

DEPARTMENT OF TRANSPORTATION**Office of the Secretary****49 CFR Part 40**

[Docket DOT–OST–2021–0093]

RIN 2105–AE94

Procedures for Transportation Workplace Drug and Alcohol Testing Programs: Addition of Oral Fluid Specimen Testing for Drugs**AGENCY:** Office of the Secretary, U.S. Department of Transportation (DOT).**ACTION:** Notice of proposed rulemaking.

SUMMARY: The U.S. Department of Transportation is proposing to amend the transportation industry drug testing program procedures regulation to include oral fluid testing. This will give employers a choice that will help combat employee cheating on urine drug tests and provide a more economical, less intrusive means of achieving the safety goals of the program. The proposal includes other provisions to update the Department's regulation, and to harmonize, as needed, with the new Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid established by the U.S. Department of Health and Human Services.

DATES: Comments to the notice of proposed rulemaking should be submitted by March 30, 2022. Late-filed comments will be considered to the extent practicable.

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

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

Instructions: To ensure proper docketing of your comment, please include the agency name and docket number DOT–OST–2021–0093 or the Regulatory Identification Number (RIN), 2105–AE94 for the rulemaking at the beginning of your comments. All comments received will be posted without change to <http://>

www.regulations.gov, including any personal information provided.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:**I. Purpose**

The Department of Transportation (DOT) is issuing this notice of proposed rulemaking (NPRM) to revise part 40 of title 49 of the Code of Federal Regulations (Part 40), “Procedures for Transportation Workplace Drug and Alcohol Testing Programs” to add the oral fluid testing procedures to the existing urine drug testing procedures for safety-sensitive transportation employees subject to drug testing under Part 40 (hereinafter referred to as “employees”). This action is based on the Department of Health and Human Services’ (HHS) establishment of the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) for Federal workplace drug testing programs. HHS determined that oral fluid testing conducted in accordance with the OFMG provides “the same scientific and forensic supportability of drug test results as the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine” (84 FR 57554). The OFMG final rule was published on October 25, 2019, and became effective January 1, 2020.

In addition to adding oral fluid as a drug testing method and harmonizing with pertinent OFMG sections, we also propose to clarify certain Part 40 provisions that cover urine drug testing procedures; to remove provisions that no longer are necessary; to add clarifying language to other provisions such as updated definitions and web links, as appropriate; and to update provisions to reflect issues that have arisen in recent practice.

II. Authority for This Rulemaking

This rulemaking is promulgated under the authority originally enacted in the Omnibus Transportation Employee Testing Act (OTETA) of 1991, codified at 49 U.S.C. 45102 and 45104 (aviation industry testing), 49 U.S.C. 20140 (rail), 49 U.S.C. 31306 (motor carrier), and 49 U.S.C. 5331 (transit). OTETA requires that the Department incorporate the HHS Mandatory Guidelines, including amendments, into the Department's regulations for testing and laboratory requirements for aviation, rail, motor carrier, and transit

testing. Additional authority at 5 U.S.C. 7301 note 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.

While DOT has discretion concerning many aspects of its regulations governing testing in the transportation industries' regulated programs, DOT follows the HHS Mandatory Guidelines for the laboratory and specimen testing procedures. Effective January 1, 2020, the OFMG allowed the option to use oral fluid specimens for Federal drug testing. As described in the OFMG rulemaking, the advantage of every oral fluid collection is that it will be directly observed, as opposed to most urine collections, which are unobserved. While directly observed urine specimen collections have long been the most effective method for preventing individuals from cheating on their drug tests by substituting or adulterating their specimens, directly observed urine collection may only be done in certain circumstances due to employee privacy concerns (see 49 CFR 40.67). Unlike directly observed urine collections, an oral fluid collection is much less intrusive on the tested employee's privacy. By providing the option of collecting an oral fluid specimen, DOT is broadening options for the testing of safety-sensitive employees in the transportation industries. As discussed below, oral fluid collection can also reduce costs of compliance with Part 40.

III. Background

On November 21, 1988, the Department first published its drug testing program procedures regulation, Part 40, as an interim final rule (53 FR 47002). The Department based the scientific requirements in that rule on the 1988 HHS Mandatory Guidelines for Federal Agency Employee Drug Testing Programs (53 FR 11970, Apr. 11, 1988), which set forth the scientific procedures for laboratories to analyze urine specimens for the presence of specified drugs at the HHS-required cutoff levels for the initial and confirmation tests for each specific drug in urine testing. These cutoff levels for urine were established at levels to show prohibited use of the specified drugs.

When the Department adopted its first drug testing final rule, we established a procedure for urine collections generally to take place with visual and aural privacy afforded to each employee, unless suspicious activity under 49 CFR 40.25(f)(14), (16) and (23) (53 FR 47002, Nov. 21, 1988) called for

a direct observed collection (*i.e.*, body-to-bottle observation). In December of 2000, the Department comprehensively rewrote Part 40 into plain language. The direct observation provisions for urine were placed in 49 CFR 40.67, with the body-to-bottle observation requirement remaining unchanged. (65 FR 79462, Dec. 19, 2000).

Urine collections are potentially invasive searches and seizures of private citizens, subject to scrutiny under the Fourth Amendment of the United States Constitution. Consequently, the Department has always approached the collection of urine from transportation safety-sensitive employees with a concern for employee privacy, which must be balanced carefully against the Department's need to protect transportation safety. The Department protects individual rights by ensuring visual and aural privacy for employees undergoing urine testing. Allowing directly observed collections only for "cause" (*i.e.*, suspicious activity at the collection site or as determined by the laboratory testing of a specimen) is another protection. Yet, because the vast majority of DOT-regulated urine drug collections are unobserved, the program remains vulnerable to cheating by employees at the collection site, which can result in adulteration or substitution.

In June 2008, the Department added provisions to strengthen directly observed collection requirements to include more effective observation procedures and expanded the circumstances that would warrant a direct observation procedure to address cheating on drug tests. (73 FR 35961, June 25, 2008). Although the 2008 final rule was challenged in court and initially stayed, the stay was lifted, and the final rule was reinstated. (74 FR 37949, July 30, 2019). This action was based on the unanimous decision of the United States Court of Appeals for the District of Columbia Circuit. The court's decision affirmed the Department's enhanced direct observation procedures to prevent the use of prosthetic devices used for cheating and to expand direct observation to tests of people who had already violated the rules (*e.g.*, return-to-duty and follow-up tests for persons who had tested positive or refused to test). See *BNSF Railway Company v. Department of Transportation*, 566 F.3d 200 (D.C. Cir. 2009).

Before the Department's move to expand the direct observation procedures, HHS was aware of the potential for cheating on urine tests and had begun its own rulemaking to explore alternative testing methods. In 2004, HHS solicited public comment

upon the following alternative testing methods, all of which would be directly observed: oral fluid, hair, and sweat testing. (69 FR 19673, Apr. 13, 2004). HHS stated: "Addition of these specimens to the Federal Workplace Drug Testing Program would complement urine drug testing and aid in combating the threat from industries devoted to subverting drug testing through adulteration, substitution, and dilution." (*Id.* at 19675). HHS noted that there were problems with all three of the proposed alternative matrices but asked for additional scientific information and sought information on appropriate levels for proficiency testing for these alternatives.

While the science supporting oral fluid testing did not meet the standards of HHS in 2004, science and research studies have now reached a point where HHS is able to determine that oral fluid testing is an appropriate alternative testing method for identifying illicit drug use in the Federal workplace. As such, HHS proposed adding oral fluid testing to the Federal employee workplace testing program (80 FR 28054, May 15, 2015) and finalized this proposal, which became effective for Federal employee workplace testing on January 1, 2020 (84 FR 57554, Oct. 25, 2019).

The Department is proposing to add oral fluid testing as an alternative testing method because, as noted above, it has been determined by HHS to be scientifically viable for Federal workplace programs and because it provides a directly observed collection for every test. The collection of oral fluid is less invasive than directly observed urine collection and, therefore, is consistent with the careful balancing of an individual's right to privacy with the Department's strong interest in preserving transportation safety by deterring illicit drug use.

The Department's testing statutes specifically require that the Department incorporate the HHS Mandatory Guidelines, which are scientific and technical guidelines that "establish comprehensive standards for all aspects of laboratory-controlled substances testing" to ensure full reliability and accuracy in testing. Because HHS has published its final OFMG, thereby approving oral fluid testing as a reliable means of detecting illicit drug use for Federal employees, the Department is proposing to allow, but not require, oral fluid specimen testing as an alternative method under Part 40, for use by DOT-regulated employers for required transportation industry workplace testing. Specifically, we are seeking comments as to whether there are

circumstances where either urine or oral fluid should be mandatory. We are also proposing to amend some of our provisions that pertain to both urine and oral fluid testing to harmonize with pertinent sections of the urine and oral fluid HHS Mandatory Guidelines. We are proposing to clarify certain existing Part 40 provisions that cover the handling of urine specimens, remove provisions that are no longer necessary (such as erroneous compliance dates), add clarifying language to other provisions (such as updated definitions and web links where necessary), and modify a few substantive provisions to address issues that have arisen in practice (such as whether a test cancelled by a medical review officer (MRO) can ever be uncanceled, and whether a Substance Abuse Professional (SAP) should be allowed to conduct evaluations virtually).

IV. Principal Policy Considerations

Oral Fluid as an Alternative Drug Testing Method for Workplace Testing

Since 2004, when HHS previously considered oral fluid testing, the scientific viability of that testing has advanced. In its 2019 final rule, HHS stated that "[t]he scientific basis for the use of oral fluid as an alternative specimen for drug testing has now been broadly established and the advances in the use of oral fluid in detecting drugs have made it possible for this alternative specimen to be used in Federal programs with the same level of confidence that has been applied to the use of urine." (84 FR 57554; Oct. 25, 2019). Importantly, HHS stated that its "OFMG provide the same scientific and forensic supportability of drug test results as the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine" *Id.*

In its 2019 OFMG, HHS recognized that products have emerged that can help people to adulterate a urine specimen. HHS emphasized that establishing oral fluid as a testing method would allow Federal agencies greater flexibility to address testing needs while minimizing the opportunity for specimen adulteration or substitution. (84 FR 57554, 57571; Oct. 25, 2019).

Adulterating and substituting unobserved urine specimens is not a new issue to drug testing. In upholding the Office of Drug and Alcohol Policy and Compliance's (ODAPC) 2008 final rule allowing additional direct observation procedures, the U.S. Court of Appeals for the District of Columbia Circuit recognized the "cheating" problem: "especially in light of

evidence of a growing proliferation of products that facilitate cheating on drug tests, the Department solicited comment on additional procedures to strengthen testing integrity.” *BNSF Railway v. US Department of Transportation*, 566 F.3d at 202.

In the *BNSF* court case, the D.C. Circuit upheld directly observed urine collections under the specific circumstances imposed by the Department because of the imminent threat of individuals cheating on drug tests. The court acknowledged that “the Department determined that it was ‘not practicable’ to ignore the cheating problem.” *Id.* at 204. The court also accepted that oral fluid testing was not an acceptable method because HHS had not yet approved any specimen testing except urine. *Id.* at 205. With all of this considered, the court upheld the Department’s direct observation procedures. *Id.* at 208–209. If the proposal to allow oral fluid testing is adopted, we could allow the use of oral fluid testing in lieu of observed urine tests to assist in addressing the cheating problem acknowledged in the *BNSF* case.

While the Department does not have data on how much cheating is occurring, the problem exists and poses a direct threat to transportation safety. The court in *BNSF* noted: “Acknowledging that it had no statistics on the rates of actual use of such devices, the Department inferred their use from the anecdotal evidence of their availability.” Because the successful use of a cheating device would produce a negative drug test result, this would not show up in statistical reports as “cheating.” Thus, the court agreed with DOT that “it was ‘illogical’ to require statistical evidence of cheating. Given that people presumably buy cheating devices to use them, we think this approach quite reasonable” Consequently, the court recognized that the DOT could not base the rulemaking on statistical data on cheating. The court concluded, “It is one thing to set aside agency action under the Administrative Procedure Act because of failure to adduce empirical data that can readily be obtained. It is something else to insist upon obtaining the unobtainable. *BNSF*, 566 F.3d at 204 (internal citations omitted)).

The Department recognizes that the court upheld directly observed urine tests in specific circumstances covered in the regulation. In this rulemaking, the Department is proposing, as an option to employers, a specimen collection methodology that is inherently a directly observed collection and a much

less invasive form of direct observation drug test collection.

In evaluating the progress of science of oral fluid testing and its scientific viability, HHS also looked at its forensic defensibility in workplace testing. Specifically, HHS addressed concerns about passive exposure as the result of someone else’s drug use (e.g., from second-hand smoke) in the context of cutoffs or metabolites used in oral fluid testing, particularly with regard to marijuana. (84 FR 57557, 57558; Oct. 25, 2019). HHS concluded that a 4 ng/mL screening test cutoff for THC would detect use of marijuana while eliminating possibilities of positive tests resulting from passive exposure, as directed by the SUPPORT for Patients and Communities Act, Public Law 115–271, 8107(b). (See 84 FR at 57558; Oct. 25, 2019).

HHS has verified the science, set the cutoffs for testing, and begun the laboratory certification process for oral fluid testing. Pursuant to the statutory directive to incorporate HHS’s scientific and technical guidelines, the Department proposes to offer oral fluid testing to DOT-regulated employers as an alternative to urine testing.

Using Oral Fluid Testing as an Alternative Method Can Reduce Costs

We recognize that oral fluid testing is generally less expensive than urine testing. We understand that an oral fluid test can cost between \$10 to \$20 less than a urine testing (e.g., about \$50 for a typical urine testing process, vs. about \$35 for an oral fluid testing process, with the largest part of the difference being attributable to the collection process). We are seeking public comment on the costs of oral fluid testing as compared to urine testing so that we can affirm or adjust that cost assumption.

We also seek public comment on whether DOT-regulated employers would continue to utilize the services of external qualified collectors for oral fluid, or whether employers would train their own company personnel to become qualified collectors for oral fluid testing purposes. If companies train internal personnel instead of contracting with external providers, would this be due to costs, convenience or other reasons, and what would be the cost implications of the two approaches?

In addition to flexibility for employers, there are potential cost savings in the “shy bladder” collection procedures and related medical examinations. Currently there are situations in which a urine specimen collection is attempted but not

completed. For example, when an employee is unable to provide a sufficient quantity of urine, Part 40 provides an alternative process with multiple steps. The employee receives up to three hours of time to provide a sufficient specimen and is urged to consume up to 40 ounces of fluids. If after three hours these procedures do not result in a sufficient urine specimen, the employee must be medically evaluated to determine whether there is an adequate medical explanation why the employee could not provide sufficient urine. (49 CFR 40.193 and 40.195). This involves much time on the part of the collector, employee, employer, MRO, and physician. In addition, there are the costs of medical examinations for individuals who have short-term and long-term medical conditions that cause, or are claimed to cause, an inability to provide a sufficient urine specimen.

Since the Part 40 comprehensive rewrite in the late 1990s, groups representing individuals with “Paruresis” have raised concerns that a urine collection is problematic for individuals with this condition. Also, employees who are undergoing dialysis treatments or who have significant prostate issues could have difficulty providing a urine specimen and may require referrals to evaluating physicians to determine the legitimacy of their medical inability to provide a urine specimen. With the above in mind, collecting an oral fluid specimen may eliminate the need for a medical evaluation and result in a shorter employee visit to the collection site.

Allowing Alternative Specimens Provides Flexibility to Employers

In proposing oral fluid testing, the Department is not requiring employers to use oral fluid testing instead of urine testing, or for every test reason (e.g., pre-employment, random, etc.). Instead, we are proposing to offer employers the flexibility in the type of specimen they collect. That flexibility will provide several benefits. For example, when an employer determines that a DOT post-accident or a reasonable cause/suspicion test is needed, oral fluid collections could be done at the scene of the accident or the incident. The collection could be done by any oral fluid collector qualified under Part 40—either an external contractor or a DOT-regulated company employee. There are fewer requirements for oral fluid collection sites, as discussed below. The ready availability of collectors and the reduced expectations for collection site requirements should facilitate prompt, less expensive collections for post-

accident and reasonable cause/suspicion testing. We would appreciate public comments on these matters.

Understanding Windows of Detection

In proposing oral fluid testing, the Department is offering an alternative specimen for drug testing; however, we are not proposing to eliminate urine drug testing. Each specimen type offers different benefits to assist employers in

detecting and deterring illegal drug use, and no single specimen type is perfect for every situation. It is important to understand the benefits and limitations of each method.

There are different windows of detection that employers should consider when deciding whether to use a urine test or an oral fluid test as the preferred form of testing for any specific test reason. We have reviewed various

scientific sources referenced below to compile the list of windows of detection, and we invite public comment, especially from oral fluid device manufacturers and laboratories, as to the accuracy of the information presented in the chart below. Any additional public comments pertaining to the accuracy and completeness of the table below would also be appreciated.

Category of drug ¹	Oral fluid testing window of detection	Urine testing window of detection
Amphetamines	1–3 days ²	1–9 days ² .
Methamphetamines	1–4 days ²	2–4 days ² .
Cocaine	1–4 days ^{2,3}	1–5 days ^{2,3} .
Opioids	1–2 days ²	2–4 days ² .
Marijuana	Up to 24 hours ^{2,4}	3–67 days ^{2,5} .
Phencyclidine (PCP)	1–3 days ⁶	Up to 5 days ⁶ .

¹ Detection windows in the sources are dependent on amount of drug ingested, situations such as regular heavy use, and cutoff concentrations used.

² Cone E.J., Huestis MA. *Ann N.Y. Acad Sci.* 2007;1098:51–103, pp. 35–37, 42, 45–51, 54 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2700061/pdf/nihms118888.pdf>.

³ Jufer R., Walsh S.L., Cone E.J., et al. *J Anal Toxicol.* 2006;30(7):458–462, 460. <https://academic.oup.com/jat/article/30/7/458/711502>.

⁴ Newmeyer M.N., Desrosiers N.A., Lee D., et al. *Drug Test Anal.* 2014;6(10):1002–1010 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4169757/pdf/nihms578748.pdf>.

⁵ Huestis M.A., Mitchell J.M., Cone E.J. *J Anal Toxicol.* 1996;20(6):441–452 <https://academic.oup.com/jat/article/20/6/441/777647>.

⁶ Cook C.E., Brine D.S., Jeffcoat A.R., et al. *Clinical Pharmacology and Therapeutics.* 1982; 31(5):625–634—While the authors did not report oral fluid concentrations, they did report correlation between plasma levels and oral fluid levels. As PCP was detectable in plasma for 72 h (last time point) it is reasonable to assume PCP can also be detected in oral fluid that long.

If an employer is looking to detect recent drug use, (i.e., reasonable cause/suspicion, post-accident), an employer may find that the more immediate window of detection associated with oral fluid is acceptable. However, if an employer is looking to detect a pattern of intermittent drug use through pre-employment, random, return-to-duty, follow-up testing, the delayed windows of detection in urine may be preferable. We seek comment on whether oral fluid or urine should be mandated, or prohibited, for certain test reasons, based on windows of detection. Should an employer and its service agent be allowed to opt for a different methodology if the first test cannot be completed because of an insufficient specimen or other reason? Because there is no drug testing that determines impairment, oral fluid is being introduced to detect use, as urine has done throughout the history of the DOT-regulated drug testing program.

Substance Abuse Professional Remote Evaluations

During the COVID–19 public health emergency, the Department recognized that it might not be possible or advisable for a SAP to meet face-to-face with a client. As a result, we issued a guidance document on April 4, 2020 to allow remote evaluations for a period of time, and we extended the guidance several

times. The Department’s COVID guidance was issued in 2020–2021 and can be viewed at: www.transportation.gov/odapc/Statement_of_Enforcement_Discretion_SAPs_and_Service_Agents. We said that, while a remote evaluation may not provide as much information as an in-person meeting, it is preferable to not having a SAP evaluation at all. To make a remote evaluation as effective as possible, the guidance document recommended certain technical parameters and added that SAPs should document the format of the assessment in the final SAP report. We also said that we would not view a remote evaluation as being an act of serious noncompliance meriting resort to the Public Interest Exclusion (PIE) process.

Based on informal contacts with the SAP community, we believe this guidance has been well received, with a considerable use of remote evaluations by SAPs since the inception of the guidance. Moreover, it is plausible that telehealth will become a regular part of medical practice in a wide variety of fields in the future.

To make remote evaluations or assessments a regular option for the SAP’s practice under Part 40, we are proposing amendments to several sections of the regulation. Consistent with guidance issued in the context of the COVID–19 public health emergency,

this proposal would give SAPs the option of choosing to conduct evaluations remotely in lieu of face-to-face meetings. Part 40 currently requires all SAP assessments to be done face-to-face. An in-person evaluation provides SAPs with the opportunity to objectively evaluate “non-verbals”—physical cues to internal feelings, thoughts, and behaviors. It allows the SAP to be aware of the client’s appearance, posture, carriage, ability to make eye contact, and ability to relate in person, as well as other physical characteristics that might be indicative of problems associated with alcohol abuse and/or drug use.

The most important proposed change regarding SAP evaluations is to § 40.291(a)(1). The amendment would replace the current requirement for a face-to-face meeting with an option: The SAP could do the evaluation either face-to-face or remotely. If the evaluation is to be done remotely, there would be three criteria that the process would need to meet, to ensure that the SAP can still objectively evaluate “non-verbals” and physical characteristics to a sufficient extent. These criteria are also based on the provisions of the Department’s guidance document.

First, the technology used must permit real-time two-way audio and visual interaction between the SAP and the employee. A phone conversation not

including video would not meet this criterion.

Second, the quality of the technology (*e.g.*, speed of the internet connection, clarity of the display), would have to be sufficient to allow the SAP to gather all the visual and audible information the SAP would normally observe in a face-to-face interaction. In addition, the technology would have to have sufficiently robust security to protect the confidentiality of the conversation.

Third, a SAP could only use the technology in question if the SAP's State-issued license authorizes the SAP to do so. The SAP's use of the technology would have to stay within the parameters of that authority (*e.g.*, a State license may permit a practitioner to work only with clients in the State of licensure). We are also seeking public comment, especially from SAPs, regarding whether their respective State license would allow them to evaluate individuals who live in a different State from where the SAP is licensed. Is this already allowed? Now that virtual video evaluations are often done outside of the DOT-regulated context, would evaluation of individuals not in one's State of licensure be allowed? For a SAP remotely evaluating an individual outside of the SAP's locality, what steps could ensure a working knowledge of quality programs and qualified counselors available to the employee?

While we continue to believe that face-to-face interactions are the "gold standard" for the SAP evaluations, we also believe that the remote evaluation option may have considerable merit, and we seek comment on the proposed approach, as well as on the specific technical parameters under which SAPs would perform remote virtual evaluations. We welcome comments regarding the experience of both SAP and employees under the COVID-19 guidance. We also seek comment on whether remote virtual evaluations and assessments should be limited to certain circumstances, *e.g.*, natural disasters, pandemic situations, and where there are few or no SAPs available.

Other Matters of Interest

As noted above, the Department works closely with HHS on matters concerning workplace drug testing. On September 10, 2020, HHS published a notice of proposed Mandatory Guidelines proposing to add hair testing to the drug testing specimen types authorized for the Federal employee testing program. (85 FR 56108). Because HHS is still considering amendments to its Mandatory Guidelines to permit hair testing, comments to DOT concerning

the use of hair testing are not relevant at this time.

In addition, we are proposing to amend § 40.67 to address situations where a same gender observer is not available for the collection of urine specimens. Specifically, we request public comment on allowing direct observations by any licensed or certified medical professional legally authorized to take part in a medical examination in the jurisdiction where the collection takes place.

Currently, per § 40.141(b), MROs must personally contact pharmacies to verify a prescription that an employee has cited as a potential legitimate medical explanation for a laboratory-confirmed positive test. We believe it would increase efficiency and assist MRO office workflow if MRO staff were able to make these inquiries. The Department seeks comment on whether this change is advisable and what the estimated cost savings would be.

In addition to the above, we request comments on whether there are situations in which a test, once cancelled, should be "uncancelled" if circumstances dictate (*e.g.*, a test is cancelled because paperwork is missing or delayed, but the paperwork is later found and provided to the MRO). Or, alternatively, should a test, once cancelled, remain cancelled to ensure finality? We specifically seek comment from MROs on the practicality of administering such a process, and from employers on the effect that an "uncancelled" test would have when administering their drug testing program. To be clear, this would not apply to those specimens "rejected" by the laboratory because of a fatal flaw and ultimately reported by the MRO as cancelled. We have proposed language in § 40.207(d) to address this circumstance. We have also included a requirement for a party seeking to reverse a cancellation to consult ODAPC if the decision is being made more than 60 days after the cancellation, which is the same consultation requirement we have in § 40.149(a)(4), where we allow an MRO to reopen a verified test after 60 days. Providing this information helps ODAPC to provide advice to MROs regarding what to consider and potential concerns.

V. Section-by-Section Analysis

In drafting the proposed oral fluid amendments to Part 40, the Department is not creating a separate subpart of Part 40 concerning oral fluid testing. Since many of the provisions of Part 40 can be applied to specimen types in addition to urine, we have sought to integrate provisions concerning oral fluid testing

within the current Part 40 structure. However, since the provisions applicable to Alcohol Testing, SAPs, the PIE process, and some other provisions would not change based on which specimen types are authorized, we are not proposing changes to those provisions.

Consistent with changes made in the substantive provisions of the rule, we propose to modify some section titles as well as adding new sections. In many cases, the modifications revise current titles specifying urine testing so that they address oral fluid and potential future testing matrices.

40.3 What do the terms used in this part mean?

In addition to proposing to delete the definition of "screening drug test" because the term is not used in Part 40, the proposed rule would delete the definition of "Invalid drug test" because that is a term that HHS does not use, as such.

The term "invalid result" is an HHS term with a very specific meaning and HHS does not have a defined term of "Invalid drug test." The term "invalid" is sometimes misunderstood in arbitrations, courtrooms, and other settings to incorrectly suggest a lack of certainty about the underlying testing event. A laboratory reporting an invalid result to the MRO does not mean that the underlying drug testing event was not valid. For example, when the laboratory reports that there was an "invalid result," it is not a characterization of the employer's authority to conduct the testing, the collection process, etc. The "invalid result" refers only to the fact that the laboratory has not been able to complete testing or obtain a valid drug test result (*e.g.*, because of an unidentified adulterant, an interfering substance, or an abnormal physical characteristic). Also, for consistency with HHS terminology, we are removing the defined term "invalid drug test" in the definitions section, § 40.3, and are updating §§ 40.123(c), 40.129(a) and 40.129(d) to use the term "invalid result".

The proposal would add definitions of seven terms as part of our effort to harmonize Part 40 with the HHS Guidelines and to update Part 40 as needed. An "alternative specimen" is an authorized specimen of a type other than the one previously collected. For example, in a case where the initial collection was urine, oral fluid would be an alternative specimen. The "cutoff" is the quantitative point distinguishing a need for further testing or whether a laboratory result, for example, is

positive or negative (e.g., 2 ng/ml is the confirmatory test cutoff for a positive vs. negative oral fluid result reported by the laboratory for THC). We are also proposing to add definitions for “oral fluid specimen” and “urine specimen.” “Specimen” is the generic term for any fluid, breath or material collected from someone for a drug or alcohol test. We are proposing to add “Undiluted (neat) oral fluid”, using the same language HHS uses in Section 1.5 of its Oral Fluid Mandatory Guidelines. We have also added a definition for the FMCSA’s Commercial Driver’s License (CDL) Drug and Alcohol Clearinghouse (Clearinghouse).

We are also proposing to add a new definition for “SSN or Employee ID No.”, and some minor changes to rule language in §§ 40.14, 40.45, 40.97, 40.163 and 40.311 for the following reasons. Since its inception in 1988, Part 40 has required program participants to use the donor’s Social Security Number (SSN) or an employee identification (ID) number in various sections. For example, the employer must supply the collection site with the “Donor SSN, Employee I.D., or CDL State and No.” as referenced on the Federal Drug Testing Custody and Control Form (CCF). For the Alcohol Testing Form (ATF), the employer must supply the donor’s “SSN or Employee ID No.” In addition to the unique specimen ID number on the CCF and the specimen seals, having the SSN or employee ID number on the form assists the MRO in matching the Copy 1 of the CCF from the laboratory with their copy, Copy 2 of the CCF. The SSN or the employee ID number may be used by the employer to, for example, run random selection lists and ensure that test results are associated with the correct employee. The SAP is required to utilize the SSN on the SAP initial and final reports to the employer.

In the Federal Motor Carrier Safety Administration’s (FMCSA) Commercial Driver’s License Clearinghouse final rule (81 FR 87686; Dec. 5, 2016), which required the creation of the Drug and Alcohol Clearinghouse database (Clearinghouse), the FMCSA amended 49 CFR 382.123(a) and (b) to require that, for FMCSA-regulated drivers undergoing DOT-regulated testing, the employer use a Commercial Driver’s License (CDL) number and State of issuance, instead of the SSN or other employee ID number, on the CCF and Alcohol Testing Form (ATF) for all drug and alcohol tests conducted under part 382. It is important to note that the Clearinghouse final rule did not affect or otherwise allow use of the CDL number for a CDL driver operating under

another DOT agency’s regulation and subject to a test not under Part 382 (e.g., employers of CDL drivers under PHMSA or FTA). Under this proposal, those employers could also use the CDL numbers, which could potentially increase efficiency and reduce confusion.

We are proposing to create a definition of “SSN or Employee No.” in § 40.3 that would conform to and explicitly acknowledge this existing requirement for CDL holders regulated by the FMCSA and to allow the use of the CDL number for the drivers being tested under the regulations of the other DOT agencies.

In addition, we are proposing the changes because some employers already consider an employee’s ID number to be the individual’s personal driver’s license number, State-issued identification number, or other State-issued or federally issued identification number. We believe that it would be less confusing to explicitly state that it is allowable to use these forms of ID, which can be verified by viewing the actual ID.

With increasing concerns of identity theft, SAPs, employers and others have indicated that the use of one’s SSN is becoming increasingly difficult and risky. Some corporations are only allowing the use of 4 or 6 digits of the SSN, and others prohibit the use of the SSN entirely. We are proposing the additional options of other official identifications issued by State or Federal authorities to also address these concerns.

Consequently, we are proposing to create a new definition “SSN or Employee No.” that will allow a collector, MRO, SAP, BAT, STT or other service agent or employer to utilize only the CDL number and State of issuance for FMCSA-regulated drivers tested under Part 382, and to allow the CDL number to be used as an option on tests conducted under the authority of the other DOT Agencies. The definition would also allow any other State-issued or federally- issued identification number to fulfill Part 40 requirement for a unique identification number.

We are proposing to modify seventeen definitions. For the most part, the changes are not substantive, and would simply conform Part 40’s wording with that of the HHS guidelines. For example, “collection container” refers to vessels used in all collections, whether of urine or oral fluid. In the definition of “specimen bottle,” we propose noting that the term could include terms like “tube” or “vial” used in oral fluid testing.

§ 40.13 How do DOT drug and alcohol tests relate to non-DOT tests?

The Department is proposing minor changes to paragraphs (b), (c), and (d) of this section to clarify them in the context of oral fluid testing. For example, paragraph (d) is made applicable only to urine testing since oral fluid testing is not part of the normal medical examination procedure to which the paragraph applies.

We propose to redesignate paragraphs the current paragraphs (e) and (f), as new paragraphs (f) and (g), and would add a new paragraph (e) emphasizing that a drug or alcohol test administered as directed by a medical examiner, exclusively as part of a medical examination required for an employee to qualify for a certificate or license, is not a DOT drug or alcohol test under Part 40 and related DOT agency drug and alcohol testing rules. For example, if a certified medical examiner decided to give a motor carrier driver a drug test as part of an examination for medical card purposes, that would be a “non-DOT test.” An employer could request a required DOT pre-employment test be conducted when the medical examination is being conducted, as currently permitted under 49 U.S.C. 31306(d).

We added a new paragraph (h) to further emphasize that DOT drug and alcohol tests are authorized to be conducted only on safety-sensitive employees as designated in the agency drug and alcohol testing regulations and must not be conducted on non-regulated persons. (See Section II of this proposed rule for a discussion of DOT’s testing authorities.) DOT testing is a legal warrantless search and seizure permitted by the Fourth Amendment of the Constitution. The DOT’s strong interest in maintaining transportation safety, when weighed against an individual’s right to privacy, allows DOT’s regulated testing to pass Constitutional scrutiny. See *Bluestein v. Skinner*, 908 F.2d 451 (9th Cir. 1990); *Skinner v. Railway Labor Executives’ Assn.*, 489 U.S. 682 (1989); *Treasury Employees v. Von Raab*, 489 U.S. 656 (1989). However, there is no Federal transportation safety interest in using this testing for individuals other than safety-sensitive employees. Consequently, DOT testing cannot be conducted on employees not regulated by the DOT agencies. DOT regulations also do not allow company-authorized non-DOT testing to satisfy an employer’s obligation to meet its minimal annual testing rate for DOT testing.

§ 40.14 What information must employers provide to collectors?

Paragraph (b) in this section would be modified for clarity and to recognize that, in the motor carrier industry, FMCSA requires the CDL to be used for purposes of the Drug and Alcohol Clearinghouse (Clearinghouse) (see 49 CFR 382.705). A new paragraph (k) would be inserted for “the specimen type to be collected” and a new paragraph (l) is proposed to specify if a urine test is to be directly observed.

§ 40.21 May an employer stand down an employee before the MRO has completed the verification process?

Where there is a stand down waiver in place, the proposed rule would add a new paragraph (c)(2)(vii)(C) of this section to explain that an employer, after receiving a verified negative result, must not send an employee back in for another test using a different specimen type. We have clarified that the employer can send an employee in for an alternative specimen collection if the MRO cancelled the tested (e.g., per the requirements of § 40.159). The authority to stand down an employee is very limited and requires an employer to obtain an actual waiver from the DOT agency before implementing a stand down policy. The waiver authorizes the employer to ‘stand down’ an employee from performing safety-sensitive functions based on a laboratory confirmed positive result until the MRO issues the employer a verified result, which may be negative. We are proposing that an employer cannot conduct another test on the employee after an MRO verifies the test as negative. We want to prevent harassment of employees who ultimately have an MRO-verified negative result and we do not want employers to attempt to conduct a second test to see if the window of detection could later impact the result.

§ 40.23 What actions do employers take after receiving verified test results?

The proposed rule would make minor conforming changes in the language of this section to account for the proposed use of oral fluid testing. In the introductory language of paragraph (f), the specification of urine testing would be deleted because the paragraph would apply to oral fluid as well as urine testing. In paragraphs (f)(1) and (5), language would be added emphasizing that oral fluid collection is always directly observed. In the event of an invalid specimen, the subsequent direct observation collection could either be

an oral fluid collection or a urine collection under direct observation.

§ 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?

In January 2020, FMCSA implemented its Clearinghouse regulation requiring FMCSA-regulated employers that employ drivers subject to the CDL testing requirements of 49 CFR part 382 to query the Clearinghouse drug and alcohol database for information about an employee’s past violations of the drug and alcohol testing rules. Until January 2023, FMCSA-regulated employers have dual requirements: Query the Clearinghouse and continue to follow the procedure of § 40.25, as set forth in § 382.413.

Beginning January 6, 2023, FMCSA-regulated employers will rely solely on querying the Clearinghouse with respect to present or former FMCSA-regulated employers of an FMCSA-regulated applicant, in accordance with § 382.413(b). For example, after January 6, 2023, a motor carrier vetting a prospective employee would check the Clearinghouse to determine whether the driver’s previous FMCSA-regulated employer(s) reported drug and alcohol testing program violations by that driver. To conform the requirements of § 40.25 with these existing FMCSA requirements, we are proposing to add a paragraph stating if an applicant’s past employment was with an employer regulated by, for example, the Federal Transit Administration or the Federal Aviation Administration (FAA), the gaining motor carrier employer would continue to use § 40.25 to check on that individual’s past compliance with the Department’s rules, since drug or alcohol violations incurred while the driver was employed by a DOT modal administration other than FMCSA will not have been recorded in the Clearinghouse. We are proposing to add a new paragraph (a)(3) to this section to remind employers that when hiring an employee subject to both FMCSA and another DOT agency’s drug and alcohol testing program, they must query the Clearinghouse and request the information about the employee listed in paragraphs (b) through (j) of this section from any other DOT agency for whom the employee previously worked.

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

The proposed rule would make a simple editorial change, substituting a reference to appendix J for a reference to appendix H. This conforms to a re-

designation of the appendix letters but would make no substantive changes to the section or form.

§ 40.29 and similar sections

In the current Part 40, there are several sections (§§ 40.29, 40.37, 40.113, 40.169, 40.189, 40.217, and 40.313) that list, for readers’ information, other sections of the regulation touching a given topic (e.g., employer responsibilities in § 40.29). These lists of cross-references were intended to assist readers in finding other relevant information. However, in the 20 years since these sections were placed in Part 40, electronic search tools have become much more sophisticated and ubiquitous. Under these circumstances, the Department proposes removing them as no longer necessary. The Department seeks comment on whether users continue to find the cross-reference lists helpful enough to retain.

§ 40.31 Who may collect specimens for DOT drug testing?

The provisions of this section would be updated to separately specify the requirements for collectors of urine and oral fluid specimens, respectively. We proposed adding wording to require oral fluid collectors to be qualified. In addition, we added wording to make it clear that employees, relatives, and close friends of the employees cannot conduct collections, consistent with existing guidance in the Department’s Specimen Collection Guidelines. The Department seeks comment on these proposed revisions.

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

The proposed rule would change the title of § 40.33 to reflect its focus on urine collectors. We are also proposing a change to § 40.33(f) to clarify that damage to a specimen resulting in it being cancelled does not require retraining of the collector, unless the error actually occurred during the collection process. We understand that some MROs are requiring collector retraining when a specimen is cancelled because the damage occurred during the transportation process. When a specimen is damaged by a delivery truck, sort facility, or other part of the transportation process, or is lost in transit, it would not be the result of an error by the collector during the collection process. Consequently, we are proposing language to clarify a collector is not subject to the time and costs of retraining for errors outside the collection process.

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

The proposed rule would renumber existing § 40.35 to become § 40.36, and add a new section § 40.35 concerning training for oral fluid collectors. Our intent is to parallel, as closely as possible, our existing training requirements for urine specimen collectors. We seek comment on any differences that may exist between the training for collectors for each specimen type. We anticipate, in many cases, that collectors may be cross-trained in the two modes of collection.

In discussing who is authorized to monitor the mock collections exercise for oral fluid collectors, the proposed rule retains the provision applicable to urine collector training, which states that someone who has performed DOT collections for at least a year is qualified. However, since the oral fluid collection process is new to the DOT testing regime, there initially will not be anyone who has collected DOT oral fluid specimens for a year. The Department seeks comment on how best to address this transition issue. For example, would it be sufficient for a monitor, during the first year or two under the DOT oral fluid testing process, to have had experience in oral fluid collections in non-DOT oral fluid testing? Should only someone who has been through a “train the trainer” course be able to monitor the mock collections test until there are oral fluid collectors with a year of experience in DOT oral fluid collections? What role, if any, should oral fluid device manufacturers play in the process?

Redesignation Table

Beginning with subpart D (see below), the Department is proposing to redesignate (*i.e.*, renumber and reorder) numerous sections of Part 40 to provide a more easily followed flow for users of the regulation provisions specific to oral fluid drug testing. For the convenience of the reader, we are displaying these proposed redesignations in the preamble section of the NPRM.

The Department recognizes that practitioners have likely become accustomed to particular section numbers for drug testing procedures under the present regulation. While we believe that the reorganization will create a logical structure for the rule, we seek comment on whether the reorganization would cause any significant degree of confusion for practitioners, and if so, how confusion could be mitigated.

For the convenience of the reader, we are including this redesignation table to show what the renumbering would be, if the proposed changes are adopted:

PROPOSED REDESIGNATIONS THE FOLLOWING SECTIONS OF PART 40 AS FOLLOWS

Old section	New section
40.35	40.36.
40.41	40.42.
40.45	40.40.
40.47	40.41.
40.49	40.44.
40.51	40.45.
40.73	40.79.
40.85	40.82.
40.87	40.85.
40.89	40.86.
40.91	40.87.
40.93	40.88.
40.95	40.89.
40.96	40.90.
40.99	40.84.
Appendix B	Appendix D.
Appendix C	Appendix E.
Appendix D	Appendix F.
Appendix E	Appendix G.
Appendix F	Appendix H.
Appendix G	Appendix I.
Appendix H	Appendix J.

Subpart D—Collection Sites, Forms, Equipment and Supplies Used in DOT Collections

As a starting point, it is important to remember that oral fluid drug testing and saliva alcohol testing are completely distinct. The devices, procedures and outcomes are never interchangeable. In Part 40, we are only proposing the provisions applicable to oral fluid testing procedures in subpart D. The saliva alcohol testing provisions in subparts K–L remain unchanged.

To accommodate the addition of provisions pertaining to oral fluid drug testing, the Department is proposing to reorganize subpart D. Sections applying to the DOT drug testing process generally, regardless of specimen type, would come first. Renumbered §§ 40.40 and 40.41 would contain the content of present §§ 40.45 and 40.47, concerning the use of the Federal Drug Testing Custody and Control Form (CCF) in all DOT collections. We note that HHS revised the CCF in August 2020. The 2020 CCF and instructions for completing the CCF for both urine and oral fluid collections are available on the HHS website, <https://www.samhsa.gov>. The DOT has posted the 2020 CCF on our website, <https://www.transportation.gov/odapc>, and we will post instructions for oral fluid collections upon promulgation of any final rule to allow oral fluid for DOT-regulated drug testing.

The above sections would no longer contain the words “urine” and “urination,” because these sections now would apply to oral fluid collections and would include “any other appropriate contact information” to permit the inclusion of email addresses or other means of contacting the appropriate parties. The Department is considering removing requirements related to fax numbers on the CCF, allowing the fax number if the parties have one. We seek comment on whether specifying the use of fax numbers remains relevant. We are proposing to add a provision allowing the Designated Employer Representative’s (DER) name and contact information to be preprinted on the CCF. We specifically seek comments from the laboratories on the availability of space on the CCF to pre-print the information, as well as the logistics and timeliness of sending out updated CCFs with the new DER information. To recognize the responsibility of collectors, as well as collection site operators, for proper collections, we would add “collectors” to the title of § 40.43.

In the proposed reorganization of the subpart, §§ 40.42–40.45 would cover urine testing (renumbered § 40.42 in the proposed rule contains the material now found in § 40.41, while renumbered §§ 40.44 and 40.45 contain the material now found in §§ 40.49 and 40.51). Then we would add new §§ 40.47–40.51, covering oral fluid testing. These provisions largely parallel their urine testing counterparts. We seek comment on the content of the new oral fluid provisions, including whether it would be useful to address any additional differences between the urine and oral fluid testing procedures.

We are proposing to modify renumbered § 40.40 to clarify what address and telephone number a collector must provide on the CCF. In January of 2002, ODAPC issued a Question and Answer (Q&A) explaining that the collection site address should not be a corporate or “main office” address. In addition, the Q&A stated that the collector’s telephone number on the CCF should be the number to directly reach the individual collector and/or the collector’s supervisor and not a corporate “toll free” number to a call center. Under the proposal, if an MRO, laboratory, employer or any DOT staff need to speak with the collector, the telephone number provided on the CCF must give access directly to that collector. This proposal would codify requirements for the collection site address and collector’s telephone number, which would render the Q&A unnecessary.

In § 40.48(c)(1), we use the term “dry mouth.” This is shorthand, similar to the term “shy bladder” used for urine collections, for a situation in which an employee is unable to produce a sufficient specimen.

§ 40.49 What materials are used to collect oral fluid?

We are proposing to add this section to require that collection devices meet the requirements being set forth in a new appendix B. The devices meeting the requirements in appendix B would be allowed for DOT-regulated collections. It is important to note that not all of the devices that HHS would allow for the OFMG will be allowed for DOT-regulated collections under 49 CFR part 40. Each collection must include a split that is subdivided from the original specimen collection. *See* 49 U.S.C. 45104(5) (aviation industry testing), 49 U.S.C. 20140(c)(5) (rail), 49 U.S.C. 31306(c)(5) (motor carrier), and 49 U.S.C. 5331(d)(5) (transit). All the devices meeting the requirements in appendix B will allow a single specimen to be subdivided in the presence of the donor. For example, a device could allow two specimens to be collected simultaneously using a single collection device that directs the oral fluid into two separate collection tubes; or a device could collect a specimen with a single pad, which can be subdivided into two separate collection tubes. We are seeking public comment as to whether there are other device types we should mention that allow one single specimen to be collected and then subdivided in the donor’s presence.

We are also seeking public comment as to whether the devices should be sufficiently transparent so the collector can observe whether there is anything unusual about the specimen collected and take action to perform a re-collection, if appropriate.

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

In paragraphs (b)(1) and (3), the term “drug testing” or “drug test” would be used in place of “urine,” since the provision applies to the testing of either specimen type. We propose to split the existing (b)(3) into (b)(3) and a revised (b)(4). The proposed revision to (b)(3) prohibits collection of any kind of specimen from an unconscious donor. The proposed revision to (b)(4) includes the remaining sentences of the current (b)(3), with a change to the final sentence of proposed paragraph (b)(4). The final sentence in (b)(4), if adopted, would be changed to emphasize that an employer must decide whether a given circumstance constitutes a refusal. In

paragraph (f)(5)(i), we would note that, when a directly observed test is needed, either a directly observed urine collection or oral fluid collection would suffice. In (f)(5)(i), we propose to remind the collector to note on the CCF whether a directly observed urine or oral fluid test will be conducted.

In addition, we are proposing changes to §§ 40.61(e) and § 40.73(a)(1) (proposed to be redesignated as § 40.79(a)(1) because HHS made changes to the CCF. The DOT requires its regulated entities to use HHS’s OMB-approved CCF.

DOT worked closely with HHS on the revised CCF, which incorporates changes necessary as a result of HHS’s establishment of scientific and technical guidelines for the inclusion of oral fluid specimens in the Mandatory Guidelines for Federal Workplace Drug Testing Programs. The majority of changes to the CCF were made to allow the collection of oral fluid specimens, which are not currently authorized in the DOT drug testing. The revisions also include other changes to improve the clarity and presentation of the form.

However, because of the revisions to the CCF, it is necessary for DOT to amend two sections of Part 40. Specifically, the instructions for completing the old CCF were provided on the back of Copy 5 of that form. These instructions are not provided on the revised CCF, and instead, instructions for completing the form can be found on the HHS and DOT (Office of Drug and Alcohol Policy and Compliance) websites. Consequently, we are proposing to amend the rule text in 49 CFR 40.61(e) to reflect the repositioning of the instructions. Also, we are proposing to amend § 40.73(a)(1) (proposed to be redesignated as § 40.79(a)(1)) to note that the employee needs to provide all information required in Step 5 of the revised CCF. This information includes the donor’s printed name and signature, date of the collection, date of birth, daytime and evening phone numbers, and email address.

§ 40.63 What steps does the collector take in the collection process before the employee provides a urine specimen?

We are proposing to modify § 40.63(a) to remind collectors to ensure that all items in Step 1 of the CCF are completed. Specifically, we propose to add a parenthetical to remind collectors to check the box for the DOT agency in Step 1.D, and to write an address for the actual collection site in Step 1.G.

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

The proposed rule would make two changes to the current regulation to ensure that when an immediate re-collection under direct observation is needed (*e.g.*, because the temperature of a urine specimen is out of range or there were signs of tampering), regardless of whether the first specimen was urine or oral fluid, the required directly observed collection could be either urine or oral fluid. For example, if a directly observed collection is needed after a urine collection, the second could be either an oral fluid collection (inherently directly observed) or a urine collection carried out under the direct observation procedures set forth in § 40.67. After the second collection is done, each specimen collected must be sent to the appropriate laboratory (*i.e.*, a laboratory certified by HHS for that specimen type).

We are asking for public comment about how communication would take place between the employer and the collection site to ensure that an alternate methodology is or even should be available. Who should decide whether to collect an alternative specimen? Should the collector be the one to determine whether to collect an alternate specimen when a situation allows for it? Should the employer and the service agents communicate in advance to ensure that the alternate specimen type is authorized, if the employer wants one—with devices and laboratories designated? Could this be accomplished through the contract between the employer and the service agent? Are there other means of communication to facilitate the collection site process?

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

In addition to altering the title of the section to refer only to urine collections, the proposed rule would make a substantive change to paragraph (g), regarding who may act as the observer in a directly observed urine collection. The paragraph would retain the general requirement that the observer have the same gender as the employee, but make an exception for licensed or certified medical professionals or those who are legally authorized to take part in a medical examination in the jurisdiction where the collection takes place. It is commonplace in medical settings for opposite-gender personnel to take part in examining a patient (*e.g.*, a female doctor, physician’s assistant, nurse, Emergency Medical Technician, or an

individual who holds a “Persons-In-Charge Medical Care” U.S. Coast Guard designation who might be examining a male patient). To reduce the circumstances in which an observed urine collection might be delayed for lack of a same-gender observer, we propose that an opposite-gender medical professional, if available, could perform this task. The donor would not be permitted to decline the direct observed collection by an opposite gender medical professional and such a refusal would fall under § 40.191(a)(4), if the proposal is adopted. We seek comment on whether there should be any limitations on the types of medical professionals who could perform this function. In addition, we would appreciate comments on whether there are religious or other concerns that should be considered in the regulatory language proposed.

We want to clarify that the collector does not enter the reason for the direct observation in the “Remarks” section of the CCF if the employer is sending the employee in for a required directly observed collection (e.g., a return-to-duty test, a follow-up test, a test where the MRO has instructed the employer to send an employee in for a directly observed collection). The “Remarks” section needs to be used only when the collector moves to a directly observed collection and the employer did not know about it in advance. Thus, we are proposing to amend § 40.67(e)(2) to change a cross-reference to “§ 40.67(b)” to become a cross-reference to “§ 40.67(c)(2)-(4)”. This is because § 40.67(e)(2) is an instruction to collectors to follow through with an entry on the “Remarks” line on a CCF when an event under § 40.67(c) takes place. This has nothing to do with § 40.67(b), so this cross-reference is being corrected. We are proposing to make a technical amendment to § 40.67(c)(1) to strike the reference to paragraph (b) because it is an incorrect reference.

§ 40.69 How is a monitored urine collection conducted?

The proposed rule would add new introductory language emphasizing that a monitored collection would be conducted if a urine collection takes place in a multi-stall restroom and the collector cannot secure all sources of water and other substances that could be used for adulteration and substitution (49 CFR 40.42(f)(2)(ii)).

§ 40.71 How does the collector prepare the urine specimens?

The proposed rule would make a minor clarifying change, instructing the

collector of a urine specimen to check both the boxes for “urine” and “split specimen” on the CCF.

§ 40.72–§ 40.74

These three new proposed sections would establish the collection procedures for oral fluid testing, consistent with the HHS OFMG and parallel, in many respects, to the administrative aspects of urine collections. For information on the parallel HHS provisions and the HHS rationale for putting them into effect, please see the OFMG, (84 FR 57554, Oct. 25, 2019).

At several points in these sections (e.g., § 40.72(a)(2)), the proposed rule emphasizes the proper relationship between collection sites and employers in cases involving conduct that could be considered a refusal. In each case, the collector does not make a unilateral, final decision, but rather provides information on the circumstances to the employer, who per § 40.355(i), has the non-delegable duty to make decisions in these cases.

The oral fluid specimen collector is expected to follow both the Part 40 requirements for collections, as well as the manufacturer’s instructions on how to collect the specimen. The collector must check the expiration date on each device. Each device will have its own instructions and, therefore, these are not specifically covered in the proposed regulatory text. When we refer to conducting the collection “correctly” in these sections, we mean using the oral fluid device in the manner described by its manufacturer.

Subpart F

The proposed rule would reorganize subpart F (49 CFR 40.81–40.97), which addresses drug testing laboratories, to create a logical progression of urine drug testing, oral fluid drug testing, and provisions common to both. This reorganization involves renumbering several provisions and, in some cases, adding language to specify where a provision applies only to urine drug testing. For example, the title of renumbered § 40.86 (§ 40.89 in the current regulation) would be changed to read “§ 40.86 What is urine validity testing, and are laboratories required to conduct it?”

In several places in the text of § 40.97, several requirements are specified to apply only to urine testing, as they have no application to oral fluid testing. We restated § 40.97 in its entirety, given the number of individual changes made for this purpose.

These editorial changes are not intended to modify the substance of the

provisions in question. However, we would call readers’ attention to two proposed substantive changes. First, in renumbered § 40.84 (§ 40.99 in the current regulation), laboratories would be required to keep non-negative specimens for only 90 days, rather than the present one-year requirement. This change is intended to reduce storage burdens on laboratories. We are not aware of any reason a laboratory would need to keep the actual specimen beyond 90 days. This change would not affect the 2-year record retention requirement that HHS has set for documentation supporting the laboratory’s analysis of a non-negative specimen. This would not change a litigation hold placed upon the specimen and the paperwork. We seek comment on this change, as well as the more general question of whether interested parties find the reorganization of the Subpart F useful.

The most notable new portion of this subpart, consisting of §§ 40.91–40.93, concerns cutoff concentrations and validity testing for oral fluid specimens. These three new sections are drawn from the HHS OFMG and are intended to be consistent with the HHS provisions. For information on the parallel HHS provisions and the HHS rationale for putting them into effect, see the OFMG (84 FR 57554).

In § 40.111, we propose to add language to paragraphs (a) and (d) to clarify that in their statistical reports to employers and DOT, laboratories need to submit reports to employers for the specimens for which the laboratory tests.

In addition, we added language in § 40.111 to clarify that a laboratory withdrawing from National Laboratory Certification Program (NLCP) program certification is required to file with both employers and the DOT an aggregate statistical summary for the last period in which it conducted DOT-regulated testing. This data is important to the Department because it helps DOT identify trends regarding non-negative results (e.g., positives, adulterated, substituted and invalid) and cancelled tests.

Subpart G—Medical Review Officers

For the most part, MROs would continue to do their jobs as they have under the current regulation. However, the Department is proposing a few changes to the MRO provisions. Specifically, in § 40.121, we would delete the word “urine” from paragraph (c)(1)(i), because training for MROs should also include oral fluid testing. We seek comment on whether existing and/or new MROs should receive

additional training specifically with respect to their role in oral fluid testing and, if so, what subjects it should cover.

In § 40.127, concerning MRO reviews of negative results, we propose specifying that MROs need not review more than 500 negative results “of all specimen types combined” in any quarter. This is to clarify that, by adding oral fluid testing to the regulation, we do not intend to increase MROs’ negative test result review requirements.

In § 40.129(d), we propose deleting “drug test report” and adding the word “result” following “invalid test.” In § 40.135(d), we propose deleting the word “test” and adding the word “result.” This would keep the language of that paragraph internally consistent and consistent with the definition of the term “invalid result” in § 40.3.

In § 40.139(b), we are proposing to add the cutoffs for oral fluid laboratory-confirmed results. This is important because there are different cutoffs for the MRO to consider when the specimen is oral fluid versus urine. These cutoffs trigger a clinical examination for the use of the naturally occurring opiates, codeine and morphine. In addition, in § 40.139(c), we propose to delete a reference to “urine,” since the provision would apply to all DOT drug tests.

The proposed rule would make two clarifying changes to § 40.145. In § 40.145(g)(3), we would delete the word “urine” and substitute “drug,” since in this context we would apply the requirement to test in an HHS-certified laboratory to any such test, whether urine or oral fluid. In paragraph (h) we would add the word “urine” after “substituted”.

In § 40.151, we propose clarifying the language of paragraph (a) to direct MROs not to accept the result of any drug test not collected and tested under Part 40 procedures. In talking to employees who contact ODAPC following a positive drug test, we often hear, “I went to my own doctor the next day and took another test and it was negative.” This paragraph emphasizes that MROs cannot accept such a claim, which does not overturn the MRO’s decision. We also deleted language referring to DNA tests since use of those tests is prohibited elsewhere in the regulation (see 49 CFR 40.153(e) and 40.331(f)). In paragraph (b), we would change “urine” container to “collection” container in recognition of the advent of oral fluid testing. In paragraph (g), we deleted reference to “MDEA”, since it had been removed in a previous rulemaking (82 FR 52229 (Nov. 13, 2017)), in response to HHS deleting MDEA from the drug testing

panel. MDEA is a Schedule I drug in the amphetamines class that was previously a required confirmatory test analyte under the HHS Guidelines, but which HHS removed.

In § 40.151, we also propose a technical amendment to paragraph (i), replacing the wording “with no detectable creatinine” with “when the creatinine level is below the laboratory’s limit of detection.” This would ensure consistency with the requirement for laboratories to provide a numerical value for a substituted result (see 49 CFR 40.97(e)(2)). Also, it is our understanding that all HHS/NLCP-certified laboratories must have an established limit of detection for creatinine of 1mg/dL or less. Therefore, when a laboratory reports a creatinine concentration level at less than its limit of detection, MROs can be assured that it falls below the creatinine concentration of 2mg/dL for a substituted specimen and that an individual cannot physiologically produce such a urine specimen.

In § 40.159, in paragraph (a)(1) we propose to correct the reference to § 40.96(c) to become § 40.96(b) and we propose adding a new sentence to paragraph (a)(5)(ii), which would require re-collection when an invalid test is cancelled. The added sentence would direct that an alternative specimen be collected if practicable (e.g., oral fluid, if the specimen was urine). This could result in a more efficient process and reduce the likelihood of multiple invalid specimens resulting from use of the same specimen type.

In § 40.163(c)(2), we propose a small change, substituting “employee” for “donor.” In § 40.163(e), we are also making minor wording changes to clarify what records the MRO needs to retain after having reported a result and to clarify that when completing Copy 2 of the CCF, either the MRO must sign and date it (for both negatives and non-negatives) or MRO staff must stamp and date it (for negatives only).

§ 40.177 What does the second laboratory do with the split specimen when it is tested to reconfirm the presence of a drug or drug metabolite?

In § 40.177, we propose adding a reference to the sections pertaining to oral fluid testing.

§ 40.179 What does the second laboratory do with the split specimen when it is tested to reconfirm an adulterated test result?

In § 40.179, the proposed rule would change referenced section numbers in accordance with renumbering and new

oral fluid provisions elsewhere in the regulations.

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

In § 40.181, the proposed rule would change referenced section numbers in accordance with renumbering and new oral fluid provisions elsewhere in the regulations. In addition, § 40.181 would be changed to refer only to urine testing, since the creatinine and specific gravity apply only to urine testing.

§ 40.187 What does the MRO do with split specimen laboratory results?

In § 40.187, the proposed rule would change references to appendix D to appendix F in accordance with the redesignations.

§ 40.191 What is a refusal to take a DOT drug test, and what are the consequences?

This proposed provision carries through the main points of Part 40’s existing refusals provision, the main addition being a provision describing what can constitute a refusal in an oral fluid collection. The proposed section would make a variety of small wording changes to take oral fluid testing into account (e.g., in paragraph (a)(8)), “fail to permit an inspection of the employee’s oral cavity or fail to remove objects from his or her mouth”), as well as specifying situations that are applicable only to urine testing (e.g., in paragraph (a)(9)), “fail to comply with an instruction to permit inspection to allow the observer to determine whether there is a prosthetic device in use”).

Like the pre-employment urine collection process, the oral fluid pre-employment collection process generally would not begin until the device is unwrapped. If an employee does not appear for a pre-employment drug test or leaves the collection site before receiving or unwrapping the device, this is not a refusal under § 40.191. However, as in urine testing, certain blatant conduct by the employee at the collection site could constitute a refusal before the collection device is unwrapped. For example, if an employee arriving for a pre-employment test, engages in disruptive or combative conduct at the collection site, a collector could report a refusal to the employer for determination.

In addition, it is important to note that when an employee is undergoing a pre-employment test and the collector switches to an alternate device, it is considered a continuation of the original collection and is not subject to

the pre-employment exception for leaving the collection site before the second device is opened. For example, if a collector begins with one specimen methodology (e.g., urine) and switches to oral fluid (e.g., because the employee was unable to provide a sufficient specimen), the employee must not leave the collection site without refusal consequences.

The proposed rule would revise § 40.191(d) and add a new paragraph (c)(1) to § 40.261 to clarify an often-misunderstood point about who has the authority to declare that conduct at the collection site constitutes a refusal to test. The Department has received many inquiries in which employers have automatically treated as a refusal any situation in which the collection site notes a refusal in the remarks section of the CCF. This is not correct.

Under the long-existing § 40.355(i), making collection site refusal decisions is a “non-delegable” duty of the actual employer. Service agents, such as collectors, BATs or STTs, are not authorized to make this decision. Their role is to provide information to the employer concerning the circumstances of the event. Then the employer, who as a matter of prudence would contact the employee and the collector or BAT to gather information, should make the decision, taking the entirety of the circumstances into account. The employer would have the discretion to consider circumstances that may satisfactorily excuse the employee’s conduct. For FMCSA-regulated owner-operators, C/TPAs stand in the shoes of employers for the purposes of determining whether the individual refused a test (49 CFR 382.705(b)(6)).

For example, we have heard multiple times about situations in which an employee provides an insufficient quantity of urine, begins the “shy bladder” procedure, but the procedure is cut short because the collection site closes before the employee has had three hours to produce a sufficient urine specimen, as allowed by § 40.193(b)(2). If the collection site nevertheless reports the matter to the employer as a refusal, the employer has discretion to determine that there was no intent on the part of the employee to evade the process. If the employer determines that a refusal did not occur, the employer would treat the test as an administratively closed non-event. FMCSA-regulated employers would have the discretion not report such non-events to the Clearinghouse as refusals. The same thinking might apply in a situation in which a documented family medical emergency led the employee to leave the collection site.

For random tests administratively closed as a non-event by the employer, no further action is required. For those testing events that require a “negative” test result (e.g., return-to-duty, follow-up), the employer would send the employee back for another collection. In all cases, the employer should document exactly what happened to explain why the employer concluded a refusal did not occur.

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

The most important change that this section would make is the addition of oral fluid testing to paragraph (a), adding insufficient specimen provisions for oral fluid testing, parallel to, but briefer than, the existing provisions of dealing with insufficient urine specimens. Because of the differences between the two types of specimen collections, the insufficient specimen collection procedure is shorter in duration than the insufficient urine specimen collection procedure (e.g., in an oral fluid collection, there would not be a need for a three-hour wait period). In paragraph (e), the proposed rule would add examples of conditions that might succeed as medical explanations of providing an insufficient quantity of oral fluid (e.g., autoimmune diseases), as well as examples that would not constitute a valid medical explanation (e.g., unsupported assertions of dehydration). We seek comment on what sort of evidence is needed to avoid an assertion being viewed as “unsupported” for this purpose. We note that because alternative specimens will be available, using a different type of specimen in an insufficient quantity case may be an option. That is, if a urine specimen is insufficient, the collector could follow up with an oral fluid collection, or vice-versa. In such a case, following the insufficient urine specimen procedures would become unnecessary. The Department seeks comment on both this concept and whether specific language to this effect should be included in the regulatory text.

We also seek public comment, especially from device manufacturers, regarding whether allowing a donor to rinse with up to 8 ounces of water is an appropriate amount of fluid for rinsing for the purposes of both §§ 40.72(b) and 40.193(b)(2). Should we allow more or less? Would measuring less than 8 ounces be difficult for collectors?

We also seek comment on whether a qualified collector should be able to make a decision about what methodology to use after an insufficient

specimen occurs, or whether this should be a decision left to the employer, depending, for example on the employer’s contract with a C/TPA, laboratory, or collection site. In addition, when following an insufficient specimen collection, consistent with the HHS OFMG, the collector would complete a new CCF for the alternative specimen collection. Is this an appropriate way of handling such situations, or would it be better to continue the current practice and use the original CCF with relevant cross-outs and notations in the remarks section?

§ 40.195 What happens when an individual is unable to provide a sufficient amount of specimen for a pre-employment follow-up or return-to-duty test because of a permanent or long-term medical condition?

The only textual change in § 40.195 in the proposed rule is in the title, where the more general “specimen” is substituted for “urine,” in view of the addition of oral fluid testing to the program.

§ 40.197 What happens when an employer receives a report of a dilute urine specimen?

The only textual change in § 40.197 in the proposed rule is in the title, where the word urine would be inserted because this section concerns situations that arise only in urine testing.

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

Section 40.199, the “fatal flaws” section of the rule, would be expanded by adding a new fatal flaw for use of an expired oral fluid collection device, in paragraph (b)(8). In paragraph (b)(7) of § 40.199, the term “urine” would be replaced with “specimen,” reflecting the addition of oral fluid testing to the program.

§ 40.201 What problems always cause a drug test to be cancelled and may result in a requirement for another collection?

In paragraph (b)(7) of § 40.199 and paragraph (f) of § 40.201, the term “urine” would be replaced with “specimen,” reflecting the addition of oral fluid testing to the program.

§ 40.207 What is the effect of a cancelled drug test?

Throughout the history of Part 40, there has not been a regulatory provision that allows an MRO to “uncancel” a test that the MRO has cancelled. New paragraph (d) is proposed so that an MRO can reverse

the cancellation of a test. Currently, §§ 40.203, 40.205, and 40.208 address situations that require a test to be cancelled by an MRO, if there is not corrective action. For example, if an MRO does not receive a timely memorandum for the record from a collector regarding required information that was omitted from the CCF, the MRO may cancel the test. Once an MRO cancels a test due to an uncorrected correctable error, there is currently no authority for the MRO to reverse that cancellation decision. So, if the memorandum for the record arrives, but the MRO staff misses it, the cancelled test cannot be reversed without this proposed rule change. That inability has created additional cost for the employer, inconvenience for the employee, and also confusion because some MROs think they already have this authority. Adding this provision will reduce costs and confusion. In addition, for those testing events for which an employer needs a negative result (*i.e.*, pre-employment, return-to-duty or follow-up), an employee must go in and re-take the test, if the MRO cannot un-cancel it after the error is corrected.

§ 40.210 *What kinds of drug tests are permitted under the regulations?*

This proposed revision notes that oral fluid and/or urine specimens can be collected, and must be tested at HHS-certified laboratories. No other specimen methodologies are currently permitted.

We are proposing that an employer can use one or the other, but not both urine and oral fluid methodologies at the beginning of the testing event. For example, if an employee is sent for a test, either a urine or oral fluid specimen can be collected, but not both simultaneously. However, if there is a problem in the collection that necessitates a second collection (*e.g.*, insufficient quantity of urine, temperature out of range, or insufficient oral fluid), we want to propose that a second methodology could be used to complete the collection process for the testing event. If we adopt this provision, would the employer and/or its service agent be the correct one(s) to make the decision as to which methodology to use in the second collection?

§ 40.225 *What form is used for an alcohol test?*

This proposed revision would make a conforming change to § 40.225 and redesignate appendix G to be appendix I.

§ 40.261 *What is a refusal to take an alcohol test, and what are the consequences?*

We are proposing to add a new paragraph (c)(1) to this section, parallel to the proposed § 40.191(b) for drug testing. It spells out the respective responsibilities of the service agent(s) and the DER in making decisions about whether a situation during an alcohol test constitutes a refusal to test. In a situation in which there is not an employee signature, at Step 2 of the ATF (see paragraph (a)(6) of this section), but a result is nonetheless forwarded to the employer, we recommend that the employer take a case-by-case approach, for example not treating as a refusal a situation in which there is no signature but there is an affidavit from an STT or BAT explaining the situation.

§ 40.283 *How does a certification organization obtain recognition for its members as SAPs?*

In § 40.283, there is a conforming change redesignating aappendix E to aappendix G.

§ 40.285 *When is a SAP evaluation required?*

In § 40.285, the word “urine” would be removed if oral fluid testing is added.

§ 40.345 *In what circumstances may a C/TPA act as an intermediary in the transmission of drug and alcohol testing information to employers?*

A conforming change, from aappendix F to aappendix H, would be made in § 40.345.

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

In § 40.355(n) (Example 3), the word “urine” would be removed in light of the addition of oral fluid testing.

§ 40.291 *What is the role of the SAP in the evaluation, referral, and treatment process of an employee who has violated DOT agency drug and alcohol testing regulations?*

As discussed in the Principal Policy Considerations section, the Department is proposing to permit substance abuse professionals (SAPs) to conduct evaluations or assessments remotely. The proposed rule would amend §§ 40.291(a)(1) and (3) to remove the requirement that SAP evaluations be only “face-to-face” and to explain what is required for remote evaluations. Specifically, the technology must be able to allow real-time audio and visual interaction between the SAP and the employee. Telephone calls, therefore, would not be acceptable. In addition,

the proposal would require that the quality of the technology be sufficient to allow the SAP to gather all visual and audible information that would be apparent in a face-to-face interaction.

§ 40.293 *What is the SAP’s function in conducting the initial evaluation of an employee?*

The proposal would remove the words “face-to-face” from paragraph (a) this provision. This change, if adopted, would allow remote evaluations.

§ 40.301 *What is the SAP’s function in the follow-up evaluation of an employee?*

The proposal would remove the words “face-to-face” from paragraph (b)(2) this provision. It would also add the words “meeting the requirements of § 40.291(a)(1) of this part”, if adopted. This proposed change would allow remote evaluations.

§ 40.311 *What are the requirements concerning SAP reports?*

The proposal would add the words “and format (*i.e.*, face-to-face or remote)” to § 40.311(c)(4), (d)(4), and (e)(4). In addition, we would amend § 40.311 to direct SAPs to note on their SAP reports whether a given evaluation occurred face-to-face or remotely.

We also propose to change “SSN” to “SSN or employee ID number” in paragraphs § 40.311(c)(1), (d)(1) and (e)(1) for consistency of terms in Part 40 and to allow the use of additional identification numbers in SAP reports, instead of solely the Social Security Number.

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

We propose to amend § 40.365 to say that a PIE could occur because a SAP failed to conduct an evaluation using the means provided in § 40.291(a)(1), rather than because there was no face-to-face evaluation.

§ 40.327 *When must the MRO report medical information gathered in the verification process?*

In § 40.327, we would add a clarification that MROs are not to use the CCF to transmit information about safety concerns to employers or other authorized parties. Rather, a separate communication (*e.g.*, secure email, letter) is to be used. The communication should specify whether the MRO’s safety concern relates to the use of a medication, the type of medical condition for which such a medication is typically prescribed, or some combination of the two. The purpose of

providing this information is to allow the employer and/or any third parties to focus on the MRO's specific concern, rather than having to make an open-ended inquiry. The Department seeks comment on this matter. This clarification would echo the Department's 2017 final rule preamble discussion that medical information is sent apart from the verified result report. (82 FR 52229, 52236; Nov. 13, 2017).

Appendices

Appendix A, concerning urine collection kits, would remain unchanged. The proposed rule would add a new appendix B, establishing standards for oral fluid collection kits, based on material in the HHS OFMG and consistent with OTETA requirements for a split specimen. The Department seeks comments on the details of the proposed standards.

The remainder of the appendices would be renumbered and reordered. For a summary of these changes, see the redesignation table immediately preceding the discussion of subpart D in section V of the preamble. The Department seeks comment on the new organization of the appendices.

Current appendix B, concerning semi-annual reports by laboratories to employers, would become appendix D. The new version of the appendix would break out matters to be reported with respect to urine and oral fluid testing respectively. Current appendix C, regarding semi-annual reports by laboratories to the Department, would become appendix E. Meanwhile, the appendix C slot would be reserved.

In the redesignated appendix E (the former appendix C), the Department proposes to amend the data elements that HHS/NLCP certified laboratories would submit to DOT semi-annually. Specifically, we propose to require laboratories to continue to provide the DOT with the drug testing data but to be broken out by specimen type (*i.e.*, urine and oral fluid), DOT agency (*i.e.*, FMCSA, FAA, FRA, FTA, PHMSA, U.S. Coast Guard) and test reason (*i.e.*, pre-employment, random, reasonable suspicion/cause, post-accident, return-to-duty, other, and follow-up). The proposal would require each laboratory to submit multiple data summaries as opposed to the one data summary they now provide. By providing the additional data elements, we hope to evaluate the efficacy of testing by oral fluid versus urine. We also hope to get a better understanding of any trends in drug testing by specimen type, DOT agency and/or test reason(s).

We do not anticipate that providing the amended data summaries will prove to be burdensome to the laboratories. It is our understanding that most, if not all of the HHS/NLCP-certified laboratories capture these data elements either as a result of implementing the electronic Federal Drug Testing Custody and Control Form, or in their Laboratory Information Management System, as part of tracking the specimens and reporting out test results to the Medical Review Officer. We would appreciate information from laboratories as to whether adding the new data elements would increase their costs or otherwise impose a quantifiable burden of what the costs of adding the new data elements would be.

Current appendix D, concerning reports on split specimen failures to reconfirm, would become appendix F. We propose to add the "specimen type" as another element to the information the MRO currently provides so we can track the two specimen types. Current appendix E, on SAP equivalency requirements for certification organizations, would become appendix G.

Current appendix F, concerning drug and alcohol testing information can be transmitted by C/TPAs, would become appendix H. Current appendix G, the Alcohol Testing Form, would become appendix I. Finally, appendix H, the MIS data collection form, would be found in appendix J.

VI. Regulatory Analyses and Notices

Executive Order 12866

The Secretary has examined the impact of the proposed Part 40 amendments under Executive Order 12866, which directs Federal agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). This examination draws upon the evaluation performed by HHS in its final guidelines concerning oral fluid testing, published October 25, 2019 (84 FR 57554), as well as data reflecting the Department's experience in implementing its existing drug testing program.

According to Executive Order 12866, a regulatory action is "significant" if it meets any one of a number of specified conditions, including having an annual effect on the economy of \$100 million; adversely affecting in a material way a sector of the economy, competition, or jobs; or if it raises novel legal or policy

issues. The proposed amendments do modify existing regulatory requirements and allow an activity that was formerly prohibited, but they do not meet the Executive Order's criteria for being a significant rule. Consequently, OMB has determined that this document proposes a nonsignificant rule.

Need for Regulation

The Department believes that this proposed rule is needed because it makes several improvements in the integrity and effectiveness of an important safety program, as well as potentially reducing some costs to regulated parties. The reasons for this belief include the following:

Enhanced Flexibility

The proposed rule, consistent with the HHS OFMG, would revise the requirement to collect only a urine specimen, which has existed since Part 40 was first published in 1988. Urine drug testing is subject to issues related to an employee's inability to produce a sufficient urine specimen. In such situations, the employee's inability to provide a sufficient urine specimen creates delays in getting a result to the employer because of the requirement to have the employee evaluated by a medical professional to assess the employee's inability to provide a sufficient specimen.

When the proposed amendments to Part 40 permitting oral fluid testing are used by a transportation employer, the employer will be authorized to collect an oral fluid specimen from an individual who is unable to provide a sufficient urine specimen. This added flexibility will reduce the need for the Medical Review Officer (MRO) to arrange a medical evaluation of an employee's inability to provide a specimen. Therefore, the proposed amendments would provide flexibility to address workplace drug testing needs of transportation employers by permitting the selection of the specimen type best suited for their needs and authorizing collection of an alternative specimen type when an employee is unable to provide a sufficient urine specimen. The added flexibility will also benefit employees, who should be able to provide one of the specimen types, thereby facilitating the drug test required for their employment.

Enhanced Versatility

Urine collection requires use of a collection facility, secured restrooms, and other special requirements. An oral fluid collection does not require an enclosure, the way that a urine collection does. With oral fluids, there

is more flexibility regarding the collection site. Specifically, an acceptable oral fluid collection site must allow the collector to observe the employee, maintain control of the collection device(s) during the process, maintain record storage, and protect employee privacy. This would provide employers with more flexibility about where to conduct a collection. For example, especially in the railroad and pipeline industries, where selected employees may be part of “travelling gangs” or in remote locations (*e.g.*, away from locations with traditional brick-and-mortar buildings) an enclosure is often difficult to find for collecting DOT-regulated specimens.

Having oral fluid testing as an option available to an employer provides flexibility for the employer to choose whether urine or oral fluid testing is better due to logistics, costs, and the specific facts of a situation. Among other things, when a problematic situation occurs at a collection site (*e.g.*, a urine specimen is out of temperature range), the ensuing directly observed test could be conducted using oral fluid. Choosing the oral fluid testing option in such situations can save the employer significant time and money.

Decreased Numbers of Substituted and Adulterated Tests

All unobserved specimen collections are at risk for substitution and adulteration. Per HHS’s OFMG preamble, information from the drug testing industry indicates that 0.05 to 3% of urine specimens collected for drug use detection are determined to be substituted or adulterated. (84 FR 57571; Oct. 25, 2019). All oral fluid collections will occur under direct observation, which should substantially reduce the risks of specimen substitution and adulteration that has been associated with urine specimen collections, most of which are unobserved. With the above in mind, and to harmonize with HHS, we are proposing changes to §§ 40.91 and 40.93 to authorize laboratories to conduct specimen validity testing (*e.g.*, testing for a biomarker such as albumin or immunoglobulin G, IgG or for a specific adulterant).

Time and Cost Savings

Collecting an oral fluid specimen can require less time than collecting a urine specimen, and thereby reduce the employee’s time away from the workplace and costs to the employer. First, most urine collections take place in separate facilities dedicated to collections, requiring employees to travel from their workplace to those

facilities and back. Their time away from their workplace is a cost to their employers. On the other hand, most oral fluid collections are likely to take place at or near the workplace, making this travel time and cost unnecessary.

The Department does not currently have data on the percentage of urine collections that are conducted in dedicated collection facilities, or the percentage of oral fluid collections that would likely be conducted on-site. We request that commenters submit information that would help the Department approximate a calculation of the travel time savings that could result from making oral fluid testing available as an alternative to urine testing.

Second, some urine collection events involve the employee’s inability to provide a sufficient specimen. In these cases, the current regulation affords the employee up to three hours to make a second attempt at providing a sufficient urine specimen. This wait period can be avoided by immediately switching to an oral fluid collection, saving up to three hours of time in such cases. From 2018 MIS data, about 334 insufficient specimen collections resulted in refusals, a number that does not include those instances in which the situation is resolved without a refusal being declared. The Department seeks comment on the incidence of “shy bladder” situations, to get a better sense of how much time and costs would be saved by eliminating them by the use of oral fluid testing.

In addition, fewer insufficient specimen situations would mean fewer medical evaluations, which could also result in time and cost savings. The option to collect a urine specimen in the event that the employee cannot provide an oral fluid specimen (and vice versa) will avoid the need for the MRO to arrange for a medical evaluation of an employee’s inability to provide a sufficient specimen. We seek comment on what degree of time and cost savings might result from this proposal.

We also note that urine testing is subject to other events that may involve additional testing. For instance, if an initial urine specimen is out of temperature range, or the color or odor of a specimen may indicate an attempt to tamper with a specimen, there must be an immediate re-collection under direct observation. Many of these situations may well evolve into a “shy bladder” situation as, having just voided, the employee may be unable to produce another specimen quickly. These subsequent collections involve time and other costs. We seek comment on how frequently such subsequent

collections occur, and how much time they add to the process.

Reduced Need for Collection Site Security Measures

Urine testing requires that access to water sources or to any potential adulterants or substituting products be secured and prohibited. This requires securing of the collection site to ensure the integrity of the unobserved testing process and protection against cheating. We are proposing substantially fewer steps for oral fluid collection site integrity and security because all oral fluid specimen collection is directly observed.

Providing urine is a bodily function that requires more privacy than having the employee place a collection device in the employee’s mouth, in accordance with the collector’s instructions. Consequently, oral fluid testing is less intrusive and time-consuming than even unobserved urine testing.

Versatility in Detection

Adding oral fluid as an alternate specimen type would allow an employer to select the specimen type based on the circumstances of the test. For example, in a reasonable suspicion/cause or post-accident test, an oral fluid test may show the presence of an active drug, which may indicate recent use of the drug, and which might not be detected in a urine drug test.

An oral fluid drug test can detect marijuana use in the past 24 hours, while a urine drug test detects use ranging from 3–67 days prior to collection (see preamble “Understanding Windows of Detection”). Thus, oral fluid testing may give employers more interpretative insight into recent drug use.

Lower Likelihood of Adulteration, Substitution or Cheating

Urine was the original specimen of choice for workplace drug testing, and urine testing is expected to remain an established and reliable component of DOT’s drug testing program. However, a major challenge to urine drug testing has been the proliferation and use of available commercial products used to adulterate or substitute an employee’s urine specimen. Due to individual privacy rights, most urine collections are unobserved, allowing the opportunity to use such products. As under HHS Urine Mandatory Guidelines, laboratories have developed procedures to identify adulterated and/or substituted specimens, manufacturers have developed new products to avoid detection. The use of these products is expected to continue. Like HHS, DOT

believes that oral fluid testing is likely to be less susceptible to these problems because the oral fluid collection is a directly observed collection.

Costs and Benefits

Using data obtained from the Federal Workplace Drug Testing Programs and HHS-certified laboratories, HHS estimated that approximately 7% (or 10,500) of the 150,000 specimens tested in the Federal employee program per year would be oral fluid specimens and 93% would continue to be urine specimens. HHS further estimated that subsequent transition to oral fluid testing would be gradual and steady over the course of four years, when it could account for about 30% of all tests.

If, as the Department believes based on industry experience, the cost of a urine test is approximately \$50, while the cost of an oral fluid test is \$35, this means that each oral fluid test that is done in place of a urine test results in a saving of \$15. By this calculation, oral fluid testing would cost \$14.7 million in the first year and \$63 million after the four-year transition period. This represents a potential savings of \$6.3 million the first year and \$27 million in the fourth year, compared to a scenario in which all the tests in question were urine tests. The Department seeks comment on whether the assumptions

behind these calculations make sense and whether and how we should modify them.

It is possible that, over time, the proportion of tests conducted using oral fluid could increase beyond this projection, as employers take advantage of the lower costs and greater flexibility associated with oral fluid testing. If so, then the cost savings of these amendments would increase. We do not have data on which to base an estimate of how large and how quickly this trend might become. The Department seeks comment on this matter.

Employers and C/TPAs choosing to use oral fluid in their drug testing programs may incur collector training costs. Based on an average of the limited number of published training costs for oral fluid collectors in the non-DOT drug testing industry, oral fluid collection training would cost about \$348 per collector trained.

The Department estimates that there are about 25,000 collectors currently participating in the DOT-regulated urine drug testing program. We assume, per HHS’s projection, that after the first year of oral fluid testing, 7% of tests would use oral fluid and around 7% of collectors would be trained in oral fluid collection by that point. Seven percent of 25,000 collectors is 1,750. Their

training would cost \$609,000. By the same logic, by the end of the fourth year, 30% of those 25,000 collectors, or 7,500, would have been trained in collecting oral fluid. The cost for oral fluid testing training an additional 23% of the 25,000 collectors, or 5,750 individuals, in years 2–4 would be \$2,001,000. The Department seeks information and comment on this approach and these projections.

As noted in the time savings discussion above, in a “shy bladder” situation, a collector can switch from urine to oral fluid collection. Likewise, in a “dry mouth” situation, a collector can switch from oral fluid to urine collection. This flexibility minimizes the required waiting period involved in “shy bladder/dry mouth” situations at the collection site. It also avoids costs and time expenses of subsequent medical evaluations to determine whether there is a medical explanation of employee’s inability to provide a sufficient specimen. As noted above, we are seeking information on the number and costs of such evaluations. Table 1 summarizes the quantified economic effects of the proposed rule. The proposed rule has annual net cost savings (benefits) of \$5,61,000 in the first year, increasing to \$24,999,000 in the fourth and subsequent years.

TABLE 1—ECONOMIC EFFECTS OF PROPOSED RULE

Year	Costs	Cost savings	Net cost savings
1	\$609,000	\$6,300,000	\$5,691,000
2	\$957,000	\$11,475,000	\$10,518,000
3	\$1,305,000	\$11,475,000	\$10,170,000
4 and beyond	\$2,001,000	\$27,000,000	\$24,999,000

Regulatory Flexibility Act and SBREFA

This rule does affect small entities, including employees, small transportation companies and collection sites. DOT anticipates, however, that there will be an overall reduction in costs if drug testing is expanded to provide the option of oral fluid testing under Part 40. The added flexibility to use either specimen type will permit employers to select the specimen type best suited for their needs and to authorize collection of an alternative specimen type when an employee is unable to provide the specimen type originally authorized. This added flexibility will also benefit employees, who should be able to provide one of the specimen types, thereby facilitating the completion of drug tests required for their employment. For these reasons, and as explained in more detail in the preamble to this proposed rule, the

Secretary has determined that the proposed rule would not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act (5 U.S.C. 605(b)). Consequently, an initial regulatory flexibility analysis is not required for this proposed rule.

The Secretary has determined that this NPRM is not a “major rule” for the purpose of congressional review. For the purpose of congressional review, a major rule is one which is likely to cause an annual effect on the economy of \$100 million or more; a major increase in costs or prices; significant effects on competition, employment, productivity, or innovation; or significant effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. The proposed rule does

none of these things, and hence does not constitute a major rule under the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996.

Unfunded Mandates

The Secretary has examined the impact of the proposed rule under the Unfunded Mandates Reform Act (UMRA) of 1995 (Pub. L. 104–4). This notice 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 (adjusted annually for inflation) or more by either State, local, and tribal governments in the aggregate or by the private sector in any one year. In fact, by providing a lower cost alternative to urine drug testing, the NPRM would reduce costs to regulated parties, including State and local entities (e.g.,

public transit authorities, public works departments) whose employees are subject to testing.

Environmental Impact

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

Executive Order 13132: Federalism

The Secretary has analyzed the proposed rule in accordance with Executive Order 13132: Federalism. Executive Order 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, public works departments); however, as noted above, this proposal would reduce costs of the Department's

drug testing program and provide additional flexibility for regulated parties. Accordingly, the Secretary has determined that the proposed rules do not contain policies that have federalism implications.

Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175 (65 FR 67249, November 6, 2000) requires Federal agencies to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" as defined in the Executive Order, include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." This proposed rule does not have tribal implications. Nor will they have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175.

Information Collection/Record Keeping Requirements

The proposed rule would not impose additional information collection burdens. In August 2020, OMB approved the revised CCF (OMB Control No. 0930-0158). It is a single CCF that can be used for either urine or oral fluid testing. Collectors, laboratories, MROs and other parties in the DOT drug testing program are required to use the 2020 CCF for urine testing. Upon issuance of any final rule authorizing oral fluid testing, the 2020 CCF will be required for oral fluid testing.

Notwithstanding any other provision of law, no person is required to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA unless that collection of information displays a currently valid OMB control number.

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.

For the reasons stated in the preamble, the Department proposes to amend 49 CFR part 40 as follows:

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

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

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

■ 2. In § 40.3:

- a. Remove the definitions of "Invalid drug test" and "Screening drug test";
- b. Remove the definition of "Initial drug test (also known as "Screening drug text") and add a definition for "Initial drug test" in its place;
- c. Remove the definition of "Limit of Quantification" and add a definition for "Limit of Quantification (LOQ)" in its place;
- d. Add in alphabetical order definitions for "Alternative specimen", "Commercial Driver's License Drug and Alcohol Clearinghouse (Clearinghouse)", "Cutoff", "Oral Fluid Specimen", "Specimen", "SSN or Employee ID No.", "Undiluted (neat) oral fluid", and "Urine Specimen"; and
- e. Revise the definitions of "Collection container", "Collection site", "Confirmatory drug test", "Initial drug test", "Initial specimen validity test", "Invalid Result", "Laboratory", "Limit of Detection (LOD)", "Limit of Quantitation (LOQ)", "Non-negative specimen", "Primary specimen", "Reconfirmed", "Shipping container", "Specimen bottle", "Split specimen", "Split specimen collection", and "Substituted specimen".

The additions and revisions read as follows:

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

* * * * *

Alternative specimen. An authorized specimen, other than the type of specimen previously collected or attempted to be collected.

* * * * *

Collection container. A container used to collect a specimen.

Collection site. A place selected by the employer where employees present themselves for the purpose of providing a specimen for a drug test.

* * * * *

Commercial Driver's License Drug and Alcohol Clearinghouse (Clearinghouse). A database, administered by the Federal Motor Carrier Safety Administration, containing records of commercial motor vehicle drivers' violations of controlled

substances and alcohol testing program requirements, as set forth in part 382 of this title, as well as their return-to-duty status.

* * * * *

Confirmatory drug test. A second analytical procedure performed on a different aliquot of the original specimen to identify and quantify a specific drug or drug metabolite.

* * * * *

Cutoff. The analytical value (e.g., drug or drug metabolite 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 drug test. The first test used to differentiate a negative specimen from one that requires further testing for drugs or drug metabolites.

Initial specimen validity test. The first test used to determine if a specimen is adulterated, diluted, substituted, or invalid.

Invalid result. The result reported by a laboratory for a specimen in which the laboratory has not been able to complete testing or obtain a valid drug test result (e.g., because of an unidentified adulterant, an interfering substance, or an abnormal physical characteristic).

Laboratory. Any U.S. laboratory certified by HHS under the National Laboratory Certification Program as meeting the minimum standards set by HHS; or, in the case of foreign laboratories, a laboratory approved for participation by DOT under this part.

Limit of Detection (LOD). The lowest concentration at which the analyte (e.g., drug or drug metabolite) can be identified.

Limit of Quantitation (LOQ). For quantitative assays, the lowest concentration at which the identity and concentration of the analyte (e.g., drug or drug metabolite) can be accurately established.

* * * * *

Non-negative specimen. A specimen that is reported as adulterated, substituted, positive (for drug(s) or drug metabolite(s)), or invalid.

* * * * *

Oral Fluid Specimen. A specimen that is collected from an employee's oral cavity and is a combination of physiological fluids produced primarily by the salivary glands.

* * * * *

Primary specimen. In drug testing, the specimen bottle that is opened and tested by a first laboratory to determine whether the employee has a drug or drug metabolite in his or her system;

and for the purpose of specimen validity testing. The primary specimen is the portion of the donor's subdivided specimen designated as the primary ("A") specimen by the collector to distinguish it from the split ("B") specimen, as defined in this section.

* * * * *

Reconfirmed. The result reported for a split (Bottle B) specimen when the second HHS-certified laboratory corroborates the original result reported for the primary (Bottle A) specimen.

* * * * *

Shipping container. A container that is used for transporting and protecting specimen bottles and associated documents from the collection site to the laboratory.

Specimen. Fluid, breath, or other material collected from an employee at the collection site for the purpose of a drug or alcohol test.

Specimen bottle. The bottle that, after being sealed and labeled according to the procedures in this part, is used to hold a primary ("A") or split ("B") specimen during transportation to the laboratory. In the context of oral fluid testing, it may be referred to as a "vial," "tube," or "bottle."

Split specimen. In drug testing, the specimen that is sent to a first laboratory and stored with its original seal intact, and which is transported to a second laboratory for retesting at the employee's request following MRO verification of the primary specimen as positive, adulterated or substituted.

Split specimen collection. A collection in which the single specimen collected is divided into two separate specimen bottles, the primary specimen (Bottle A) and the split specimen (Bottle B).

SSN or Employee ID No. This number serves as a unique identifier that must be used on the Federal Drug Testing Custody and Control Form (CCF) or Alcohol Testing Form (ATF) for a donor, on the MRO's reports, on SAP reports, or on other documents that are required under this part. For all purposes of this part, this term means: Only the Commercial Driver's License (CDL) Number and State of issuance for drivers tested under the authority of the Federal Motor Carrier Safety Administration (FMCSA); and, for all drivers and other safety-sensitive employees tested under the authority of the other DOT agencies, this can be the individual's actual Social Security Number, a unique identifier issued by the employer, a State-issued identification card number, a State-issued driver's license number (including a CDL number) or any other

State-issued or federally-issued identification number.

* * * * *

Substituted specimen. An employee's 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 so diminished, or so divergent that they are not consistent with normal human urine).

* * * * *

Undiluted (neat) oral fluid. An oral fluid specimen to which no other solid or liquid has been added. For example: A collection device that uses a diluent (or other component, process, or method that modifies the volume of the testable specimen) must collect at least 1 mL of undiluted (neat) oral fluid.

Urine specimen. Urine collected from an employee at the collection site for the purpose of a drug test.

* * * * *

■ 3. In § 40.13, revise paragraphs (b), (c), and (d), redesignate paragraphs (e) and (f) as paragraphs (f) and (g), respectively, add new paragraph (e), and add paragraph (h).

The revisions and additions to read as follows:

§ 40.13 How do DOT drug and alcohol tests relate to non-DOT tests?

* * * * *

(b) DOT tests must take priority and must be conducted and completed before a non-DOT test is begun. When conducting a urine DOT drug test, you must discard any excess urine left over from a DOT test and collect a separate urine void for the subsequent non-DOT test.

(c) Except as provided in paragraph (d) of this section, you must not perform any tests on DOT specimens other than those tests specifically authorized by this part or DOT agency regulations. For example, you must not test a DOT specimen for additional drugs. In addition, a laboratory is prohibited from making a DOT specimen available for a DNA test or other types of specimen identity testing.

(d) When a DOT urine drug test collection is conducted as part of a physical examination required by DOT agency regulations, it is permissible to conduct medical tests related to this physical examination (e.g., for glucose) on any specimen remaining in the collection container after the DOT portion has been sealed into the specimen bottles.

(e) A non-DOT drug or alcohol test administered, as part of a physical examination, is not a DOT drug or alcohol test for purposes of this part and

related DOT agency drug and alcohol testing rules, if that test was performed to determine if an employee is medically qualified for a license or certificate. Consequently, the results of such a test do not have consequences under this part.

* * * * *

(h) No one is permitted to conduct a DOT drug or alcohol test on an individual who is not a DOT-regulated employee, as defined by the DOT agency regulations.

■ 4. In § 40.14, revise paragraph (b) and add paragraphs (k) and (l) to read as follows:

§ 40.14 What information must employers provide to collectors?

* * * * *

(b) SSN or Employee ID No.”;

* * * * *

(k) Specimen type to be collected (*i.e.*, oral fluid or urine).

(l) If a urine specimen is to be collected under direct observation.

■ 5. In § 40.21:

■ a. In paragraph (c)(2)(vii)(B), remove the word “and” from the end;

■ b. Redesignate paragraph (c)(2)(vii)(C) as paragraph (c)(2)(vii)(D); and

■ c. Add a new paragraph (c)(2)(vii)(C). The addition reads as follows:

§ 40.21 May an employer stand down an employee before the MRO has completed the verification process?

* * * * *

- (c) * * *
- (2) * * *
- (vii) * * *

(C) For a verified negative result, the employee will not be required to submit an alternative specimen for the same testing action. For a cancelled result, the employee could be required to submit an alternative specimen on a re-collection; and

* * * * *

■ 6. In § 40.23, revise paragraphs (f) introductory text and (f)(1) and (5) to read as follows:

§ 40.23 What actions do employers take after receiving verified test results?

* * * * *

(f) As an employer who receives a drug test result indicating that the employee’s test was cancelled because it was invalid and that a second collection must take place under direct observation—

(1) You must immediately direct the employee to provide a new specimen under direct observation (either an oral fluid specimen or a urine specimen under direct observation).

* * * * *

(5) You must ensure that the collector conducts the collection under direct

observation (either an oral fluid specimen or a urine specimen under direct observation).

* * * * *

■ 7. In § 40.25, revise paragraph (a) to read as follows:

§ 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)(1) Yes, as an employer, you must, after obtaining an employee’s written consent, request the information about the employee listed in paragraphs (b) through (j) of this section. This requirement applies only to employees seeking to begin performing safety-sensitive duties for you for the first time (*i.e.*, a new hire, an employee transferring into a safety-sensitive position). If the employee refuses to provide this written consent, you must not permit the employee to perform safety-sensitive functions.

(2) If you are an employer regulated by FMCSA, beginning January 6, 2023, you are not required to comply with the requirements of this section when checking an employee’s testing history with other employers regulated by FMCSA. You must continue to comply with the requirements of section 40.25 when checking an employee’s testing history with employers regulated by a DOT operating administration other than FMCSA.

(3) If you are an employer regulated by FMCSA, with a prospective employee subject to drug and alcohol testing with a DOT agency other than FMCSA, you must continue to request the information about the employee listed in paragraphs (b) through (j) of this section. For example, if you are an employer regulated by both FMCSA and PHMSA, and you are hiring an employee to perform functions regulated by both DOT Agencies, then you must query FMCSA’s Clearinghouse to satisfy FMCSA’s requirements and you must request the information listed in paragraphs (b) through (j) of this section to satisfy PHMSA’s requirements.

* * * * *

§ 40.26 [Amended]

■ 8. In § 40.26, remove “Appendix H” and add in its place “Appendix J”.

§ 40.29 [Removed]

■ 9. Remove § 40.29.

■ 10. In § 40.31,

■ a. Revise the section heading;

■ b. Revise paragraphs (b);

■ c. Redesignate paragraphs (c) and (d) as paragraphs (d) and (e)

■ d. Add new paragraph (c);

■ e. Revise newly redesignated paragraph (d); and

■ f. Add paragraph (f).

The revisions and additions read as follows:

§ 40.31 Who may collect specimens for DOT drug testing?

* * * * *

(b) A urine collector must meet training requirements of § 40.33.

(c) An oral fluid collector must meet the training requirements of § 40.35.

(d) To avoid the appearance of a conflict of interest, if you are the immediate supervisor of the employee being tested, you must not act as the collector when that employee is tested, unless no other collector is available and you are permitted to do so under DOT agency drug and alcohol regulations.

* * * * *

(f) Employees are not permitted to be their own collector.

(1) An employee who is a qualified collector is not permitted to be their own collector; another qualified collector must perform the collection in accordance with this part.

(2) To avoid a potential conflict of interest, a collector must not be related to the employee being tested (*e.g.*, spouse, ex-spouse, relative) or a close personal friend.

■ 11. In § 40.33, revise the section heading, introductory text, and paragraph (f) to read as follows:

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

To be permitted to act as a urine collector in the DOT drug testing program, you must meet each of the requirements of this section:

* * * * *

(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. Errors that cause cancellation but occur 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 would not be the result of an error by the collector during the collection process and does not require the collector to be retrained.

* * * * *

§ 40.35 [Redesignated as § 40.36]

■ 12. Redesignate § 40.35 as § 40.36.

■ 13. Add a new § 40.35 to read as follows:

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

To be permitted to act as an oral fluid collector in the DOT drug testing program, you must meet each of the requirements of this section:

(a) *Basic information.* You must be knowledgeable about this part, the current applicable guidelines and DOT agency regulations applicable to the employers for whom you perform collections. DOT agency regulations, guidelines, and other materials are available from ODAPC (Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, 202-366-3784, or on the ODAPC website (<https://www.transportation.gov/odapc>). You must keep current on any changes to these materials. You must subscribe to the ODAPC list-serve at: <https://www.transportation.gov/odapc/get-odapc-email-updates>.

(b) *Qualification training.* You must receive qualification training meeting the requirements of this paragraph. Qualification training must provide instruction on the following subjects:

(1) The oral fluid collection device manufacturer's training for each device the collector will use for DOT-regulated collections;

(2) All steps necessary to complete a collection correctly and the proper completion and transmission of the CCF;

(3) "Problem" collections (*e.g.*, situations like "dry mouth" and attempts to tamper with a specimen);

(4) Fatal flaws, correctable flaws, and how to correct problems in collections; and

(5) The collector's responsibility for maintaining the integrity of the collection process, ensuring the privacy of employees being tested, ensuring the security of the specimen, and avoiding conduct or statements that could be viewed as offensive or inappropriate.

(c) *Initial proficiency demonstration.* Following your completion of qualification training under paragraph (b) of this section, you must demonstrate proficiency in collections under this part by completing five consecutive error-free mock collections.

(1) The five mock collections 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.

(2) Another person must monitor and evaluate your performance, in person or

by a means that provides real-time observation and interaction between you and the qualified collector, who must attest in writing that the mock collections are "error-free." This person must be a qualified collector who has demonstrated necessary knowledge, skills, and abilities by—

(i) Regularly conducting DOT drug test collections for a period of at least one year;

(ii) Conducting collector training under this part for at least one year; or

(iii) Successfully completing a "train the trainer" course.

(d) *Schedule for qualification training and initial proficiency demonstration.* You must meet the requirements of paragraphs (b) and (c) of this section before you begin to perform collector functions.

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

(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.

(1) Error correction training must be provided and your proficiency documented in writing by a person who meets the requirements of paragraph (c)(2) of this section.

(2) Error correction training is required to cover only the subject matter area(s) in which the error that caused the test to be cancelled occurred.

(3) As part of the error correction training, you must demonstrate your proficiency in the collection procedures of this part by completing three consecutive error-free mock collections. The mock collections must include one uneventful scenario and two scenarios related to the area(s) in which your error(s) occurred. The person providing the training must monitor and evaluate your performance and attest in writing that the mock collections were "error-free."

(g) *Documentation.* You must maintain documentation showing that you currently meet all requirements of this section. You must provide this documentation on request to DOT agency representatives and to employers and C/TPAs who are using or negotiating to use your services.

§ 40.37 [Removed]

■ 14. Remove § 40.37.

Subpart D [Amended]

■ 15. In the heading for subpart D, remove the word "Urine".

§ 40.41 [Redesignated as § 40.42]

■ 16. Redesignate § 40.41 as § 40.42.

§ 40.45 [Redesignated as § 40.40]

■ 17. Redesignate § 40.45 as § 40.40.

■ 18. In newly redesignated § 40.40:

■ a. Revise the section heading and paragraphs (a) and (b), (c) introductory text, and (c)(1) through (4); and

■ b. Amend paragraph (d) by removing the words "social security number (SSN) or other employee identification (ID) number" and adding in their place "SSN or Employee ID No.".

The revisions read as follows:

§ 40.40 What form is used to document a DOT collection?

(a) The Federal Drug Testing Custody and Control Form (CCF) must be used to document every collection required by the DOT drug testing program. You may view this form on the Department's website (<http://www.transportation.gov/odapc>) or the HHS website (<http://www.workplace.samhsa.gov>).

(b) You must not use a non-Federal form or an expired CCF to conduct a DOT collection. As a laboratory, C/TPA or other party that provides CCFs to employers, collection sites, or other customers, you must not provide copies of an expired CCF to these participants. You must also affirmatively notify these participants that they must not use an expired CCF.

(c) As a participant in the DOT drug testing program, you are not permitted to modify or revise the CCF except as follows:

(1) You may include, in the area outside the border of the form, other information needed for billing or other purposes necessary to the collection process.

(2) The CCF must include the names, addresses, telephone numbers and any other appropriate contact information (*e.g.*, an email address of the employer and the MRO), including the DER's name and contact information. All of this information must be preprinted, typed, or handwritten. Fax numbers may be included, but are not required. The MRO information must include the physician's name and address, as opposed to only a generic clinic, health care organization, or company name. This information is required, and an employer, collector, service agent or any other party is prohibited from omitting it. In addition, a C/TPA's name, address,

telephone and fax numbers, and any other appropriate contact information should be included, but is not required. The employer may use a C/TPA's address in place of its own, but must continue to include its name, telephone and fax numbers, and any other appropriate contact information.

(3) As an employer you may preprint the box in Step 1–D of the CCF for the DOT agency under whose authority the test will occur.

(4) As a collector, you may use a CCF with your name, address, telephone number, and fax number preprinted, but under no circumstances may you sign the form before the collection event. If a collection takes place at a clinic, the actual address of the clinic should be used, not a corporate address of the collection company. If the collection takes place onsite at the employer, the employer's address must be noted as the collection site address. If the collection takes place in a "mobile unit" or at an accident site, the collector must enter the actual location address of the collection or as near an approximation as possible. The collector must ensure that the required collector telephone number is the number that the laboratory, MRO, or employer may use to directly contact the individual collector and/or the collector's supervisor.

* * * * *

§ 40.47 [Redesignated as § 40.41]

■ 19. Redesignate § 40.47 as § 40.41.

§ 40.41 [Amended]

■ 20. In newly redesignated § 40.41, in paragraph (a), remove the word "urine" wherever it appears.

■ 21. In § 40.43, revise the section heading to read as follows:

§ 40.43 What steps must operators of collection sites and collectors take to protect the security and integrity of urine collections?

* * * * *

§ 40.49 [Redesignated as § 40.44]

■ 22. Redesignate § 40.49 as § 40.44.

§ 40.51 [Redesignated as § 40.45]

■ 23. Redesignate § 40.51 as § 40.45.

■ 24. Add §§ 40.47, 40.48, 40.49, and 40.51 to subpart D to read as follows:

* * * * *

Sec.

40.47 Where does an oral fluid collection for a DOT drug test take place?

40.48 What steps must operators of collection sites and collectors take to protect the security and integrity of oral fluid collections?

40.49 What materials are used to collect oral fluid specimens?

40.51 What materials are used to send oral fluid specimens to the laboratory?

* * * * *

§ 40.47 Where does an oral fluid collection for a DOT drug test take place?

(a) An oral fluid collection for a DOT drug test must take place in a collection site meeting the requirements of this section.

(b) If you are operating an oral fluid collection site:

(1) You must ensure that it meets the security requirements of § 40.48;

(2) The site may be a permanent or temporary facility located either at the work site or at a remote site;

(3) The site may be in a medical facility, a mobile facility (e.g., a van), a dedicated collection facility, or any other location meeting the requirements of this section; and

(4) You must have all necessary personnel, materials, equipment, and facilities that include privacy and supervision to provide for the collection, temporary storage, and shipping of specimens to a laboratory, and a suitable clean surface for writing.

(c) If a collection site is not accessible and there is an immediate requirement to collect an oral fluid specimen (e.g., an accident investigation), another site may be used for the collection, if the collection is performed by a collector who has been trained to collect oral fluid specimens in accordance with this part and the manufacturer's procedures for the collection device.

§ 40.48 What steps must operators of collection sites and collectors take to protect the security and integrity of oral fluid collections?

(a) Collectors and operators of collection sites must take the steps listed in this section to prevent unauthorized access that could compromise the integrity of collections.

(b) As a collector, you must do the following before each collection to deter tampering with specimens:

(1) Ensure that access to collection materials and specimens is effectively restricted;

(2) Ensure that undetected access (e.g., through a door not in your view) is not possible; and

(3) Secure facility against access during the procedure to ensure privacy to the employee and prevent distraction of the collector. Limited-access signs must be posted.

(c) As a collector, you must take the following additional steps to ensure security during the collection process:

(1) To avoid distraction that could compromise security, you are limited to conducting a collection for only one

employee at a time. However, during the time one employee is in the period for drinking fluids in a "dry mouth" situation (see § 40.72(b)(1)), you may conduct a collection for another employee as long as the employee with "dry mouth" remains supervised.

(2) To the greatest extent practicable, keep an employee's collection container within view of both you and the employee between the time the employee has provided the oral fluid specimen and the specimen is sealed.

(3) Ensure you are the only person in addition to the employee who handles the specimen before it is sealed with tamper-evident seals.

(4) In the time between when the employee gives you the specimen and when you seal the specimen, remain within the collection site.

(5) Maintain personal control over each specimen and CCF throughout the collection process.

(d) If you are operating a collection site, you must implement a policy and procedures to prevent unauthorized personnel from entering any part of the site in which oral fluid specimens are collected or stored.

(1) Only employees being tested, collectors and other collection site workers, DERs, employee and employer representatives authorized by the employer (e.g., employer policy, collective bargaining agreement), and DOT agency representatives are authorized persons for purposes of paragraph (e) of this section.

(2) You must ensure that all authorized persons are under the supervision of a collector at all times when permitted into the site.

(3) You or the collector may remove any person who obstructs, interferes with, or causes a delay in the collection process.

(e) If you are operating a collection site, you must minimize the number of persons handling specimens.

§ 40.49 What materials are used to collect oral fluid specimens?

For each DOT drug test, you must use a collection device meeting the requirements of appendix B of this part.

§ 40.51 What materials are used to send oral fluid specimens to the laboratory?

(a) Except as provided in paragraph (b) of this section, you must use a shipping container that adequately protects the specimen bottles from damage in the transport of specimens from the collection site to the laboratory.

(b) You are not required to use a shipping container if a laboratory courier hand-delivers the specimens

from the collection site to the laboratory.

Subpart E—[Amended]

- 25. In the heading for subpart E, remove the word “Urine”.
- 26. In § 40.61, revise the section heading and paragraphs (a), (b)(1) introductory text, (b)(3) and (4), (e), and (f)(5)(i) to read as follows:

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

* * * * *

(a) When a specific time for an employee’s test has been scheduled, or the collection site is at the employee’s work site, and the employee does not appear at the collection site at the scheduled time, contact the DER to determine the appropriate interval within which the DER has determined the employee is authorized to arrive. If the employee’s arrival is delayed beyond that time, you must notify the DER that the employee has not reported for testing. In a situation where a C/TPA has notified an owner/operator or other individual employee to report for testing (other than for a pre-employment test) and the employee does not appear, the C/TPA must determine whether the employee has refused to test (see § 40.191(a)(1)).

(b) * * *

(1) If the employee is also going to take a DOT alcohol test, you must ensure, to the greatest extent practicable, that the alcohol test is completed before the drug testing collection process begins.

* * * * *

(3) You must not collect a specimen from an unconscious employee to conduct a drug test under this part.

(4) You must not catheterize a conscious employee for purposes of a urine test. However, you must inform an employee who normally voids through self-catheterization that the employee is required to provide a specimen in that manner. If an employee normally voids through self-catheterization, but declines to do so for the urine test, the collector should notify the DER of the circumstances, so that the employer can determine whether the situation constitutes a refusal to test by the employee.

* * * * *

(e) Explain the basic collection procedure to the employee, and notify the employee that instructions for completing the CCF can be found at the HHS (www.samhsa.gov/workplace) and DOT (www.transportation.gov/odapc) websites.

(f) * * *

(5) * * *

(i) Determine if the material appears to be brought to the collection site with the intent to alter the specimen, and, if it is, either conduct a directly observed urine collection using direct observation procedures (see § 40.67) or an oral fluid specimen collection, make a note on the CCF and continue with collection process; or

- * * * * *
- 27. In § 40.63, revise paragraph (a) to read as follows:

§ 40.63 What steps does the collector take in the collection process before the employee provides a urine specimen?

* * * * *

(a) Ensure all items under Step 1 of the CCF are complete and accurate (e.g., if Step 1.D is not checked, put a check mark for the “Specify DOT Agency” under the authority of which the test will take place; if the address where the collection is actually taking place is not in Step 1.G, update that.)

- * * * * *
- 28. In § 40.65, revise the section heading and paragraphs (b)(5) and (6), and (c)(1) to read as follows:

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

* * * * *

(b) * * *

(5) If the specimen temperature is outside the acceptable range, you must immediately conduct a new urine collection using direct observation procedures (see § 40.67) or an oral fluid collection.

(6) In a case where a specimen is collected under direct observation because of the temperature being out of range, you must process both the original specimen and the specimen collected using direct observation (including oral fluid) and send the two sets of specimens to their respective laboratories. This is true even in a case in which the original specimen has insufficient volume and the temperature is out of range. You must also, as soon as possible, inform the DER and collection site supervisor that a collection took place under direct observation and the reason for doing so.

* * * * *

(c) * * *

(1) If it is apparent from this inspection that the employee has tampered with the specimen (e.g., blue dye in the specimen, excessive foaming when shaken, or smell of bleach), you must immediately conduct a new urine collection using direct observation

procedures (see § 40.67) or an oral fluid collection.

- * * * * *
- 29. In § 40.67:
 - a. Revise the section heading;
 - b. In paragraph (c)(1), remove “paragraphs (a) and (b)” and add “paragraph (a)” in its place;
 - c. Revise paragraph (d)(2);
 - d. In paragraph (e)(2), remove “§ 40.67(b)” and add in its place “§ 40.67(c)(2) through (4)”; and
 - e. Revise paragraph (g).

The revisions and additions read as follows:

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

* * * * *

(d) * * *

(2) As the collector, you must explain to the employee the reason, if known, under this part for a directly observed collection.

* * * * *

(g) As the collector, you must ensure that the observer is the same gender as the employee unless the observer is a medical professional (e.g., nurse, doctor, physician’s assistant, technologist, technician licensed or certified to practice in the jurisdiction in which the collection takes place). The observer can be a different person from the collector and need not be a qualified collector.

- 30. In § 40.69, revise the section heading, redesignate paragraphs (a) through (g) as paragraphs (b) through (h); add new paragraph (a), and revise newly redesignated paragraph (e) to read as follows:

§ 40.69 How is a monitored urine collection conducted?

(a) As stated in § 40.42(f)(2), if you are conducting a urine collection in a multi-stall restroom and you cannot secure all sources of water and other substances that could be used for adulteration and substitution, you must conduct a monitored collection. This is the only circumstance in which you must conduct a monitored collection.

* * * * *

(e) As the monitor, you must not watch the employee urinate into the collection container. If you hear sounds or make other observations indicating an attempt to tamper with a specimen, there must be an additional collection under direct observation. See §§ 40.63(e), 40.65(c), and 40.67(c)(2)(3).

- 31. In § 40.71, revise the section heading and paragraph (b)(1) to read as follows:

§ 40.71 How does the collector prepare the urine specimen?

* * * * *

(b) * * *

(1) Check the box on the CCF (Step 2) indicating that this was a “Urine” and “Split” specimen collection.

* * * * *

§ 40.73 [Redesignated as § 40.79]

■ 32. Redesignate § 40.73 as § 40.79.

■ 33. Add new §§ 40.72 through 40.74 to read as follows:

* * * * *

Sec.

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

40.73 How is an oral fluid specimen collected?

40.74 How does the collector prepare the oral fluid specimens?

* * * * *

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

(a) The collector requests that the employee open the employee’s mouth, and the collector inspects the oral cavity to ensure that it is free of any items that could impede or interfere with the collection of an oral fluid specimen (e.g., candy, gum, food, or tobacco) or could be used to adulterate, substitute, or alter the specimen.

(1) If the employee claims that he or she has a medical condition that prevents opening his or her mouth for inspection, the collector follows the procedure described in § 40.193(a).

(2) If the collector observes materials brought to the collection site or the employee’s conduct clearly indicates an attempt to adulterate, substitute, or alter the specimen, the collector must terminate the collection, note the circumstances in the Remarks section of the CCF, and report the circumstances to the DER, so that the employer can decide whether to deem the situation a refusal in accordance with § 40.191(a).

(b) If an item is present that might impede or interfere with the collection of an oral fluid specimen, the collector must request the employee remove the item.

(1) If the employee removes any item that could impede or interfere with the collection of an oral fluid specimen, the employee has abnormally colored saliva, or the employee claims to have “dry mouth,” then the collector must give the employee water, up to 8 ounces, to rinse their mouth. The employee may drink the water. The collector must then wait 10 minutes before beginning the specimen collection.

(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 to test as described in § 40.191(a)(8) (failure to cooperate), so that the employer can decide whether to deem the situation a refusal.

(c) If there is nothing of concern in the oral cavity and no “dry mouth” condition, the collector starts the 10-minute wait period and proceeds with the steps below before beginning the specimen collection as described in § 40.73.

(d) During the 10-minute wait:

(1) Review with the employee the procedures required for a successful oral fluid specimen collection as stated in the manufacturer’s instructions for the specimen collection device.

(2) Complete all items under Step 1 of the CCF, and for clarification:

(i) In Step 1.D of the CCF, the collector must put a check mark for the “Specify DOT Agency” under whose authority the test will take place.

(ii) In Step 1.G of the CCF for the “Collection Site Address”, the collector must provide the address where the collection took place.

(3) The collector will complete Step 2 of the CCF.

(i) Check “Oral Fluid”,

(ii) For “Oral Fluid: Split Type” check “Subdivided,” and

(iii) Check “Each Device Within Expiration Date?” after ensuring that each device is within its expiration date.

(4) The collector must instruct the employee to use hand sanitizer, put on gloves, or wash and dry his or her hands.

(e) The collector will provide, or the employee may select, a specimen collection device that is clean, unused, and wrapped/sealed in original packaging. The collector must open the specimen collection device in view of the employee.

(f) To the greatest extent practicable, the collector must keep the employee’s unwrapped collection device within view of both you and the employee, between the time the employee has provided a specimen and the specimen is sealed.

§ 40.73 How is an oral fluid specimen collected?

(a) The collector must be present and maintain visual contact with the employee during the procedures outlined in this section.

(b) The collector must note any unusual behavior or appearance of the employee on the CCF. If the collector detects any conduct that clearly indicates an attempt to tamper with a specimen (e.g., an attempt to bring into the collection site an adulterant or oral

fluid substitute), the collector must terminate the collection and report the information to the DER so that the employer can decide whether to deem the situation a refusal.

(c) The employee and collector must complete the specimen collection in accordance with the manufacturer instructions for the collection device.

(1) The collector must ensure the collection is performed correctly (i.e., using the oral fluid device in the manner described by its manufacturer), that the collection device is working properly, and that a sufficient specimen volume is collected.

(i) If there is a failure to collect the specimen, the collector must start the process again, beginning with § 40.72(e), using a new specimen collection device, and noting the failed collection attempt on the CCF.

(ii) If the employee states that he or she is unable to provide an oral fluid specimen during the collection process, or after multiple failures to collect the specimen, the collector follows the procedure in § 40.193.

(2) The collector must inspect the specimen for unusual color, presence of foreign objects or material, or other signs of tampering. If it is apparent from this inspection that the employee has tampered with the specimen, you must conduct a new collection.

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

(ii) Proceed with obtaining the new oral fluid specimen from the donor. Note on the new CCF that this is another collection for the same testing event. (i.e., 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.)

§ 40.74 How does the collector prepare the oral fluid specimens?

(a) The collector follows the manufacturer’s instructions to package the split specimen collections.

(b) A volume of at least 1 mL of undiluted (neat) oral fluid is collected for the specimen designated as “Tube A” and a volume of at least 1 mL of undiluted (neat) oral fluid is collected for the specimen designated as “Tube B”.

(c) In the presence of the employee, the collector places a tamper-evident seal from the CCF over the cap of each specimen container, taking care not to obstruct the expiration date on the collection containers. The collector must record the date of the collection on the tamper-evident seals, after they are affixed to the specimen containers.

(d) The collector instructs the employee to initial the tamper-evident seals on each specimen container. If the employee declines to do so, the collector must note this in the “Remarks” line of the CCF (Step 2) and complete the collection process.

§§ 40.75–40.78 [Reserved]

■ 34. Add reserved §§ 40.75 through 40.78.

■ 35. In newly redesignated § 40.79, revise paragraph (a)(1) to read as follows:

§ 40.79 How is the collection process completed?

* * * * *

(a) * * *

(1) Direct the employee to read and sign the certification statement on Copy 2 of the CCF and provide all information required in Step 5. If the employee declines to sign the CCF or to provide any of the required information, you must note this in the “Remarks” line (Step 2) of the CCF and complete the collection. If the employee declines to fill out any information, you must, as a minimum, print the employee’s name in the appropriate place.

* * * * *

§ 40.81 [Amended]

■ 36. In § 40.81, in paragraph (a), remove the words “all testing” and add in their place the words “each specimen testing methodology performed”.

§ 40.83 [Amended]

■ 37. In § 40.83:

■ a. In paragraph (c)(7), remove the word “urine” and add in its place the word “specimen”;

■ b. In paragraph (f) introductory text, add the word “urine” before the word “specimen”;

■ c. In paragraph (g) introductory text, remove the cross-reference “40.45(a)” and adding in its place “40.40(a)”;

■ d. a. In paragraphs (h)(1)(i), (iii), and (iv), remove the word “urine” and add in its place the word “specimen”; and
 ■ e. In paragraph (h)(2) removing the cross-reference “(g)(1)” and adding in its place “(h)(1)”.

§ 40.99 [Redesignated as § 40.84]

■ 38. Redesignate § 40.99 as § 40.84.

§ 40.84 [Amended]

■ 39. In newly redesignated § 40.84:

■ a. In paragraph (a), remove the words “one year” and add, in their place, the words “90 days”;

■ b. In the first sentence of paragraph (c) remove the words “one-year” and add in their the words “90-day”;

■ c. In the last sentence of paragraph (c) remove the word “year” and add in its place the words “90-day period”.

§ 40.85 [Redesignated as § 40.82]

■ 40. Redesignate § 40.85 as § 40.82.

§ 40.87 [Redesignated as § 40.85]

■ 41. Redesignate § 40.87 as § 40.85.

§ 40.89 [Redesignated as § 40.86]

■ 42. Redesignate § 40.89 as § 40.86.

■ 43. In newly redesignated § 40.86, revise the section heading to read as follows:

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

* * * * *

§ 40.91 [Redesignaed as § 40.87]

■ 44. Redesignate § 40.91 as § 40.87.

■ 45. In newly redesignated § 40.87, revise the section heading, and in the introductory text, remove “§ 40.89” and add in its place “§ 40.86”.

The revision reads as follows:

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

* * * * *

§ 40.93 [Redesignated as § 40.88]

■ 46. Redesignate § 40.93 as § 40.88.

■ 47. In newly redesignated § 40.88, revise the section heading to read as follows:

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

* * * * *

§ 40.95 [Redesignated § 40.89]

■ 48. Redesignate § 40.95 as § 40.89.

■ 49. In newly redesignated § 40.89, revise the section heading to read as follows:

§ 40.89 What are the adulterant cutoff concentrations for initial and confirmation urine tests?

* * * * *

§ 40.96 [Redesignated as § 40.90]

■ 50. Redesignate existing § 40.96 as § 40.90.

■ 51. In newly redesignated § 40.90, revise the section heading to read as follows:

§ 40.90 What criteria do laboratories use to establish that a urine specimen is invalid?

* * * * *

■ 52. Add new §§ 40.91 through 40.93 to read as follows:

Sec.

* * * * *

40.91 What are the cutoff concentrations for undiluted (neat) oral fluid drug tests?

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

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

* * * * *

§ 40.91 What are the cutoff concentrations for undiluted (neat) oral fluid drug tests?

As a laboratory, you must use the cutoff concentrations displayed in table 1 to this section for initial and confirmatory drug tests for oral fluid specimens. All cutoff concentrations are expressed in nanograms per milliliter (ng/mL).

TABLE 1 TO § 40.91—ORAL FLUID TESTING CUTOFF CONCENTRATIONS

Initial test analyte	Initial test cutoff ¹	Confirmatory test analyte	Confirmatory test cutoff concentration
Marijuana (THC) ²	4 ng/mL ³	THC	2 ng/mL.
Cocaine/Benzoylcegonine	15 ng/mL	Cocaine	8 ng/mL.
		Benzoylcegonine	8 ng/mL.
Codeine/Morphine	30 ng/mL	Codeine	15 ng/mL.
		Morphine	15 ng/mL.
Hydrocodone/Hydromorphone	30 ng/mL	Hydrocodone	15 ng/mL.
		Hydromorphone	15 ng/mL.
Oxycodone/Oxymorphone	30 ng/mL	Oxycodone	15 ng/mL.
		Oxymorphone	15 ng/mL.
6-Acetylmorphine	4 ng/mL ³	6-Acetylmorphine	2 ng/mL.
Phencyclidine	10 ng/mL	Phencyclidine	10 ng/mL.
Amphetamine/Methamphetamine	50 ng/mL	Amphetamine	25 ng/mL.
		Methamphetamine	25 ng/mL.

TABLE 1 TO § 40.91—ORAL FLUID TESTING CUTOFF CONCENTRATIONS—Continued

Initial test analyte	Initial test cutoff ¹	Confirmatory test analyte	Confirmatory test cutoff concentration
MDMA ⁴ /MDA ⁵	50 ng/mL	MDMA	25 ng/mL.
		MDA	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. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present (*i.e.*, with concentrations equal to or greater than the laboratory's validated limit of quantification) must be equal to or greater than the initial test cutoff.

² An immunoassay must be calibrated with the target analyte.

³ *Alternate technology (THC and 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 THC, 2 ng/mL for 6-AM).

⁴ Methylendioxyamphetamine (MDMA).

⁵ Methylendioxyamphetamine (MDA).

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

(a) Specimen validity testing is the evaluation of the specimen to determine if it is consistent with normal human oral fluid. The purpose of validity testing is to determine whether certain adulterants or foreign substances were added to the oral fluid, if the oral fluid was altered.

(b) If a specimen exhibits abnormal characteristics (*e.g.*, unusual odor or color), causes reactions or responses characteristic of an adulterant during initial or confirmatory drug tests (*e.g.*, non-recovery of internal standard, unusual response), or contains an unidentified substance that interferes with the confirmatory analysis, then you may conduct validity testing.

(c) If you determine that the specimen is invalid and HHS guidelines direct you to contact the MRO, you must contact the MRO and together decide if testing the primary specimen by another HHS-certified laboratory would be useful in being able to report a positive or adulterated test result.

(b) You must also report the results for each primary specimen, which will fall into one of the following three categories. As a laboratory, you must report the actual results (and not the categories):

(1) Category 1: Negative Results. As a laboratory, when you find a specimen to be negative, you must report the test result as being one of the following, as applicable:

- (i) Negative, or
- (ii) For urine only, negative-dilute, with numerical values for creatinine and specific gravity.

(2) Category 2: Non-negative Results. As a laboratory, when you find a specimen to be non-negative, you must report the test result as being one or more of the following, as applicable:

- (i) Positive, with drug(s)/metabolite(s) noted, with numerical values for the drug(s) or drug metabolite(s).
- (ii) Adulterated, with adulterant(s) noted, with confirmatory test values (when applicable), and with remarks(s);
- (iii) For urine only, positive-dilute, with drug(s)/metabolite(s) noted, with numerical values for the drug(s) or drug metabolite(s) and with numerical values for creatinine and specific gravity;
- (iv) For urine only, substituted, with confirmatory test values for creatinine and specific gravity; or
- (v) For urine only, invalid result, with remark(s). Laboratories will report actual values for pH results.
- (vi) For oral fluid only, invalid result, with remark(s). Laboratories must report numerical values of the specimen validity test results that support a specimen reported as invalid.

(3) Category 3: Rejected for Testing. As a laboratory, when you reject a specimen for testing, you must report the result as being Rejected for Testing, with remark(s).

(c) As a laboratory, you must report laboratory results directly, and only, to

the MRO at his or her place of business. You must not report results to or through the DER or a service agent (*e.g.*, a C/TPA).

(1) Negative results: You must fax, courier, mail, or electronically transmit a legible image or copy of the fully completed Copy 1 of the CCF which has been signed by the certifying scientist, or you may provide the laboratory results report electronically (*i.e.*, computer data file).

(i) If you elect to provide the laboratory results report, you must include the following elements, as a minimum, in the report format:

- (A) Laboratory name and address;
- (B) Employer's name (you may include I.D. or account number);
- (C) Medical review officer's name;
- (D) Specimen I.D. number;
- (E) SSN or Employee ID from Step 1C of the CCF, if provided;
- (F) Reason for test, if provided;
- (G) Collector's name and telephone number;
- (H) Date of the collection;
- (I) For oral fluid only, collection device expiration date
- (J) Date received at the laboratory;
- (K) Date certifying scientist released the results;
- (L) Certifying scientist's name;
- (M) Results (*e.g.*, positive, adulterated) as listed in paragraph (a) of this section; and
- (N) Remarks section, with an explanation of any situation in which a correctable flaw has been corrected.

(ii) You may release the laboratory results report only after review and approval by the certifying scientist. It must reflect the same test result information as contained on the CCF signed by the certifying scientist. The information contained in the laboratory results report must not contain information that does not appear on the CCF.

§ 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 requirements of this section.

(a) You may test for a biomarker such as albumin or immunoglobulin G (IgG) or a test for a specific adulterant.

(b) You must follow the applicable HHS requirements for any additional validity testing.

■ 53. Revise § 40.97 to read as follows:

§ 40.97 What do laboratories report and how do they report it?

(a) As a laboratory, when reporting a result of any kind, you must report the specimen type.

(iii) The results report may be transmitted through any means that ensures accuracy and confidentiality. You, as the laboratory, together with the MRO, must ensure that the information is adequately protected from unauthorized access or release, both during transmission and in storage (e.g., see § 40.351).

(2) Non-negative and Rejected for Testing results: You must fax, courier, mail, or electronically transmit a legible image or copy of the fully completed Copy 1 of the CCF that has been signed by the certifying scientist. In addition, you may provide the electronic laboratory results report following the format and procedures set forth in paragraphs (b)(1)(i) and (ii) of this section.

(d) In transmitting laboratory results to the MRO, you, as the laboratory, together with the MRO, must ensure that the information is adequately protected from unauthorized access or release, both during transmission and in storage. If the results are provided by fax or other electronic means, the electronic communication must be accessible only to authorized individuals.

(e) You must transmit test results to the MRO in a timely manner, preferably the same day that review by the certifying scientist is completed.

(f)(1) You must provide quantitative values for confirmed positive drug test results to the MRO.

(2) You must provide numerical values that support the adulterated (when applicable) or substituted result, without a request from the MRO.

(3) You must also provide the MRO numerical values for creatinine and specific gravity for the negative-dilute urine test result, without a request from the MRO.

(g) You must provide quantitative values for confirmed positive morphine and/or codeine urine results at or below 15,000 ng/mL, and for confirmed positive morphine or codeine oral fluid results at or below 150 ng/mL.

■ 54. In § 40.111, revise paragraphs (a) and (d) to read as follows:

§ 40.111 When and how must a laboratory disclose statistical summaries and other information it maintains?

(a) As a laboratory, you must transmit an aggregate statistical summary, by employer, of the data listed in appendix D of this part with respect to each specimen type for which you conduct tests to the employer on a semi-annual basis.

* * * * *

(d) As a laboratory, you must transmit an aggregate statistical summary listed in appendix E of this part for each

specimen type for which you conduct testing to DOT on a semi-annual basis. The summary must be sent by January 31 of each year for July 1 through December 31 of the prior year. It must be sent by July 31 of each year for January 1 through June 30 of the current year. If you withdraw or are removed from NLCP's laboratory certification during a reporting period, you must provide the aggregate statistical summary to the DOT-regulated employers and to ODAPC for the last period in which you conducted DOT-regulated testing.

§ 40.121 [Amended]

■ 55. In § 40.121, in paragraph (c)(1)(i), remove the word "urine".

§ 40.123 [Amended]

■ 56. In § 40.123, in paragraph (c), remove the words "invalid drug tests results" and add in their place "invalid results".

§ 40.127 [Amended]

■ 57. In § 40.127, in paragraph (g)(2), add the words "of all specimen types combined" before the words "in any quarter".

§ 40.129 [Amended]

■ 58. In § 40.129, in paragraph (a) introductory text, remove the words "invalid drug tests" and add in their place "invalid results"; in paragraph (d), remove "drug test report" and add "result" in its place.

§ 40.135 [Amended]

■ 59. In § 40.135, in paragraph (d) introductory text, remove the word "test" and add in its place the word "result".

■ 60. In § 40.139, revise paragraph (b), and in paragraph (c), remove the word "urine".

The revision reads as follows:

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

* * * * *

(b) In the absence of 6-AM, if the laboratory confirms the presence of either morphine or codeine equal to or above 15,000 ng/mL (in urine) or equal to or above 150 ng/mL (in oral fluid), you must verify the test result as positive, unless the employee presents a legitimate medical explanation for the presence of the drug or drug metabolite in his or her system, as in the case of other drugs (see § 40.139). Consumption of food products (e.g., poppy seeds) must not be considered a legitimate medical explanation for the employee

having morphine or codeine at these concentrations.

* * * * *

§ 40.145 [Amended]

■ 61. In § 40.145, in paragraph (g)(3), remove the word "urine" and add the word "drug" in its place; and in paragraph (h) introductory text, add the word "urine" before the word "result".

■ 62. In § 40.151, revise paragraphs (a), (b), (g), and (i) to read as follows:

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

* * * * *

(a) You must not consider any evidence (verbal or written information) from any drug tests that are not collected or tested in accordance with this part. For example, if an employee tells you he went to his own physician, provided a urine specimen, sent it to a laboratory, and received a negative test result, you are required to ignore this test result.

(b) It is not your function to make decisions about factual disputes between the employee and the collector concerning matters occurring at the collection site that are not reflected on the CCF (e.g., concerning allegations that the collector left the area or left open collection containers where other people could access them.)

* * * * *

(g) You must not accept an assertion that there is a legitimate medical explanation for the presence of PCP, 6-AM, MDMA, or MDA in a specimen.

* * * * *

(i) You must not accept, as a legitimate medical explanation for a substituted specimen, an assertion that an employee can produce a urine specimen for which the creatinine level is below the laboratory's limit of detection. There are no physiological means through which a person can produce a urine specimen having this characteristic.

■ 63. In § 40.159, revise paragraphs (a)(1) and (a)(5)(ii) to read as follows:

§ 40.159 What does the MRO do when a drug test result is invalid?

(a) * * *

(1) Discuss the laboratory results with a certifying scientist to determine if the primary specimen should be tested at another HHS-certified laboratory. If the laboratory did not contact you as required by §§ 40.91(e) and 40.96(b), you must contact the laboratory.

* * * * *

(5) * * *

(ii) Report to the DER that the test is cancelled, the reason for cancellation, and that a second collection must take

place immediately under direct observation. Recommend to the employer that an alternative specimen should be collected if practicable (e.g., oral fluid, if the specimen was urine).

* * * * *

■ 64. In § 40.163, in paragraph (c)(2), remove the words “donor SSN or employee ID number” and add in their place the words “SSN or employee ID No.” and revise paragraph (e).

The revision reads as follows:

§ 40.163 How does the MRO report drug test results?

* * * * *

(e) If you use a written report as provided in paragraph (c) of this section to report results, you must retain a copy of the written report. If you use the electronic data file to report negatives, as provided in paragraph (d) of this section, you must retain a retrievable copy of that report in a format suitable for inspection and audit by a DOT representative. In either case, you must keep the completed Copy 2 of the CCF. When completing Copy 2, either the MRO must sign and date it (for both negatives and non-negatives) or MRO staff must stamp and date it (for negatives only).

* * * * *

■ 65. In § 40.177, revise paragraphs (a) through (c) to read as follows:

§ 40.177 What does the second laboratory do with the split specimen when it is tested to reconfirm the presence of a drug or drug metabolite?

* * * * *

(a) As the laboratory testing the split specimen, you must test the split specimen for the drug(s)/drug metabolite(s) confirmed in the primary specimen.

(b) You must conduct this test without regard to the cutoff concentrations of § 40.85 or § 40.91, as applicable.

(c) If the test fails to reconfirm the presence of the drug(s)/drug metabolite(s) that were reported in the primary specimen, you must conduct validity tests in an attempt to determine the reason for being unable to reconfirm the presence of the drug(s)/metabolite(s). You should conduct the same validity tests as you would conduct on a primary specimen set forth in § 40.87 or § 40.93, as applicable.

* * * * *

§ 40.179 [Amended]

■ 66. In § 40.179, in paragraph (a), remove “§ 40.95” and add in its place “§ 40.89 or § 40.93, as applicable”.

■ 67. Revise § 40.181 to read as follows:

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

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.

§ 40.187 [Amended]

■ 68. In § 40.187, in paragraphs (b)(1), (c)(1)(iii), and (c)(2)(iii), remove “Appendix D” and add in its place “appendix F”, and in paragraph (e)(3), remove “appendix D” and add in its place “appendix F”.

■ 69. In § 40.191, revise paragraphs (a)(2) through (9) and (d)(1) to read as follows:

§ 40.191 What is a refusal to take a DOT drug test, and what are the consequences?

(a) * * *

(2) *Fail to remain at the testing site until the testing process is complete.* Provided that an employee who leaves the collection site before the testing process commences (see § 40.63(c) or § 40.72(e), as applicable) for a pre-employment test is not deemed to have refused to test;

(3) Fail to provide a specimen for any drug test required by this part or DOT agency regulations. Provided that an employee who does not provide a specimen because he or she has left the testing site before the testing process commences (see § 40.63(c) or § 40.72(e), as applicable) for a pre-employment test is not deemed to have refused to test;

(4) In the case of a directly observed or monitored urine collection in a drug test, fail to permit the observation or monitoring of an employee’s provision of a specimen (see §§ 40.67(m) and 40.69(g));

(5) Fail to provide a sufficient amount of specimen when directed, and it has been determined, through a required medical evaluation, that there was no adequate medical explanation for the failure (see § 40.193(d)(2));

(6) Fail or decline to take an additional drug test the employer or collector has directed you to take (see, for instance, § 40.197(b) as applicable);

(7) Fail to undergo a medical examination or evaluation, as directed by the MRO as part of the verification process, or as directed by the DER under § 40.193(c). In the case of a pre-employment drug test, the employee is deemed to have refused to test on this basis only if the pre-employment test is conducted following a contingent offer of employment. If there was no contingent offer of employment, the MRO will cancel the test;

(8) Fail to cooperate with any part of the testing process (e.g., refuse to empty

pockets when directed by the collector, behave in a confrontational way that disrupts the collection process, fail to wash hands after being directed to do so by the collector, fail to remove objects from mouth, fail to permit inspection of the oral cavity, or fail to complete a rinse when requested);

(9) For an observed urine collection, fail to follow the observer’s instructions to raise your clothing above the waist, lower clothing and underpants, and to turn around to permit the observer to determine if you have any type of prosthetic or other device that could be used to interfere with the collection process;

* * * * *

(d) * * *

(1) As the collector, you must note the refusal in the “Remarks” line (Step 2), and sign and date the CCF. The collector does not make the final decision about whether the employee’s conduct constitutes a refusal to test; the employer has the sole responsibility to decide whether a refusal occurred, as stated in § 40.355(i), the employer has a non-delegable duty to make the decision about whether the employee has refused to test.

* * * * *

■ 70. Revise § 40.193 to read as follows:

§ 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 2 mL oral fluid in a single sampling, as applicable) you, as the collector, must provide another opportunity to the employee to do so. This can be done using the same specimen type as the original collection or, if you are qualified to collect an alternative specimen, you may use an alternative specimen collection for this purpose.

(b)(1) As the collector, you must do the following when collecting a urine specimen:

(i) Discard the insufficient specimen, except where the insufficient specimen was out of temperature range or showed evidence of adulteration or tampering (see § 40.65(b) and (c)).

(ii) Urge the employee to drink up to 40 ounces of fluid, distributed reasonably through a period of up to three hours, or until the individual has provided a sufficient urine specimen, whichever occurs first. It is not a refusal to test if the employee declines to drink. Document on the Remarks line of the CCF (Step 2), and inform the employee of the time at which the three-hour period begins and ends.

(iii) If the employee refuses to make the attempt to provide a new urine 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 section 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 three hours of the first unsuccessful attempt to provide the specimen, you must discontinue the collection, note the fact on the “Remarks” line of the CCF (Step 2), and immediately notify the DER. You must also discard any specimen the employee previously provided, including any specimen that is “out of temperature range” or shows signs of tampering. In the remarks section of the CCF that you will distribute to the MRO and DER, note the fact that the employee provided an “out of temperature range specimen” or “specimen that shows signs of tampering” and that it was discarded because the employee did not provide a second sufficient specimen.

(2) As the collector, you must do the following when collecting an oral fluid specimen:

(i) If the employee demonstrates an inability to provide a specimen after 15 minutes of 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.

(ii) 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.

(iii) Send Copy 2 of the CCF to the MRO and Copy 4 to the DER. You must send or fax these copies to the MRO and DER within 24 hours or the next business day.

(c) As the DER, if the collector informs you that the employee has not provided a sufficient amount of specimen (see paragraph (b) of this section), you must, after consulting with the MRO, direct the employee to obtain, within five days, an evaluation from a licensed physician, acceptable to the MRO, who has expertise in the medical issues raised by the employee’s failure to provide a sufficient specimen. (The MRO may perform this evaluation if the MRO has appropriate expertise.)

(1) As the MRO, if another physician will perform the evaluation, you must provide the other physician with the following information and instructions:

(i) That the employee was required to take a DOT drug test, but was unable to provide a sufficient amount of specimen to complete the test;

(ii) The consequences of the appropriate DOT agency regulation for refusing to take the required drug test;

(iii) That the referral physician must agree to follow the requirements of paragraphs (d) through (g) of this section.

(2) [Reserved]

(d) As the referral physician conducting this evaluation, you must recommend that the MRO make one of the following determinations:

(1) A medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of specimen. As the MRO, if you accept this recommendation, you must:

(i) Check “Test Cancelled” (Step 6) on the CCF; and

(ii) Sign and date the CCF.

(2) 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. As the MRO, if you accept this recommendation, you must:

(i) Check the “Refusal to Test” box and “Other” box in Step 6 on Copy 2 of the CCF and note the reason next to the “Other” box and on the “Remarks” lines, as needed.

(ii) Sign and date the CCF.

(e) For purposes of this paragraph, a medical condition includes an ascertainable physiological condition (e.g., a urinary system dysfunction in the case of a urine test or autoimmune disorder in the case of an oral fluid test), or a medically documented pre-existing psychological disorder, but does not include unsupported assertions of “situational anxiety” or dehydration.

(f) As the referral physician making the evaluation, after completing your evaluation, you must provide a written statement of your recommendations and

the basis for them to the MRO. You must not include in this statement detailed information on the employee’s medical condition beyond what is necessary to explain your conclusion.

(g) If, as the referral physician making this evaluation in the case of a pre-employment, return-to-duty, or follow-up test, you determine that the employee’s medical condition is a serious and permanent or long-term disability that is highly likely to prevent the employee from providing a sufficient amount of specimen for a very long or indefinite period of time, you must set forth your determination and the reasons for it in your written statement to the MRO. As the MRO, upon receiving such a report, you must follow the requirements of § 40.195, where applicable.

(h) As the MRO, you must seriously consider and assess the referral physician’s recommendations in making your determination about whether the employee has a medical condition that has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of specimen. You must report your determination to the DER in writing as soon as you make it.

(i) As the employer, when you receive a report from the MRO indicating that a test is cancelled as provided in paragraph (d)(1) of this section, you take no further action with respect to the employee. If the test reason was ‘random’, the employee remains in the random testing pool.

■ 71. In § 40.195, revise the section heading to read as follows:

§ 40.195 What happens when an individual is unable to provide a sufficient amount of specimen for a pre-employment, follow-up, or permanent-to-duty test because of a permanent or long-term medical condition?
* * * * *

■ 72. In § 40.197, revise the section heading to read as follows:

§ 40.197 What happens when an employer receives a report of a dilute urine specimen?
* * * * *

■ 73. In § 40.199, revise paragraph (b)(7) and add paragraph (b)(8) to read as follows:

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

(b) * * *

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

(8) For an oral fluid collection, the collector used an expired device at the time of collection.

* * * * *

§ 40.201 [Amended]

■ 74. In § 40.201, in paragraph (f), remove the word “urine” and add in its place the word “specimen”.

■ 75. In § 40.207, add paragraph (d) to read as follows:

§ 40.207 What is the effect of a cancelled drug test?

* * * * *

(d) If a test is cancelled, only the MRO who cancelled the test can reverse the cancellation and must do so within 60 days of the cancellation. After 60 days, the MRO who cancelled the test cannot reverse the cancellation without the permission of ODAPC. For example, if an MRO cancels a test because the MRO did not receive a copy of the CCF, but later receives a copy of the CCF, the MRO may reverse the decision to cancel the test within 60 days. After 60 days, the MRO must contact ODAPC for permission to reverse the cancellation. A laboratory is not authorized to reverse a cancellation due to a fatal flaw, as described in § 40.199.

§ 40.209 [Amended]

■ 76. In § 40.209, in paragraph (b)(7), remove “§ 40.41” and add in its place “§ 40.42”.

■ 77. Revise § 40.210 to read as follows:

§ 40.210 What kinds of drug tests are permitted under the regulations?

Both urine and oral fluid specimens are authorized for collection and testing under this part. An employer can use one or the other, but not both at the beginning of the testing event. For example, if an employee is sent for a test, either a urine or oral fluid specimen can be collected, but not both simultaneously. However, if there is a problem in the collection that necessitates a second collection (e.g., insufficient quantity of urine, temperature out of range, or insufficient saliva), then a different specimen type could be chosen by the employer and its service agent to complete the collection process for the testing event. Only urine and oral fluid specimens screened and confirmed at HHS-certified laboratories (see § 40.81) are allowed for drug testing under this part. Point-of-collection (POC) urine, POC oral fluid drug testing, hair testing, or instant tests are not authorized.

§ 40.225 [Amended]

■ 78. In § 40.225, in paragraph (a), remove “Appendix G” and add in its place “appendix I”.

■ 79. In § 40.261, redesignate paragraph (c) as paragraph (c)(1) and add paragraph (c)(2).

The addition reads as follows.

§ 40.261 What is a refusal to take an alcohol test?

* * * * *

(c) * * *

(2) As the BAT or STT, you must note the refusal in the “Remarks” line (Step 3), and sign and date the ATF. The BAT or STT does not make the final decision about whether the employee’s conduct constitutes a refusal to test; the employer must decide whether a refusal occurred, as stated in § 40.355(i), the employer has a non-delegable duty to make the decision about whether the employee has refused to test.

§ 40.283 [Amended]

■ 80. In § 40.283, in paragraph (c), remove “Appendix E” and add in its place “appendix G”.

§ 40.285 [Amended]

■ 81. In § 40.285, in paragraph (b), remove the word “urine”.

■ 82. In § 40.291, revise paragraphs (a)(1) and (3) to read as follows:

§ 40.291 What is the role of the SAP in the evaluation, referral, and treatment process of an employee who has violated DOT agency drug and alcohol testing regulations?

(a) * * *

(1) Making a clinical assessment and evaluation to determine what assistance is needed by the employee to resolve problems associated with alcohol and/or drug use. This assessment or evaluation may be performed face-to-face or remotely. If a SAP is not prohibited from using technology within the parameters of the SAP’s State-issued license, a remote evaluation must be must be conducted in accordance with the following criteria:

(i) The technology must permit real-time audio and visual interaction between the SAP and the employee; and

(ii) The quality of the technology (e.g., speed of the internet connection and clarity of the video display) must be sufficient to allow the SAP to gather all the visual and audible information the SAP would otherwise gather in a face-to-face interaction, while providing security to protect the confidentiality of the communication.

* * * * *

(3) Conducting an evaluation to determine if the employee has actively participated in the education and/or treatment program and has demonstrated successful compliance with the initial assessment and evaluation recommendations. This

assessment or evaluation may be performed face-to-face or remotely. A remote evaluation must be made by means that meet the criteria in paragraphs (a)(1)(i) and (ii) of this section.

* * * * *

§ 40.293 [Amended]

■ 83. In § 40.293, in paragraph (a), remove the words “face-to-face” and after the words “clinical evaluation,” add the words “meeting the requirements of § 40.291(a)(1)”.

§ 40.301 [Amended]

■ 84. In § 40.301, in paragraph (b)(2), remove the words “face-to-face” and after the words “clinical interview”, add the words “meeting the requirements of § 40.291(a)(1)”.

§ 40.311 [Amended]

■ 85. In § 40.311, in paragraphs (c)(4), (d)(4), and (e)(4), after the word “Date(s)” add the words “and format (i.e., face-to-face or remote)”; in paragraphs (c)(1), (d)(1), and (e)(1) remove “SSN” and add in its place “SSN or employee ID No.”.

■ 86. In § 40.327:

■ a. In paragraph (a), remove the reference “paragraph (c)” and add in its place “paragraph (d)”;

■ b. Redesignate paragraph (c) as paragraph (d); and

■ c. Add a new paragraph (c).

The addition reads as follows:

§ 40.327 When must the MRO report medical information gathered in the verification process?

* * * * *

(c) The MRO must not report such medical information using the CCF. Instead, the MRO must provide the information in a separate written communication (e.g., letter, secure email). The information must state the specific nature of the MRO’s safety concern (e.g., the effects of a medication the employee is taking, the employee’s underlying medical condition which the employee disclosed to the MRO).

* * * * *

§ 40.345 [Amended]

■ 87. In § 40.345, in paragraph (b), remove “Appendix F” and add in its place “appendix H”.

§ 40.355 [Amended]

■ 88. In § 40.355, in Example 3 to paragraph (n), remove the word “urine”.

§ 40.365 [Amended]

■ 89. In § 40.365, in paragraph (b)(8), remove the words “face to face interviews” and add in their place the

words “without interviews meeting the requirements of § 40.291(a)(1)”.

Appendices E Through H to Part 40 [Redesignated as Appendices G Through J to Part 40]

■ 90. Redesignate appendices E through H to part 40 as appendices G through J to part 40.

Appendix C to Part 40 [Redesignated as Appendix E to Part 40]

■ 91. Redesignate appendix C to part 40 as appendix E to part 40.

Appendix C to Part 40 [Reserved]

■ 92. Add reserved appendix C to part 40.

Appendix D to Part 40 [Redesignated as Appendix F to Part 40]

■ 93. Redesignate appendix D to part 40 as appendix F to part 40.

Appendix B to Part 40 [Redesignated as Appendix D to Part 40]

■ 94. Redesignate appendix B to Part 40 as appendix D to part 40.

■ 95. Add new appendix B to part 40 to read as follows:

Appendix B to Part 40—Oral Fluid Collection Kit Contents

1. Oral Fluid Collection Device

a. A single-use device made to simultaneously collect a total of at least 2 mL of undiluted (neat) oral fluid, which can be subdivided in the employee’s presence, into an “A” and a “B” split sample of at least 1 mL \pm 10 percent undiluted (neat) oral fluid per each included specimen bottle; or a single-use device made to simultaneously collect a sufficient amount of oral fluid, which can be subdivided in the employee’s presence, into an “A” and a “B” split sample sufficient for laboratory testing. For example, when two specimens are collected simultaneously using a single collection device that directs the oral fluid into two separate collection tubes; or when a device collects a specimen with a single pad, which can be subdivided into two separate collection tubes.

b. Must have unit markings or other indicators clearly noting that sufficient volume of oral fluid has been achieved.

c. Must be sufficiently transparent to permit a visual assessment of the contents without opening the specimen bottle.

d. Must be individually packaged in an easily visible tamper-evident system.

e. Must have the device’s expiration date on the specimen bottles or vials sent to the laboratory.

f. Must not include any substance that would interfere with an accurate analysis of analytes per HHS OFMG.

g. Must include a way to seal specimens to prevent leakage and be engineered to withstand storage and shipping while maintaining the integrity of the specimen.

h. Must be designed so that the required tamper-evident bottle seals made available on

the CCF fit with no damage to the seal when the employee initials it, and the seal overlap will not conceal printed information.

2. Instructions

a. Must include the manufacturer’s instructions within the device’s packaging. The instructions must provide sufficient detail to allow for an error-free collection when instructions are followed.

3. Leak-Resistant Plastic Bag

a. Must have two sealable compartments or pouches that are leak-resistant; one large enough to hold two specimen bottles and the other large enough to hold the CCF paperwork.

b. The sealing methodology must be such that once the compartments are sealed, any tampering or attempts to open either compartment will be evident.

4. Absorbent Material

Each kit must contain enough absorbent material to absorb the entire contents of both specimen bottles. Absorbent material must be designed to fit inside the leak-resistant plastic bag pouch into which the specimen bottles are placed.

5. Shipping Container

a. Must be designed to adequately protect the specimen bottles from damage during shipment of the specimens from the collection site to the laboratory (*e.g.*, standard courier box, small cardboard box, plastic container).

b. May be made available separately at collection sites rather than being part of an actual collection device sent to collection sites.

c. A shipping container is not necessary if a laboratory courier hand-delivers the specimen bottles in the leak-resistant plastic bags from the collection site to the laboratory.

■ 96. Revise the newly redesignated appendix D 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) Opioids (number)

(1) Codeine (number)

(2) Morphine (number)

(3) 6-AM (number)

(4) Hydrocodone (number)

(5) Hydromorphone (number)

(6) Oxycodone (number)

(7) Oxymorphone (number)

(d) Phencyclidine (number)

(e) Amphetamines (number)

(1) Amphetamine (number)

(2) Methamphetamine (number)

(3) MDMA (number)

(4) MDA (number)

5. 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 (number)

(b) Cocaine and/or Cocaine Metabolite (number)

(c) Opioids (number)

(1) Codeine (number)

(2) Morphine (number)

(3) 6-AM (number)

(4) Hydrocodone (number)

(5) Hydromorphone (number)

(6) Oxycodone (number)

(7) Oxymorphone (number)

(d) Phencyclidine (number)

(e) Amphetamines (number)

(1) Amphetamine (number)

(2) Methamphetamine (number)

(3) MDMA (number)

(4) MDA (number)

5. Oral Fluid Adulterated (number)

6. Oral Fluid Substituted (number)

7. Oral Fluid Invalid Result (number)

■ 97. Revise newly redesignated appendix E to part 40 to read as follows:

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

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

The following items are required on each report:

Reporting Period: (inclusive dates)

Laboratory Identification: (name and address)

1. Specimen Type:

—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 and/or Cocaine Metabolite (number)

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)

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)

■ 98. Revise newly redesignated appendix F to read as follows:

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

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

Submit Electronically: <https://www.transportation.gov/odapc/mro-split-specimen-cancellation-notification>.

The following items are required on each report:

1. MRO name, address, phone number, and fax number.

2. Collection site name, address, and phone number.

3. Date of collection.

4. Specimen I.D. number.

5. Specimen type.

6. Laboratory accession number.

7. Primary specimen laboratory name, address, and phone number.

8. Date result reported or certified by primary laboratory.

9. Split specimen laboratory name, address, and phone number.

10. Date split specimen result reported or certified by split specimen laboratory.

11. Primary specimen results (*e.g.*, name of drug, adulterant) in the primary specimen.

12. Reason for split specimen failure-to-reconfirm result (*e.g.*, drug or adulterant not present, specimen invalid, split not collected, insufficient volume).

13. Actions taken by the MRO (*e.g.*, notified employer of failure to reconfirm and requirement for re-collection).

14. Additional information explaining the reason for cancellation.

15. Name of individual submitting the report (if not the MRO).

Appendix H to Part 40 [Amended]

■ 99. In newly redesignated appendix H, under “Drug Testing Information,” remove the reference “§ 40.129(d)” and add in its place the reference “§ 40.129(e)”.

Signed in Washington, DC, on January 19, 2022.

Peter Paul Montgomery Buttigieg,

Secretary of Transportation.

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