-confirmed positive result. HHS also maintained a codeine/morphine level of 150 ng/mL). The MRO must report a codeine/morphine result at or above 150 ng/mL as "positive" unless the employee provides a legitimate medical explanation for the result.

HHS removed the requirement for the MRO to conduct a clinical examination (i.e., physical examination) for laboratory-reported oral fluid results between 15 ng/mL and 150 ng/mL when the donor claimed the result was due to poppy seed consumption. In these cases, the MRO reports the result as "negative" unless the employee admits illicit use. As explained in the HHS April 7, 2022 proposed OFMG (87 FR 20522), MROs routinely conduct donor interviews by telephone, rather than in-person, and some MROs had expressed concern about the feasibility of making a clinical assessment (i.e., physical examination) of the donor. HHS concluded that the additional requirement for clinical evidence of illegal opioid use in these situations was no longer practical or effective. HHS adopted the proposed revisions with no changes in the October 2023 revised OFMG.

DOT proposes to harmonize with HHS on this point as well. Given that HHS has established a "bright line" for codeine/morphine results of 150 ng/mL (having determined that results above this level cannot be caused by the ingestion of poppy seed products and that results below this level are those that MROs are most likely to report a "negative" result based on a clinical exam), the Department does not see the need for an additional decision point (clinical evidence of illegal opioid use) to rule out codeine/morphine results that may have been due to ingestion of poppy seed products. Therefore, the Department proposes to remove the requirement for the MRO to conduct a clinical exam if the result is at or above 15 mg/mL and less than 150 ng/mL, and to report codeine/morphine levels between 15 ng/mL and 150 ng/mL as "negative" when the employee claims poppy seed ingestion. If the employee does not claim poppy seed

ingestion (and for all other codeine/morphine results), the Department proposes that MROs follow the existing verification process outlined in section 40.137.

Because the Department is proposing for an MRO to report a "negative" when the oral fluid codeine/morphine oral fluid results are at or above 15 mg/mL and less than 150 ng/mL when the employee claims poppy seed ingestion, the Department is therefore also proposing to amend section 40.151(d) to include an exception for laboratory positive codeine or morphine, or both, results. Currently paragraph (d) instructs the MRO not to consider an employee's claim of passive or unknown ingestion stories as a legitimate medical explanation.

Since the Department is proposing to remove the requirement for MROs to look for clinical evidence of illegal opioid use in codeine/morphine results in urine and oral fluid specimens, and instead follow the process outlined in section 40.137, there is no need for section 40.139. The Department therefore proposes to move the verification of 6-AM results from section 40.139 to section 40.137 and to remove the remaining section 40.139 in its entirety. DOT specifically seeks comments from MROs on these issues.

Proposal to Add Biomarkers for Urine and Oral Fluid Testing

A biomarker is an endogenous substance used to validate a biological specimen. The purpose of a biomarker test is to determine if the submitted specimen is a human urine or oral fluid specimen as there are many ways a DOT-regulated transportation employee could effectively mask illicit drug use. In essence, a biomarker test is a specimen validity test (SVT). In the October 2023 revisions to the UrMG, HHS adopted its proposed changes to modify the definition of "substituted specimen" to include biomarker test results as an additional reason indicating that a specimen has been submitted in place of an actual donor specimen, and the process for adding biomarkers as well as including them in a biomarker testing panel. HHS adopted procedures to allow for review and comment before any biomarker panel change is published in the *Federal Register*. If a laboratory identifies and validates a biomarker test and submits it to HHS for approval, HHS will follow its established process for ensuring the test

result is scientifically valid and forensically defensible. A laboratory can only conduct biomarker testing once approved by HHS and the biomarker is added to the authorized biomarker panel. HHS has not made biomarker testing mandatory.

Consistent with HHS's April 2004 (69 FR 19644)[25] amendments to make SVT mandatory for Federal employee testing under the HHS Federal Workplace Drug Testing Program, the Department made SVT on DOT urine specimens mandatory in 2008 as an appropriate response to the use of adulterants and attempts to subvert the specimen collection and laboratory testing process. (73 FR35961).[26] The widespread availability of various adulteration and substitution products has not changed since then, and DOT believes that more products are available, including information and online personal testimonials from individuals who have used those products. A simple internet search for "how to beat a drug test" yields hundreds, if not thousands, of results. Any individual who intentionally tries to "beat a drug test" is of significant concern to transportation safety and the traveling public. That said, the drug testing process is in place to ensure that individuals can perform their job functions safely and effectively, and do not subvert drug testing procedures that help ensure public safety.

Given that the purpose of a biomarker test—a laboratory standard for drug testing—is to determine if the submitted specimen is a human specimen, the Department proposes to harmonize with HHS to include biomarker testing as an additional component of SVT for urine. The Department realizes that as biomarker tests are developed by individual laboratories, approved by HHS, and added to HHS's biomarker panel(s), not all laboratories may have the technical capability to conduct biomarker testing and, therefore, will not offer that testing. Therefore, the Department thinks it is prudent to wait until more laboratories have the technical ability to conduct biomarker testing before making it mandatory for DOT testing. Like HHS, DOT will not propose to make biomarker testing mandatory in either urine or oral fluid at this

[25] https://www.govinfo.gov/content/pkg/FR-2004-04-13/pdf/04-7985.pdf.

[26] https://www.govinfo.gov/content/pkg/FR-2008-06-25/pdf/E8-14218.pdf.

time. DOT proposes to amend sections 40.86, 40.87, and 40.88 to authorize biomarker testing in urine. Though DOT has already authorized SVT for oral fluid specimens (See section 40.92), the Department will clarify that SVT testing may include testing for biomarkers. DOT also proposes to amend section 40.93 by removing albumin or immunoglobulin G (IgG) as examples of biomarkers. Though they serve as examples, the Department, like HHS, is removing them because there is a process HHS established to have biomarkers approved and DOT does not want to mislead anyone into thinking that they are approved biomarkers for testing. Furthermore, DOT proposes to harmonize with HHS to amend the definition of "substituted specimen" in section 40.3, add a definition for "biomarker" in the same section, and require a laboratory to report a "substituted" result when a biomarker is absent or when its concentration is not consistent with that established for human urine. However, DOT does not propose to include a biomarker testing panel in part 40, but simply to refer to HHS's published biomarker panel as reference in the Mandatory Guidelines. The Department welcomes comments on this issue.

Because the Department proposes to amend the definition of "substituted specimen" to include the results of a urine or oral fluid biomarker test, DOT also proposes to amend an existing procedural safeguard for employees in the MRO review process for laboratory-reported substituted results. Specifically, in section 40.145, DOT proposes to include a biomarker test result as a test result for which the employee can provide medical evidence to the MRO that the employee can produce a specimen without the presence of a specific biomarker when one is expected in a human specimen, or a specimen with a biomarker concentration that is not consistent with that established for human specimens.

Proposal to Add and Revise Definitions

The Department proposes to modify some existing definitions and add a new term to section 40.3 to align more closely with definitions in the revised HHS Mandatory Guidelines. DOT welcomes your comments on these proposed changes. Specifically, the Department proposes to revise the following definitions, consistent with the HHS definitions:

- *Adulterated specimen* revised to include "nitrite" as an example of a substance present in urine that will cause a laboratory to report an adulterated result;
- *Cutoff* revised to include "biomarkers" as criteria used in the decision for the laboratory in reporting a specimen result or the need for further testing;
- *Initial specimen validity test* revised to state that a "dilute" result is applicable only to a urine specimen;
- *Negative result* revised to include the text "drug metabolite." This is to clarify that a drug or drug metabolite, or both, is either not present or less than the cutoff concentration for the drug or drug metabolite;
- *Positive result* revised to clarify that the quantity of drug reported by the laboratory is equal to or greater than the confirmatory test cutoff. This should help to alleviate any misunderstanding that the final result is not based on the initial test cutoff, but on the confirmatory test cutoff; and
- *Substituted specimen* revised to clarify that a urine or oral fluid specimen can also be reported as substituted based on evidence of either the absence of a biomarker or a biomarker concentration inconsistent with that of a human specimen.

The Department proposes to add the following definition:

- *Biomarker* is an endogenous substance used to validate a biological specimen.

Proposal to Amend Nomenclature for Marijuana and Amend Drug Testing Panel Footnotes

In the urine and oral fluid drug testing panels, HHS revised the drug analyte name and abbreviation nomenclature specifically for the marijuana metabolite. The change was made to be consistent with current scientific nomenclature. In the urine drug test panel, both the initial and confirmatory test analytes for marijuana were changed from THCA to Δ9THCC. In the oral fluid drug testing panel, both the initial and confirmatory test analytes for marijuana were changed from THC to Δ9THC. The oral fluid drug testing panel does not identify the THCA

metabolite as in the urine drug testing panel, but identifies the active Δ9THC analyte. This nomenclature change does not affect the testing process for marijuana, but instead, just affects how laboratories and MROs are to refer to the marijuana analyte. Also, based on current technology and program experience, HHS revised Footnote No. 1 to both drug testing panels to include more specific and updated criteria for alternate technology initial drug tests. In keeping with the OTETA of 1991 requirement to incorporate HHS laboratory standards, the Department proposes revising the drug testing panels in sections 40.85 and 40.91 to harmonize with HHS by incorporating this nomenclature change for marijuana and the revisions in Footnote No. 1.

Other Proposals

Section 40.14 What collection information must employers provide to collectors?

As discussed in the May 2023 final rule, section 40.40(c)(2) no longer mandates that fax numbers be included on the chain of custody form (CCF). Sections 40.14(d) and (f), however, require the employer to provide employer and MRO fax numbers to the collector. This was an oversight, and the Department proposes to correct section 40.14 to be consistent with section 40.40. Specifically, in sections 40.14(d) and (f), DOT proposes to amend the text to make providing the employer and MRO fax numbers to the collectors optional.

Section 40.25 Must an employer check on the drug and alcohol testing record of employees it is intending to use to perform safety-sensitive duties?

The Department proposes to fix an incorrect reference in section 40.25(a)(2), which states that as "…an employer regulated by FMCSA, you must comply with the requirements of this section by using the FMCSA's Drug and Alcohol Clearinghouse in accordance with 49 CFR 382.71(a)." That reference should read section 382.701(a), and not section 382.71(a). Also, in section 40.25(b)(5), DOT directs employers to request certain drug and alcohol information about a prospective employee seeking to begin performing safety-sensitive duties. Though the Department did not specify in (b)(5) all the documents relating to the return-to-duty requirements, these documents include two SAP reports (the initial assessment report and the

follow up evaluation, which also includes the follow up testing plan), the return-to-duty test result(s), and the completed follow up test results. DOT is proposing to amend (b)(5) by listing these documents so employers know what documents they need to obtain so they can verify that the prospective employee has completed the DOT return-to-duty requirements.

Section 40.31 Who may collect specimens for DOT drug testing?

As discussed in the preamble to the May 23, 2023 final rule, and consistent with numerous other deletions of the term "urine" in instances where the rule was intended to cover both urine and oral fluid specimens, the Department amended section 40.31 to separately specify the requirements for collectors of urine and oral fluid specimens. In doing so, DOT did not remove the word "urine" from paragraph (a). Also, DOT believes that paragraphs (b) and (c) should be subparagraphs to paragraph (a). As such, the Department is proposing to remove the word "urine" from paragraph (a) and redesignate (b) and (c) to be subparagraphs (a)(1) and (a)(2) respectively and redesignate paragraphs (d) to (b), (e) to (c) and (f) to (d).

Section 40.33 What training requirements must a urine collector meet for urine collection?

Section 40.35 What training requirements must an oral fluid collector meet for oral fluid collection?

Section 40.213 What training requirements must STTs and BATs meet?

Over time, the Department has heard from associations and individual trainers suggesting that the program and collectors (for urine and oral fluid) would greatly benefit if both the qualification training and the initial proficiency demonstration were completed within 30 days of the completing the qualification training. They also suggested that if an individual cannot complete the entire training within 30 days, the individual re-take the qualification training. The associations and trainers said that the longer the timeframe between the qualification training and the mock collections (i.e., the initial proficiency demonstration), the more the trainee will forget the part 40 required procedures, making it harder for the trainee to demonstrate proficiency during the mock collections. They also pointed out that the "Breath Alcohol Technician

Training: DOT Model Course" already has this standard as a recommendation. Specifically, the model course recommends that: (1) individuals arrange to take the procedural and device proficiency training simultaneously, (2) the entire training process should be completed within 30 days, and (3) the individual be required to retake the procedural training program if the student has not completed the device proficiency training within 30-days of the start of the qualification training.

The Department agrees that the closer in time the qualification training and initial training proficiency are completed, the greater the retention of information and the greater the chances of successfully completing the initial proficiency demonstration. As a program, the Department wants only those qualified to be collectors and Screening Test Technicians (STT)/Breath Alcohol Technicians (BAT) to collect specimens and administer alcohol tests. The Department also agrees that this should be the standard for all collectors and alcohol test technicians (i.e., urine collectors, oral fluid collectors, screening test technicians, and breath alcohol technicians). With the above in mind, DOT proposes to amend sections 40.33, 40.35, and 40.213 to include a 30-day timeframe within which the qualification training and initial proficiency demonstration must be completed when an individual becomes qualified as a collector or alcohol technician, or both, for the first time. There will be no additional costs associated with this proposal as the qualification training and initial proficiency demonstration are already required. The Department is not proposing, however, that the 30-day timeframe also apply to when the oral fluid collector or alcohol technician, or both, seek to qualify on a second device. Because they have already demonstrated proficiency in part 40 when they first became qualified, they will only need to complete mock collections that demonstrate proficiency on the "new-second" device they will be using.

Section 40.35 What training requirements must a collector meet for oral fluid collection?

As stated above, the Department paralleled the oral fluid collector qualifications in section 40.35 as closely as possible to our existing urine collector qualifications in section 40.33.

Regarding the mock collection scenarios specified in section 40.33(c)(1), one scenario is the employee refuses to sign the CCF *and* initial the specimen bottle tamper-evident seal. In the Department's May 2023 final rule (88 FR 27596), DOT included the first part of the scenario (refusing to sign the CCF) but inadvertently left out the second part (refusing to initial the specimen bottle tamper-evident seal). The Department proposes to correct this omission.

Also in the May 2023 final rule, DOT amended section 40.33(f) to not require error correction training for a urine collector when a test was cancelled for circumstances that are beyond the control of the collector. For example, when a specimen is damaged by a delivery truck or is lost in transit. DOT intended to mirror this amendment in section 40.35(f) for oral fluid collectors as it made sense that similar situations could happen with oral fluid specimens and the oral fluid collector should not be held accountable for those errors. To ensure as much consistency as possible, between the urine and oral fluid collector training requirements and to not burden the oral fluid collector with unnecessary error correction training, the Department is proposing to amend section 40.35(f) to not require error correction training for an oral fluid urine collector when a test is cancelled for circumstances that are beyond the control of the collector.

Section 40.61 What are the preliminary steps in the collection process?

Part 40 is clear when the employer is responsible for determining if a refusal to test occurred. For example, with respect to collections, the collector documents what happened at the collection site and provides the employer with the information for the employer to make a final decision about whether the employee's conduct constitutes a refusal to test (See sections 40.191(d)(1)) and 40.355(i)). Section 40.61(f), however, provides incorrect instructions for the specimen collector when an employee fails to comply with the collector's directions. Specifically, it directs the collector to advise the employee that failure to comply with the collector's directions constitutes a refusal to test. This is inconsistent with other sections of part 40 that, in similar circumstances, direct the collector to stop the collection, note the circumstances on the CCF, and report the information to the employer/DER to make the refusal

determination. To the maximum extent practicable, to provide for uniformity and consistency in the requirements for urine and oral fluid testing throughout part 40, the Department proposes to remove the last sentence in section 40.61(f) and mirror section 40.72(b)(2), stating the collector must terminate the collection, note the circumstances in the Remarks section of the CCF, and report the information to the DER as described in section 40.191(a)(8) (failure to cooperate) so that the employer can decide whether to deem the situation a refusal. Except for section 355(j), a service agent should not be determining a refusal that may have part 40 and DOT agency consequences; this is the purview of the employer.

Section 40.65 What does the collector check for when the employee presents a urine specimen?

Part 40 authorizes an employer to use oral fluid specimen collections. For problematic urine collections (e.g., insufficient specimen), section 40.193(a) authorizes the employer to either continue with the original specimen type (urine) for the second collection, or to continue with an alternate specimen type (oral fluid). Section 40.65, however, instructs the urine collector that, in the event of an insufficient urine specimen, the collector is to follow the "shy bladder" procedures in section 40.193(b), which instruct the collector to collect another urine specimen. This is contrary to the instructions in section 40.193(a) that offer the employer the choice of continuing with a urine specimen or to move to an oral fluid specimen. Therefore, the Department proposes to revise the incorrect reference to have section 40.65(a)(1) read "If it does not, you must follow the procedures in 40.193(a)."

Section 40.72 What steps does the collector take in the collection process before the employee provides an oral fluid specimen?

In section 40.72(b)(2), the Department proposes to correct a typographical error. Specifically, at the end of the paragraph, the last word "refusal" should read "refusal to test."

Section 40.73 How is an oral fluid specimen collected?

In § 40.73(c)(4), DOT requires an oral fluid collector to collect a second oral fluid specimen if it is apparent to the collector that the employee tampered with the first specimen.

The logical progression would be for the oral fluid collector to complete the first specimen collection, prepare it for shipment to the laboratory, immediately begin a second oral fluid specimen collection, and send both specimens to the laboratory. The instructions in section 40.73(c)(4), however, only tell the collector to collect a second specimen and are currently silent as to what to do with the tampered first specimen. The Department proposes to correct this "gap" by including supplemental instructions for the collector to complete the first collection and to send both specimens to the laboratory. In this same section, there are no instructions regarding what a collector is to do if the donor refuses to provide a subsequent oral fluid specimen due to tampering with their first specimen. Therefore, the Department proposes to add a new subparagraph to (c)(4)(iii) instructing the collector to discard any specimen the employee provided during the specimen collection procedure, and to notify the DER as soon as practicable so the employer can determine whether the situation constitutes a refusal to test by the employee. Both proposals are consistent with existing part 40 procedures for urine specimen collections (See section 40.65(c)).

Section 40.83 How do laboratories process incoming specimens?

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

HHS added a new "fatal flaw" to its OFMG specifying that the laboratory must reject an oral fluid specimen when a collector fails to document that she or he observed the volume indicator at the time of the collection. (88 FR 70814)[27] HHS's basis for this amendment was that the oral fluid specimen volume is critical to determining specimen concentration, therefore the collector must document that she or he observed the volume indicator at the time of the collection. The Department agrees with this important procedural check, and therefore proposes to amend sections 40.83(c) and 40.199(b) to add this new "fatal flaw" in each section.

[27] https://www.govinfo.gov/content/pkg/FR-2023-10-12/pdf/2023-21735.pdf.

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

MROs are authorized to ask HHS certified labs to run additional drug tests on a case-by-case basis and use the results of those tests to provide information that the MRO would use to verify a drug test result. These additional tests included D, L stereoisomers of amphetamine and methamphetamine (for amphetamine results) and tetrahydrocannabivarin (THC-V) (for marijuana results). In its October 2023 OFMG, HHS did not include testing for THC-V as it relates to oral fluid drug testing because in oral fluid drug testing the test is for active THC, the parent drug, and not for the THCA metabolite. Because the oral fluid test is for the parent drug, THC, there is no question that the employee ingested marijuana and no need for additional testing. The Department agrees and proposes to clarify in section 40.141(b)(2) that the MRO's request for additional testing for tetrahydrocannabivarin (THC-V) would only apply to urine specimens.

Section 40.181 What does the second laboratory do with the split specimen when it is tested to reconfirm a substituted test result?

In both the UrMG and OFMG, HHS added procedures for how a laboratory tests a split specimen when the primary specimen was reported substituted based on testing for a biomarker. As such, the Department is proposing to amend section 40.181 to provide instructions to the "B" laboratory on how to test a urine or oral fluid specimen when testing the split specimen for biomarkers.

When it comes to what action a laboratory and MRO must take when a split is identified as substituted, the Department looks to section 40.187(b)(2). Should biomarker testing be authorized, laboratories and MROs would need instructions on how to proceed if the split specimen was reported substituted based on biomarker testing. The Department believes section 40.187(b)(2) contains the necessary instructions for laboratories and MROs and does not propose to amend it. DOT specifically requests comments from MROs and laboratories on this issue.

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

In § 40.193(a) the Department proposes to add the words "or standing orders" after the word "instructions." This is to ensure consistency with section 40.210, which instructs the collector to follow the employer's instructions, which could be via a discussion or "standing orders" when a decision needs to be made on whether a different specimen type is to be collected during the testing event.

The Department is also proposing to amend section 40.193(b)(2) by adding two sets of instructions for the oral fluid collector. The first proposal is to discard any insufficient specimen the employee provided that had unusual characteristics or signs of tampering (See section 40.73(c)(4)), which results in a subsequent oral fluid specimen collection where the employee fails to provide a sufficient oral fluid specimen after the one hour wait period. Regarding this proposal, it makes sense to rely solely on the outcome of the insufficient specimen process (See section 40.193(c)) as the intent of the "dry mouth" evaluation is to provide the employee with an opportunity to provide an explanation for the inability to provide a sufficient oral fluid specimen. In the insufficient specimen process, an MRO with advice from a referral physician determines whether a medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of specimen. This rationale becomes blurred with a verified drug test result from the same collection event. The reasoning for discarding the insufficient "suspect" specimen is simple. It should reduce opportunities for confusion by the collector on whether to send an insufficient "specimen" to the laboratory when the employee did not provide a sufficient specimen after the one hour wait period and will leave the MRO to report only the outcome of the "dry mouth" evaluation. This proposal is consistent with the existing part 40 instructions for urine collectors during the "shy bladder" period (See section 40.193 (b)(1)(iv)).

The second proposal is to include instructions in section 40.193(b)(2) for the oral fluid collector to discontinue the collection if the employee refuses to provide a subsequent specimen and to notify the employer of the refusal event. The Department is proposing this because this section does not address this possibility. This proposal is consistent with the existing part 40 instructions for urine collectors during the "shy bladder" period (See section 40.193 (b)(1)(iii)).

In the Department's May 2023 final rule, DOT established a 15-minute period during which the employee is permitted to attempt to provide a sufficient oral fluid specimen, codified in 49 CFR § 40.193(b)(2)(i). If the employee does not provide a sufficient specimen, the oral fluid collector will again attempt to collect a sufficient specimen. DOT established the 15-minute wait period based on the HHS OFMG (84 FR 57554). According to HHS, the collector sets the reasonable time limit for the specimen collection (based on the device used, but not to exceed 15 minutes (per device)). It was our understanding that the 15-minute period was more of a general rule, and not device-specific. The Department has since learned that for at least one specific oral fluid collection device that has been approved by the Food and Drug Administration (FDA), the 15-minute period exceeds that device's instructions on the specified period (10 minutes) in which to collect a sufficient specimen. The Department understands that exceeding that device's timeframe for collecting a sufficient specimen would not in and of itself cause the device to fail, but doing so could potentially expose the device to unintentional tongue or other oral movement that may end up breaking or tearing the pad. The Department has also learned that for this specific device, if the volume indicator does not register a sufficient volume during the 10-minute period, waiting an additional 5 minutes will not result in the device registering a sufficient volume. The Department expects that other oral fluid devices will eventually be approved, and that those other devices may have different specimen collection timeframes. To ensure the timeframe in which oral fluid specimens are being collected in accordance with the device manufacturer's instructions, the Department proposes to amend section 40.193(b)(2)(i) to remove the 15-minute period, and instead refer to the manufacturer's instructions.

Section 40.311 What are the requirements concerning SAP reports?

Section 40.329(c) directs the SAP to redact the follow-up testing plan from the SAP report when providing the report to an employee. Section 40.311(f) directs the SAP to provide the SAP reports to the employee if the employee has no current employer but makes no mention of redacting the follow up testing information as stated in section 40.329(c). Without a cross-reference to section 40.329(c), it may lead the SAP or the employee to believe that the reports in their entirety are to be provided.

As such, the Department is proposing to amend section 40.311(f) to clarify that in cases where the report required by section 40.311 is provided to an employee with no current employer, the follow-up testing plan information (required by section 40.311(d)(9) of that report) must be redacted before it is sent to the employee, consistent with section 40.329(c).

Section 40.355 What limitations apply to the activities of service agents?

Section 40.355(j)(2) states that an MRO may make a determination that an employee has refused a drug or alcohol test on the basis of adulteration or substitution. However, the Department omitted the scenario in which the MRO also makes the refusal to test determination when there is not an adequate basis for determining that a medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of specimen (See section 40.191(d)(2) and section 40.193(d)(2)(i)). As such the Department is proposing to include this "refusal to test" scenario to section 40.355(j)(2) as another situation in which an MRO makes the determination on a refusal to test.

Changes to the HHS Mandatory Guidelines that DOT is Not Proposing to Adopt

While the Department is proposing to harmonize part 40 with the laboratory drug testing standards in the revised HHS Mandatory Guidelines as required by OTETA of 1991, which are the core scientific laboratory functions necessary for the DOT's program, there are some items in the revised HHS Mandatory Guidelines that are not specifically related to laboratory drug testing standards that DOT is not proposing to adopt. It is important to note the DOT has the discretion

concerning many other aspects of the regulations governing testing in the transportation industries' regulated programs.

For example, HHS established a requirement in both the UrMG and OFMG that MROs must submit semiannual reports to HHS on laboratory-reported positive specimens that were verified negative by the MRO, including the reason for the negative verification. Specifically, these reports provide HHS with oversight of the MRO reporting practices for such specimens, enhance HHS's ability to verify the accuracy of MRO reports, and address areas of confusion about the Mandatory Guideline requirements. These semiannual reports also provide HHS with a clearer picture of illicit drug use by Federal job applicants and employees.

The DOT's drug testing program already has other mechanisms in place to assess MRO compliance, and to gauge illicit drug use by applicants and DOT-regulated safety-sensitive employees. For example, during inspections, audits,[28] or both, DOT agency auditors, inspectors, or investigators review the MRO drug test verifications and reporting practices for compliance with part 40. Also, when required by DOT agency regulations, DOT-regulated employers submit their Management Information System (MIS) reports (i.e., annual aggregate drug/alcohol testing data) to the DOT agency. The DOT agencies use this data to assess illicit drug use by employees and applicants and to calculate the yearly industry annual drug/alcohol random testing rates. Therefore, requiring approximately 2,400 MROs involved in the DOT drug testing program to submit semi-annual reports on laboratory-positive/MRO-verified negative results to DOT would be an undue burden to the industry, and an added, unnecessary administrative task for DOT to review, analyze, and follow up on each report. For these reasons, the Department is not proposing this non-laboratory drug testing requirement.

HHS also revised both the UrMG and OFMG to remove two exceptions for collectors reporting a refusal to test for a pre-employment test: (1) when an applicant fails to appear for the

[28] DOT Agencies inspect/audit DOT-regulated employers and their service agents (e.g., MRO, SAP, collectors/BATs) as part of the Agency's efforts to ensure employer compliance with Part 40 and the respective modal regulations. The inspections/audits are conducted at a frequency determined by the DOT Agency.

collection in a reasonable time; and (2) when an applicant leaves the collection site before the collection process begins. HHS explained that there is no justification for altering a refusal to test determination based on whether a test is being conducted in the employment, or pre-employment, context, and removed the exceptions.[29] HHS requires all donors to arrive at the collection site in a reasonable time (as established by the Federal agency employer) and requires all donors to remain at the collection site until the collection is complete. When the collector reports a refusal to test, the Federal agency takes action consistent with applicable agency regulations.

In the August 9, 2001 final rule (66 FR 41944),[30] DOT clarified the application of refusal determinations during pre-employment testing. The Department said that an applicant can fail to appear for a test for a number of legitimate reasons (e.g., took another job, decided they did not want to change their present job, or decided they did not want to work for a particular employer). In this type of situation, the Department believed—and still does—that it would be unfair to impose the consequences of a refusal (e.g., having to complete the return-to-duty process or take actions to revoke a certification under some DOT agency regulations) on the applicant. Similarly, there can be situations in which an applicant could legitimately leave a collection site before the test actually commences (e.g., there is a long wait for the test and the applicant has another obligation). DOT additionally clarified that, for the purposes of this provision, the commencement of the pre-employment test means the collector or applicant has selected a collection container (See section 40.191(a)(2) & (3)). Once the collection has commenced, the applicant has committed to the process and must complete it. If the applicant then leaves before the process is complete, or takes another action listed in this section as a refusal, the consequences of a refusal attach. However, if the applicant leaves the site before the test commences, then the applicant is in the same situation as someone who does not appear at all for

[29] https://www.govinfo.gov/content/pkg/FR-2022-04-07/pdf/2022-06886.pdf (pg. 20563).

[30] https://www.govinfo.gov/content/pkg/FR-2001-08-09/pdf/01-19232.pdf (pg., 41947).

the pre-employment test. The consequences of a refusal do not apply in this situation. For these reasons, which the Department believes are still valid today, DOT is not proposing this non-laboratory drug testing standard issue.

Though HHS did not propose any changes to the MRO training requirements, they did receive and respond to comments. Specifically, a commenter said there needs to be substantial clarification regarding additional MRO training on the annual drug testing panel changes and suggested that MROs register with SAMHSA to get updates/announcements and acknowledge review of the information received. For oral fluid testing, a commenter stated that new and existing MROs should receive additional training for oral fluid testing.

HHS responded, and revised its MRO training requirements to clarify that MROs must be trained on any revisions to the drug and biomarker testing panels. HHS stated that it relies on the approved MRO certification entities to ensure that the MROs certified by their organizations meet the HHS Mandatory Guidelines requirements. HHS also clarified that, in addition to posting the HHS Medical Review Officer Guidance Manual and MRO case studies (urine and oral fluid) on its website, it issues notices through the NLCP to the approved MRO certification entities for dissemination to their certified MROs.

DOT believes that its MRO training requirements in section 40.121 already address both issues. First, DOT requires MROs to be knowledgeable of alternative medical explanations for laboratory-confirmed drug test results (urine and oral fluid), and issues relating to substituted specimens. Part 40 also requires the MRO training to include instruction on interpreting drug and validity test results. The Department addressed the issue of whether MROs need additional training for oral fluid testing in our May 2023 rule that permits the use of oral fluid testing in the DOT program. Based on public comments received, DOT stated that it would not require MROs to undergo recertification training, but strongly suggested that MROs seek supplemental information about oral fluid testing by the time HHS certifies at least two oral fluid drug testing laboratories. The Department also stated that it supported the approach of MRO training

organizations offering oral fluid modules to augment the training of MROs who are already current on their training certification requirements. Like HHS, DOT relies on the MRO certification organizations to ensure MROs meet the DOT training requirements. Second, regarding receiving updates/announcements from DOT, the Department already has a regulatory requirement in place for MROs to subscribe to ODAPC's listserv as a mechanism for MROs to keep current on any changes to part 40 and other DOT agency-related information.[31]

HHS revised both the UrMG and OFMG to clarify that only prescription medications can be offered as a legitimate medical explanation for a positive drug test. HHS made this clarification given its concern, rightfully so, that several State laws currently allow a physician to write an "authorization" or "medical recommendation" for a Schedule I substance, specifically marijuana. However, no Schedule I drug, including marijuana, has a currently accepted medical use in the United States. Part 40 already requires the MRO to accept only a legally valid prescription consistent with the Controlled Substance Act (See section 40.137(a) & 40.141(b)).

V. Regulatory Analyses and Notices

Changes to Federal regulations must undergo several analyses. First, Executive Order (E.O.) 12866 and E.O. 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.

[31] https://www.transportation.gov/odapc/get-odapc/email-updates.

3268 (Dec. 8, 2004), and section 208 of the E-Government Act of 2002, Public Law 107-347, 116 Stat. 2889 (Dec. 17, 2002) require 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 DOT's analyses of these impacts with respect to this notice.

E.O. 12866, E.O. 13563, and DOT's Regulatory Policies and Procedures

This proposed rule is not a significant regulatory action under E.O. 12866 and E.O. 13563, as well as under the Department's Regulatory Policies and Procedures (49 CFR Part 5 and DOT Order 2100.6B). It harmonizes specific part 40 procedures with recently revised HHS Mandatory Guidelines for urine and oral fluid. The economic impact of this rulemaking is discussed in the sections that follow.

E.O. 14192

OST has reviewed this NPRM for compliance with E.O. 14192 ("Unleashing Prosperity Through Deregulation"), which requires Federal agencies to offset the number and cost of new regulations through the repeal, revocation, or revision of existing regulations. As discussed above, this action is not a significant rule under E.O. 12866. Accordingly, this proposed rule is not an E.O. 14192 regulatory action because this rule is not significant under E.O. 12866.

Costs

HHS addressed the cost burdens associated with the addition of a new drug to the drug testing panel during the March 5, 2024 DTAB open session and its January 16, 2025 Federal Register notice (90 FR 4662).[32] According to HHS, HHS-certified test facilities and MROs will incur initial costs for administrative and programming changes for the addition of fentanyl and

[32] https://www.govinfo.gov/content/pkg/FR-2025-01-16/pdf/2025-00425.pdf.

norfentanyl.[33] The cost impact of drug testing for fentanyl and norfentanyl would be minimal for those laboratories that already offer fentanyl and norfentanyl testing for non-DOT testing. Those laboratories that use the same cutoff(s) for their non-regulated clients may experience some savings compared to laboratories that do not test for these analytes. Because these costs would be realized due to participating in the Federal Workplace Drug Testing program, the proposed rule will not duplicate this cost.

Once the testing has been implemented, according to HHS, the laboratory cost for screening a specimen for the added analytes would range from $0.23 to $5.00 due to reagent and administrative costs (sample preparation, analysis, and reporting). The cost for each confirmatory test would range from $8.00 to $25.00 for each specimen due to reagent and administrative costs.[34] For our analysis, the Department will use the average of the low and high values for screening ($2.61) and confirmation ($16.5) costs for testing, given that the cost will be less based on the volume of tests a laboratory conducts and that a majority of the specimens are analyzed by less than half of the laboratories conducting the testing. DOT will not consider the cost of reviewing negative fentanyl results in this analysis as it would be duplicative of costs already incurred for the administrative task of reviewing/reporting other negative results for the same specimen. Similarly, DOT will not consider specimen collection costs as there will not be any additional costs related to the collection of a urine specimen, as the urine specimen is already being collected for the analysis of the other drugs for which the Department requires testing.

HHS indicated that based on information from non-regulated workplace drug testing for these analytes in 2017, 2019, and 2022 and testing performed on de-identified federally regulated specimens in 2023, approximately 0.19 percent of the submitted specimens are expected to be screened as positive for the added analytes and that 84 percent of those specimens that screen

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[33] SAMHSA DTAB Meeting, March 5, 2024, Transcript, at 44, https://www.samhsa.gov/sites/default/files/meeting/transcripts/dtab-meeting-transcript-03052024.pdf.

[34] SAMHSA DTAB Meeting, March 5, 2025. Presentation, slide 4.

positive will confirm positive. Based on this information and the approximate 6.9M annual DOT drug tests, DOT estimates 13,110 specimens to screen positive (6.9M x .19%) and 11,012 specimens to confirm positive (13,110 x 84%). The estimated lab costs for screening tests are $18,009,000 (6.9M x $2.61) and the estimated lab costs for confirmation tests are $216,315 (13,110 x $16.5).

Testing for fentanyl will also result in an increased number of positive results requiring MRO reviews. Regarding MRO review fees, the Department understands that most MROs offer bundled pricing (e.g., one fee for reviewing/reporting negative and non-negative results). The Department also understands that the fee for a bundled review ranges from $8–$18. Using an average of the high and low fee of $13 for our analysis, DOT estimates $143,156 in MRO costs (11,102 x $13/MRO review) for reviewing laboratory confirmed fentanyl results.

Therefore, with the estimated 6.9M drug tests conducted annually, laboratory and MRO costs, an estimated annual cost of $18,368,471 would be realized in the DOT-regulated urine drug testing program.

Regarding the adjustment to the morphine cutoff from 2,000ng/mL to 4,000 ng/ml, DOT estimates that approximately 1,782 of the 6.9 million drug tests administered in the DOT program in 2023 were reported with morphine results between 2,000 ng/mL and 15,000 ng/mL (899 tests were between 2,000–4,000 ng/mL, and 883 tests were between 4,000–15,000 ng/mL). Based on the current morphine cutoff, with an average clinical exam cost of $200 and $13 for the MRO review, DOT estimates the cost for the 1,782 clinical exams would be approximately $379,566. Given the proposed morphine cutoff, those same 1,782 test results would now just be MRO reviewed with no clinical exam resulting in a cost of $23,166 (1,782 x $13). Therefore, the Department estimates a cost savings of approximately $356,400 ($379,566 - $23,166).

At this time, HHS does not require HHS-certified test facilities to implement authorized biomarker tests. Each laboratory and IITF should conduct its own cost analysis when deciding

whether to offer biomarker testing to federally regulated clients. HHS will consider costs when deciding whether to require all certified test facilities to test for a specific biomarker.

Economic Impact

The estimated cost of adding fentanyl to the drug testing panel and adjusting the morphine cutoff level and not requiring a clinical exam would be $18,102,071. If identifying illicit drug use by safety-sensitive transportation employees subjected to drug testing prevents a single serious accident, then the benefits of this rule outweigh its minimal cost. Testing for fentanyl will add another layer of deterrence to illicit drug use. Identifying fentanyl as the drug used by the employee will assist SAPs in their assessments and determinations on the appropriate recommendations for education or treatment, or both, of the employee. This rule 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. Because fentanyl is extremely potent, powerful, addictive, and dangerous, it is a significant factor in both fatal and nonfatal overdoses in the United States, making it a crucial public safety issue. Therefore, the Department believes that the benefits of this rulemaking outweigh the associated costs.

Regulatory Flexibility Analysis

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) requires Federal agencies to consider the effects of their regulatory actions on small businesses and other small entities and minimize any significant economic impact. The term “small entities” comprises small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with a population of less than 50,000.

The Department does not expect that the proposed rule would have a significant economic impact on a substantial number of small entities. Many thousands of covered employers are small businesses (e.g., small trucking companies, small transit authorities), as are many service agents (e.g., drug testing laboratories, medical review officers), but given the small net change in

regulatory costs spread over these thousands of small entities, the cost impact per entity is expected to be negligible. Our ability to create special provisions for small entities is limited by the need to have uniform requirements to ensure safety and fairness to employees. There must be a single standard for the accuracy and integrity of the program and the protection of legitimate employee interests that cannot vary with the size of the employer or service agent.

The proposed rule, if adopted, would modify certain part 40 procedures and is intended only to further align our laboratory procedures and processes and MRO procedures, with those requirements that are being directed by the HHS Guidelines, which were considered nonsignificant. The Department would note that all HHS-certified laboratories must have the capability to accurately test for fentanyl and norfentanyl to pass certification requirements of the National Laboratory Certification Program. In addition, Federal agency employee testing programs are already testing for fentanyl and norfentanyl and MROs are no longer required to conduct clinical evaluations to determine illicit opioid use. Our harmonizing on these matters will only bring clarity and consistency to the efforts of the Federal testing programs, programs that are internal to the Federal Government, and those that are regulated by the Federal Government.

Federalism

E.O. 13132 requires Federal agencies to carefully examine actions to determine if they contain policies that have federalism implications or that preempt State law. As defined in the order, "policies that have federalism implications" refer to regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

Most of the regulated parties under the Department's drug testing program are private entities. Some regulated entities are public entities (*e.g.,* transit authorities and public works departments); however, the Secretary has determined that the proposed rule, which, if adopted,

would require the testing of safety-sensitive employees in the transportation industry for fentanyl and norfentanyl, remove the requirement for MROs to look for clinical evidence of illicit opiate use, and authorize the use of biomarker testing to determine if a specimen was substituted does not contain policies that have federalism implications.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (PRA) requires that DOT consider the impact of paperwork and other information collection burdens imposed on the public. This proposed rule would not require any new collection of information under the PRA. Notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a currently valid Office of Management and Budget (OMB) control number. Information collections for part 40 currently are approved under OMB Control No. 2105-0529. This proposed rule will not create any new paperwork or other information collection burdens that require approval.

Privacy Act

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. Anyone is able to search the electronic form of all comments received in any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit https://www.transportation.gov/privacy.

National Environmental Policy Act

The Department has analyzed the environmental impacts of this notice of proposed rulemaking pursuant to NEPA (42 U.S.C. 4321 et seq.). The Department has determined that this rule is categorically excluded pursuant to 23 CFR 771.118(c)(4). Categorical exclusions are categories of actions that the agency has determined normally do not significantly affect the

quality of the human environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS). *See* DOT Order 5610.1D § 9. 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.* § 9(b). The Department's Operating Administrations (OAs) may apply CEs established in another OA's procedures. *Id.* § 9(f). To do so, the Operating Administration "must evaluate the action for extraordinary circumstances identified in the OA procedures in which the CE is established to determine if a normally excluded action may have a significant impact and coordinate with the originating OA to ensure that the CE is being applied correctly." *Id.* This rulemaking, which proposes to amend its drug-testing program regulation, 49 CFR part 40 (part 40), to add fentanyl and norfentanyl to its drug testing program, to amend certain provisions of part 40 to harmonize, as appropriate, with the recently revised HHS Mandatory Guidelines using urine and oral fluid, and to make technical amendments, is categorically excluded pursuant to 23 CFR 771.118(c)(4): "Planning and administrative activities not involving or leading directly to construction, such as: Training, technical assistance and research; promulgation of rules, regulations, directives, or program guidance; approval of project concepts; engineering; and operating assistance to transit authorities to continue existing service or increase service to meet routine demand." The Department has coordinated with the Federal Transit Administration to ensure that this CE is being applied correctly. The Department does not anticipate any environmental impacts, and there are no extraordinary circumstances present in connection with this rulemaking.

Unfunded Mandates Reform Act

The Secretary has examined the impact of this proposed rule under the Unfunded Mandates Reform Act (UMRA) of 1995 (Pub. L. 104-4). This proposed rule does not trigger the requirement for a written statement under sec. 202(a) of the UMRA because this rulemaking

does not impose a mandate that results in an expenditure of $100 million or more by either State, local, and Tribal governments in the aggregate or by the private sector in any one year.

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 Notice of Proposed Rulemaking

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 is amended to read as follows:

Authority: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, 45101 et seq., and 60102 *et seq*.

2. In § 40.3, revise the following definitions to read as follows, keeping them in their correct alphabetical order:

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

* * * * *

Adulterated specimen. A specimen that has been altered, as evidenced by test results showing either a substance that is not a normal constituent for that type of specimen or showing an abnormal concentration of a normal constituent (*e.g.,* nitrite in urine).

* * * * *

Cutoff. The analytical value (*e.g.,* drug, drug metabolite, or biomarker concentration) used as the decision point to determine a result (*e.g.,* negative, positive, adulterated, invalid, or substituted) or the need for further testing.

* * * * *

Initial specimen validity test. The first analysis used to determine if a specimen is adulterated, invalid, substituted, or (for urine) diluted.

* * * * *

Negative result. The result reported by an HHS-certified laboratory to an MRO when a specimen contains no drug or drug metabolite, or both; or the concentration of the drug or drug metabolite is less than the cutoff for that drug or drug class and the specimen is a valid specimen.

* * * * *

Positive result. The result reported by an HHS-certified laboratory when a specimen contains a drug or drug metabolite equal to or greater than the confirmatory test cutoff.

* * * * *

Substituted specimen. A specimen not consistent with a normal human specimen, as determined by HHS (*e.g.,* a urine specimen, with creatinine and specific gravity values that are outside the physiologically producible ranges of human urine, or a urine or oral fluid specimen as evidenced by the absence of a biomarker or a biomarker concentration inconsistent with that established for a human specimen).

* * * * *

3. In § 40.3, add the following definition, in proper alphabetical order:

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

* * * * *

Biomarker is an endogenous substance used to validate a biological specimen.

* * * * *

4. In § 40.14, revise paragraphs (d) and paragraph (f) to read:

§ 40.14 What collection information must employers provide to collectors?

* * * * *

(d) Employer name, address, and phone number (can be pre-printed on the CCF at Step 1-A). A fax number may be included but is not required.

* * * * *

(f) MRO name, address, and phone number (can be pre-printed on the CCF at Step 1-B). A fax number may be included but is not required.

* * * * *

5. In § 40.25, revise subparagraph (a)(2) and subparagraph (b)(5) to read:

§ 40.25 Must an employer check on the drug and alcohol testing record of employees it is intending to use to perform safety-sensitive duties?

* * * * *

(a)(2) If you are an employer regulated by FMCSA, you must comply with the requirements of this section by using the FMCSA's Drug and Alcohol Clearinghouse in accordance with 49 CFR 382.701(a). In addition, you must continue to comply with the requirements of § 40.25 when checking an employee's testing history with employers regulated by a DOT operating administration other than FMCSA.

* * * * *

(b)(5) With respect to any employee who violated a DOT drug and alcohol regulation, documentation of the employee's successful completion of DOT return-to-duty requirements (including the initial and follow up SAP reports, which includes the follow-up testing plan, the return to duty test result(s), and completed follow-up tests). If the previous employer does not have information about an employee's return-do-duty process (e.g., an employer who did not hire an employee who tested positive on a pre-employment test), you must seek to obtain this information from the employee.

* * * * *

6. In § 40.31, revise paragraph (a) to remove the word "urine" and redesignate paragraphs (b) and (c) as subparagraphs (a)(1) and (a)(2). Redesignate paragraph (d) as paragraph (b), paragraph (e) as paragraph (c), and paragraph (f) as paragraph (d).

7. In § 40.33, revise paragraph (d) to read:

§ 40.33 What training requirements must a collector meet for urine collection?

* * * * *

(d) ***Schedule for qualification training and initial proficiency demonstration***. You must meet the requirements of paragraphs (b) and (c) of this section within 30 days of completing the qualification training. If you do not complete the initial proficiency demonstration within 30 days of successfully completing the qualification training, you must again complete the qualification training.

* * * * *

8. In § 40.35, revise subparagraph (c)(1), and paragraphs (d) and (f) to read:

§ 40.35 What training requirements must a collector meet for oral fluid collection?

* * * * *

(c)(1) The five mock collections for each device must include one uneventful collection scenario; one insufficient specimen quantity scenario; one scenario in which the employee has something in their mouth that might interfere with the collection; one scenario in which the employee attempts to tamper with the specimen; and one scenario in which the employee refuses to sign the CCF and initial the specimen bottle tamper-evident seal. For each of the five mock collections, the collector must check the expiration date of the device, show the expiration date to the employee, and record the date on the CCF used. The collector must ensure that when applying the labels, they do not cover the expiration dates.

* * * * *

(d) ***Schedule for qualification training and initial proficiency demonstration***. You must meet the requirements of paragraphs (b) and (c) of this section within 30 days of

completing the qualification training. If you do not complete the initial proficiency demonstration within 30 days of successfully completing the qualification training, you must again complete the qualification training.

* * * * *

(f) ***Error Correction Training***. If you make a mistake in the collection process that causes a test to be cancelled (i.e., a fatal or uncorrected flaw), you must undergo error correction training. This training must occur within 30 days of the date you are notified of the error that led to the need for retraining. If a cancellation is due to an error that occurs outside the collection process (e.g., when a specimen is crushed or otherwise damaged during the transportation process, or is lost in transit), the cancellation is not the result of an error by the collector during the collection process and does not require the collector to be retrained.

* * * * *

9. In § 40.61, revise the introductory text of paragraph (f) to read:

§ 40.61 What are the preliminary steps in the drug testing collection process?

* * * * *

(f) Direct the employee to remove outer clothing (e.g., coveralls, jacket, coat, hat) that could be used to conceal items or substances that could be used to tamper with a specimen. You must also direct the employee to leave these garments and any briefcase, purse, or other personal belongings with you or in a mutually agreeable location. If the employee refuses, the collector must terminate the collection, note the circumstances in the Remarks section of the CCF, and report the information to the DER as described in § 40.191(a)(8) (failure to cooperate), so that the employer can decide whether to deem the situation a refusal.

* * * * *

10. In § 40.65, revise paragraph (a)(1) to read:

§ 40.65 What does the collector check for when the employee presents a urine specimen?

* * * * *

(a)(1) "If it does not, you must follow the procedures in § 40.193(a)."

11. In § 40.72, revise subparagraph (b)(2) to read:

§ 40.72 What steps does the collector take in the collection process before the employee provides an oral fluid specimen?

* * * * *

(b)(2) If the employee refuses to remove the item or rinse, the collector must terminate the collection, note the circumstances in the Remarks section of the CCF, and report the information to the DER as described in § 40.191(a)(8) (failure to cooperate), so that the employer can decide whether to deem the situation a refusal.

* * * * *

12. In § 40.73, revise subparagraph (c)(4)(i) and (ii) and add subparagraph (c)(4)(iii) to read:

§ 40.73 How is an oral fluid specimen collected?

* * * * *

(c) * * *

(4) * * *

(i) Document any unusual characteristics referenced above in the Remarks section of the CCF and complete the collection.

(ii) Proceed with obtaining the new oral fluid specimen from the donor. You must process both the original specimen and the newly collected specimen and send the two sets of specimens to the laboratory. Note on the new CCF that this is another collection for the same testing event (e.g., document in the Remarks section that this is Specimen 2 of 2 and include the Specimen ID number of the other specimen). Make the same notation on the CCF of the suspect specimen but note that it is Specimen 1 of 2.

(iii) If the employee refuses to provide another specimen, you must discard any specimen the employee provided previously during the collection procedure. Note the circumstances in the Remarks section of the CCF and report the information to the DER as described in 40.191(a)(8) (failure to cooperate), so that the employer can determine whether to deem the situation a refusal.

13. In § 40.83 add subparagraph (c)(10) to read as follows:

§ 40.83 How do laboratories process incoming specimens?

* * * * *

(c) * * *

(10) For an oral fluid collection, the collector failed to document the observation of the volume indicator(s) at the time of the collection for a collection device containing a dilutant.

* * * * *

14. Amend § 40.85 by revising paragraph (a) to read as follows:

§ 40.85 What are the cutoff concentrations for urine drug tests?

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

Initial Test Analyte	**Initial Test Cutoff**[1]	**Confirmatory Test Analyte (abbreviation)**	**Confirmatory Test Cutoff Concentration**
Marijuana metabolite (Δ9THCC)	50 ng/mL	Δ9THCC	15 ng/mL
Cocaine metabolite (Benzoylecgonine)	150 ng/mL[2]	Benzoylecgonine	100 ng/mL
Codeine/Morphine	2000 ng/mL	Codeine Morphine	2000 ng/mL 4000 ng/mL
Hydrocodone/ Hydromorphone	300 ng/mL	Hydrocodone Hydromorphone	100 ng/mL 100 ng/mL
Oxycodone/ Oxymorphone	100 ng/mL	Oxycodone Oxymorphone	100 ng/mL 100 ng/mL
6-Acetylmorphine	10 ng/mL	6-Acetylmorphine	10 ng/mL
Phencyclidine	25 ng/mL	Phencyclidine	25 ng/mL
Fentanyl[3]	1 ng/mL	Fentanyl Norfentanyl	1 ng/mL 1 ng/mL
Amphetamine/ Methamphetamine	500 ng/mL	Amphetamine Methamphetamine	250 ng/mL 250 ng/ml
MDMA/MDA	500 ng/mL	Methylenedioxymethamphetamine Methylenedioxyamphetamine	250 ng/mL 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. For a technology that measures a response from the entire group without differentiating between analytes (e.g., an activity-based assay, a mass spectrometric assay that does not differentiate isobaric compounds), the laboratory must compare the result to the initial test cutoff. In the case of an alternate technology that differentiates and quantifies each analyte in the group, the laboratory must compare each analyte's result to the confirmatory test cutoff and reflex specimens with a positive initial test result to confirmatory testing.

[2]Alternate technology (BZE): The confirmatory test cutoff must be used for an alternate technology initial test that is specific for the target analyte (i.e., 100 ng/mL for benzoylecgonine).

[3]A fentanyl immunoassay must have at least 5% cross-reactivity to norfentanyl.

15. Amend § 40.86 by adding a new paragraph (c) to read as follows:

§ 40.86 What is urine validity testing and are laboratories required to conduct it?

* * * * *

(c) As a laboratory, you may conduct biomarker testing. If you conduct biomarker testing, you must only test for those biomarkers identified in the 'biomarker testing panel' referenced in the HHS Mandatory Guidelines, with analytes and cutoffs for initial and confirmatory biomarker tests.

16. Amend § 40.87 by adding a new paragraph (f) to read as follows:

§ 40.87 What validity tests must laboratories conduct on primary urine specimens?

* * * * *

(f) As a laboratory if you conduct biomarker testing, you must only test for those biomarkers identified in the "biomarker testing panel" referenced in the HHS Mandatory Guidelines, with analytes and cutoffs for initial and confirmatory biomarkers.

17. Amend 40.88 by adding a new paragraph (c) to read as follows:

§ 40.88 What criteria do laboratories use to establish that a urine specimen is dilute or substituted?

* * * * *

(c) As a laboratory, you must consider the primary specimen to be substituted when a biomarker is absent or when its concentration is not consistent with that established for human urine.

18. Amend § 40.91 by revising paragraph (a) to read as follows:

§ 40.91 What are the cutoff concentrations for oral fluid drug tests?

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

Initial Test Analyte	**Initial Test Cutoff**[1]	**Confirmatory Test Analyte (abbreviation)**	**Confirmatory Test Cutoff Concentration**
Marijuana (Δ9THC)	4 ng/mL	Δ9THC	2 ng/mL
Cocaine/ Benzoylecgonine	15 ng/mL	Cocaine Benzoylecgonine	8 ng/mL 8 ng/mL
Codeine/Morphine	30 ng/mL	Codeine Morphine	15 ng/mL 15 ng/mL
Hydrocodone/ Hydromorphone	30 ng/mL	Hydrocodone Hydromorphone	15 ng/mL 15 ng/mL
Oxycodone/ Oxymorphone	30 ng/mL	Oxycodone Oxymorphone	15 ng/mL 15 ng/mL
6-Acetylmorphine	4 ng/mL[2]	6-Acetylmorphine	2 ng/mL
Fentanyl	4 ng/mL	Fentanyl	1 ng/mL
Phencyclidine	10 ng/mL	Phencyclidine	10 ng/mL
Amphetamines/ Methamphetamine	50 ng/mL	Amphetamines Methamphetamine	25 ng/mL 25 ng/mL
MDMA/MDA	50 ng/mL	Methylenedioxymethamphetamine Methylenedioxyamphetamine	25 ng/mL 25 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. For a technology that measures a response from the entire group without differentiating between analytes (e.g., an activity-based assay, a mass spectrometric assay that does not differentiate isobaric compounds), the laboratory must compare the result to the initial test cutoff. In the case of an alternate technology that differentiates and quantifies each analyte in the group, the laboratory must compare each analyte's result to the confirmatory test cutoff and reflex specimens with a positive initial test result to confirmatory testing.

[2]Alternate technology (6-AM): The confirmatory test cutoff must be used for an alternate technology initial test that is specific for the target analyte (i.e., 2 ng/mL for 6-AM).

19. Revise § 40.92 by adding a new paragraph (d), redesignating paragraph (c) as paragraph (d) and revising paragraph (c) to read as follows:

§ 40.92 What is oral fluid validity testing, and are laboratories required to conduct it?

* * * * *

(c) You may perform initial and confirmation biomarker testing as authorized by the HHS Mandatory Guidelines for oral fluid.

* * * * *

20. Revise § 40.93 to read as follows:

§ 40.93 What validity tests must laboratories conduct on primary oral fluid specimens?

As a laboratory, if you conduct validity testing under § 40.92, you must conduct it in accordance with the applicable HHS Mandatory Guidelines requirements for validity testing or biomarker testing, or both.

21. Create a new § 40.95 to read as follows:

§ 40.95 What criteria do laboratories use to establish that an oral fluid specimen is substituted?

As a laboratory, you must consider the primary specimen to be substituted when a biomarker is not detected or is present at a concentration inconsistent with that established for a human oral fluid for both the initial test and the confirmatory test on two separate aliquots (i.e., using the test analytes and cutoffs listed in the HHS biomarker testing panel).

22. Amend § 40.137 by revising paragraphs (a) and (c)to read as follows:

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

(a) As the MRO, you must verify a confirmed positive test result for one or more of either marijuana, cocaine, amphetamines, opioids, or PCP, unless the employee presents a legitimate medical explanation for the presence of the drug(s)/metabolite(s) in his or her system. In determining whether an employee's legally valid prescription consistent with the Controlled Substances Act for a substance in these categories constitutes a legitimate medical explanation, you must not question whether the prescribing physician should have prescribed the substance.

* * * * *

(c)(1) The employee has the burden of proof that a legitimate medical explanation exists. The employee must present information meeting this burden at the time of the verification interview. As the MRO, you have discretion to extend the time available to the employee for this purpose for up to five days before verifying the test result, if you determine that there is a reasonable basis to believe that the employee will be able to produce relevant evidence concerning a legitimate medical explanation within that time.

(2) If the laboratory confirms the presence of 6-acetylmorphine (6-AM) in the specimen, you must verify the test result as positive.

(3) When verifying codeine or morphine results in urine, consumption of food products (e.g., poppy seeds) must not be considered a legitimate medical explanation for the employee having morphine or codeine results above the confirmatory cutoffs listed in § 40.85.

(4) When verifying codeine or morphine results in oral fluid, you must verify a result between 15 ng/mL and 150 ng/mL as "negative" when the employee claims ingestion of poppy seed products, unless the employee admits to unauthorized use.

(5) For all other results, you must verify the result as 'positive' unless the employee presents a legitimate medical explanation for the presence of the drug/metabolite in his or her system.

* * * * *

23. Remove § 40.139.

24. Revise § 40.141(b)(2) to read:

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

* * * * *

(b) * * *

(2) When verifying lab results, you may, as you deem necessary, request that an HHS-certified laboratory with validated protocols (*see* § 40.81(c)) to conduct testing for D,L stereoisomers of amphetamine and methamphetamine (for either urine or oral fluid specimens) or for tetrahydrocannabivarin (THC-V) (for urine only).

25. Revise § 40.145 (d), (e)(2), and (h) to read as follows:

§ 40.145 On what basis does the MRO verify test results involving adulteration or substitution?

* * * * *

(d) You must offer the employee the opportunity to present a legitimate medical explanation for the laboratory findings with respect to the presence of the adulterant in the specimen, the creatinine and specific gravity findings for the urine specimen, or the absence of a biomarker or a biomarker concentration that is not consistent with that established for human urine or oral fluid.

* * * * *

(e)* * *

(2) To meet this burden in the case of a substituted specimen, the employee must demonstrate that he or she did produce or could have produced a specimen through physiological means, for urine, meeting the creatinine concentration criterion of less than 2 mg/dL and the specific gravity of less than or equal to 1.0010 or greater than or equal to 1.0200 (see §40.88(b)), or for urine or oral fluid, absent a biomarker or with a biomarker concentration that is not consistent with that established for human urine or oral fluid..

* * * * *

(h) The following are examples of types of evidence an employee could present to support an assertion of a legitimate medical explanation for a substituted result.

(1) Medically valid evidence demonstrating that the employee is capable of physiologically producing urine meeting the creatinine and specific gravity criteria of §40.88(b) or producing a specimen absent a biomarker or with a biomarker concentration that is not consistent with that established for human urine or fluid.

(i) To be regarded as medically valid, the evidence must have been gathered using appropriate methodology and controls to ensure its accuracy and reliability.

(ii) Assertion by the employee that his or her personal characteristics (e.g., with respect to race, gender, weight, diet, or working conditions) are responsible for the substituted result does not, in itself, constitute a legitimate medical explanation. To make a case that there is a legitimate medical explanation, the employee must present evidence showing that the cited personal characteristics actually result in the physiological production of urine meeting the creatinine and specific gravity criteria of §40.88(b) or of a specimen absent a biomarker or with a biomarker concentration that is not consistent with that established for human urine or fluid.

(2) Information from a medical evaluation under paragraph (g) of this section that the individual has a medical condition that has been demonstrated to cause the employee to physiologically produce urine meeting the creatinine and specific gravity criteria of §40.93(b), or physiologically

producing a specimen absent a biomarker or with a biomarker concentration that is not consistent with that established for human urine or fluid.

(i) A finding or diagnosis by the physician that an employee has a medical condition does not in itself constitute a legitimate medical explanation.

(ii) To establish there is a legitimate medical explanation, the employee must demonstrate that the cited medical condition actually results in the physiological production of urine meeting the creatinine and specific gravity criteria of §40.88(b) or of a specimen absent a biomarker or with a biomarker concentration that is not consistent with that established for human urine or fluid.

26. Revise § 40.151(d) to read as follows:

§ 40.151 What are MROs prohibited from doing as part of the verification process?

* * * * *

(d) It is not your function to consider explanations of confirmed positive, adulterated, or substituted test results that would not, even if true, constitute a legitimate medical explanation. For example, an employee may tell you that someone slipped amphetamines into her drink at a party, that she unknowingly ingested a marijuana brownie, or that she traveled in a closed car with several people smoking crack. MROs are unlikely to be able to verify the facts of such passive or unknowing ingestion stories. Even if true, such stories do not present a legitimate medical explanation. Consequently, for all drugs except codeine/morphine oral fluid results as described in § 40.137(c)(4), you must not declare a test as negative based on an explanation of this kind.

* * * * *

27. Revise 40.181 to read:

§ 40.181 What does the second laboratory do with the split specimen when it is tested to reconfirm a substituted test result?

(a) As the laboratory testing a urine split specimen, you must test the split specimen using the confirmatory tests for creatinine and specific gravity, using the criteria set forth in § 40.88.

(b) As the laboratory testing a urine split specimen reported as substituted based on biomarker testing, you must test for the biomarker using its confirmatory test (i.e., using the confirmatory test analytes and cutoffs in the HHS biomarker testing panel)

(c) As the laboratory testing an oral fluid split specimen, you must only conduct the confirmatory biomarker test(s) needed to reconfirm the substituted results reported by the first HHS-certified laboratory.

28. In § 40.193, revise paragraph (a) introductory text and paragraph (b)(2) to read:

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

(a) If an employee does not provide a sufficient amount of specimen to permit a drug test (i.e., 45 mL of urine in a single void, or 2mL oral fluid in a single sampling, as applicable) you, as the collector, must provide another opportunity to the employee to do so. In accordance with the employer's instructions or standing orders, this can be done using the same specimen type as the original collection or this can be done by a collector qualified to use an alternate specimen type for this purpose.

* * * * *

(b) * * *

(2) As the collector, you must do the following when continuing with an oral fluid specimen collection under this section:

(i) Discard the insufficient specimen except where the insufficient specimen showed unusual characteristics (see § 40.73(c)(4)).

(ii) If the employee demonstrates an inability to provide a specimen in accordance with the manufacturer's instructions for using the collection device, and if the donor states that he or she could provide a specimen after drinking some fluids, urge the employee to drink (up to 8 ounces) and wait an additional 10 minutes before beginning the next specimen collection (a period of up to one hour must be provided, or until the donor has provided a sufficient oral fluid specimen, whichever occurs first). If the employee simply needs more time before attempting to provide an oral fluid specimen, the employee is not required to drink any fluids during the one-hour wait time. It is not a refusal to test if the employee declines to drink. The employee must remain at the collection site, in a monitored area designated by the collector, during the wait period.

(iii) If the employee refuses to attempt to provide a new oral fluid specimen or leaves the collection site before the collection process is complete, you must discontinue the collection, note that fact on the "Remarks" line of the CCF (Step 2), and immediately notify the DER of the conduct as provided in § 40.191(e)(1); the employer decides whether the situation is deemed to be a refusal.

(iv) If the employee has not provided a sufficient specimen within one hour 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, including any specimen that shows any unusual characteristics or signs of tampering. In the Remarks section of the CCF that you will distribute to the MRO and DER, note the fact that the employee provided a "specimen that shows unusual characteristics or signs of tampering" and that it was discarded because the employee did not provide a sufficient specimen.

* * * * *

29. Revise § 40.199 by adding a new (b)(10) to read as follows:

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

* * * * *

(b) * * *

(10) For an oral fluid collection, the collector failed to document the observation of the volume indicator(s) at the time of the collection for a collection device containing a diluent.

* * * * *

30. In § 40.213, revise paragraph (d) to read:

§ 40.213 What training requirements must STTs and BATs meet?

* * * * *

(d) ***Schedule for qualification training and initial proficiency demonstration***. You must meet the requirements of paragraphs (b) and (c) of this section within 30 days of completing the qualification training. If you do not complete the initial proficiency demonstration within 30 days of successfully completing the qualification training, you must again complete the qualification training.

* * * * *

31. In **§** 40.311, revise paragraph (f) to read:

§ 40.311 What are the requirements concerning SAP reports?

* * * * *

(f) As a SAP, you must also provide these written reports directly to the employee if the employee has no current employer and to the gaining DOT regulated employer in the event the employee obtains another transportation industry safety-sensitive position. When providing the reports to the employee, you must redact the follow up testing plan information (see § 40.329(c)).

* * * * *

32. In § 40.355, revise subparagraph (j)(2) to read:

§ 40.355 What limitations apply to the activities of service agents?

* * * * *

(j) * * *

(2) As an MRO, you determine that an individual has refused to test on the basis of adulteration, substitution, or there is not an adequate basis for determining that a medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of specimen.

* * * * *

33. Revise Appendix D to Part 40 to read as follows:

Appendix D 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)

A. Urine Specimens

1. Urine 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. Urine Specimens Reported

(a) Negative (number)

(b) Negative and Dilute (number)

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

By Reason

(a) Fatal Flaw (number)

(b) Uncorrected Flaw (number)

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

(a) Marijuana Metabolite (number)

(b) Cocaine Metabolite (number)

(c) Opiates/Opioids (number)

(1) Codeine (number)

(2) Morphine (number)

(3) 6-AM (number)

(4) Hydrocodone (number)

(5) Hydromorphone (number)

(6) Oxycodone (number)

(7) Oxymorphone (number)

(8) Fentanyl (number)

(9) Norfentanyl (number)

(d) Phencyclidine (number)

(e) Amphetamines (number)

(1) Amphetamine (number)

(2) Methamphetamine (number)

(3) MDMA (number)

(4) MDA (number)

5. Urine Adulterated (number)

6. Urine Substituted (number)

7. Urine Invalid Result (number)

B. Oral Fluid Specimens

1. Oral Fluid 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. Oral Fluid Specimens Reported

(a) Negative (number)

(b) Negative and Dilute (number)

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

By Reason

(a) Fatal Flaw (number)

(b) Uncorrected Flaw (number)

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

(a) Marijuana Metabolite (number)

(b) Cocaine Metabolite (number)

(c) Opiates/Opioids (number)

(1) Codeine (number)

(2) Morphine (number)

(3) 6-AM (number)

(4) Hydrocodone (number)

(5) Hydromorphone (number)

(6) Oxycodone (number)

(7) Oxymorphone (number)

(8) Fentanyl (number)

(d) Phencyclidine (number)

(e) Amphetamines (number)

(1) Amphetamine (number)

(2) Methamphetamine (number)

(3) MDMA (number)

(4) MDA (number)

5. Oral Fluid Adulterated (number)

6. Oral Fluid Substituted (number)

7. Oral Fluid Invalid Result (number)

34. Revise Appendix E to Part 40 to read as follows:

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

Mail, fax, or e-mail to:

U.S. Department of Transportation

Office of Drug and Alcohol Policy and Compliance

1200 New Jersey Avenue, S.E.

Washington, D.C. 20590

Fax: (202) 366-3897

E-mail: ODAPCWebMail@dot.gov

The following items are required on each report:

Reporting Period: (inclusive dates)

Laboratory Identification: (name and address)

1. Specimen

-oral fluid or urine

2. DOT agency

-FMCSA, FAA, FRA, FTA, PHMSA, or USCG

3. Test Reason

-Pre-Employment, Random, Reasonable Suspicion/Cause, Post-Accident, Return-to-Duty, Other, and Follow-up

A. DOT Specimen Results Reported (total number)

B. Negative Results Reported (total number)

    1. Negative (number)
    2. Negative-Dilute (number)

C. Rejected for Testing Results Reported (total number)

    By Reason

    1. Fatal flaw (number)
    2. Uncorrected Flaw (number)

D. Positive Results Reported (total number)

    By Drug

    1. Marijuana or Marijuana Metabolite (number)
    2. Cocaine or Cocaine Metabolite (number), or both
    3. Opioids (number)
        a. Codeine (number)
        b. Morphine (number)
        c. 6-AM (number)
        d. Hydrocodone (number)
        e. Hydromorphone (number)
        f. Oxycodone (number)

g. Oxymorphone (number)

h. Fentanyl (number)

i. Norfentanyl (number)

4. Phencyclidine (number)

5. Amphetamines (number)

a. Amphetamine (number)

b. Methamphetamine (number)

c. MDMA (number)

d. MDA (number)

E. Adulterated Results Reported (total number)

By Reason (number)

F. Substituted Results Reported (total number)

G. Invalid Results Reported (total number)

By Reason (number)

Issued in Washington, DC.

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Sean P. Duffy,

Secretary of Transportation

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