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Dot oral fluid testing 2024

The U.S. Department of Transportation recently finalized a rule updating its drug and alcohol testing regulations under Part 40, focusing on DOT-regulated oral fluid testing. This change addresses the introduction and procedural requirements for oral fluid testing, which are effective December 5, 2024. Employers in safety-sensitive industries must ensure their staff understands how these new rules differ from previous ones and what training is required to comply. The DOT has traditionally used urine specimen testing as the standard but now incorporates oral fluid testing as an authorized alternative due to advancements in methodologies and scientific guidelines from the Department of Health and Human Services. The updated rule aims to offer more flexibility, reduce opportunities for adulteration, and provide a direct correlation to recent drug use, enhancing workplace safety. The final rule includes a temporary period of regulatory relief for training and mock collection requirements, which will expire one year after the first oral fluid testing laboratory is certified by HHS. After this grace period, stricter qualification standards for oral fluid monitors and collectors will come into force. One key distinction between urine and oral fluid testing lies in their detection windows for recent drug use: Urine tests generally detect metabolites for longer periods, while oral fluid tests typically detect recent use within 24-48 hours. This narrower window provides a more direct correlation to recent on-duty impairment risk, making it valuable for safety-sensitive roles. HR managers must understand these differences to make informed decisions about testing and training their staff. Oral fluid testing can be a more immediate indicator of impairment, potentially reducing on-the-job risks, but may not be suitable for cases requiring longer-term pattern identification. Temporary Qualification Standards for Oral Fluid Testing Implemented by the DOT to meet Part 40 standards include understanding device usage, volume verification, chain-of-custody maintenance and recent guidance from the Department of Transportation (DOT). In order to implement oral fluid testing, the DOT provides temporary qualification pathways for oral fluid monitors. Temporary Relief Measures enable trainees to serve as monitors if they have successfully completed a Train-the-Trainer program or conducted oral fluid collector training. This rule prescribes specific measures to ensure the integrity of the oral fluid testing process including authorized observers and volume verification requirements. The introduction of oral fluid testing allows for quicker scaling of programs while ensuring collectors and trainers gain necessary experience and knowledge. The Department of Transportation (DOT) is proposing to add oral fluid testing procedures to its existing urine drug testing procedures for safety-sensitive transportation employees. This move is based on the Department of Health and Human Services' (HHS) establishment of guidelines for federal workplace drug testing programs using oral fluid. The HHS guidelines have been deemed equivalent in scientific and forensic supportability to the existing urine testing procedures. Key aspects of this new policy include shorter detection windows, distinct qualifications for collectors, temporary flexibility measures, inclusive and respectful testing environments, documentation and integrity protocols, forward-looking compliance strategies, and a need for employees and organizations to update their policies and procedures accordingly. The new regulations became effective on January 1, 2020, adding oral fluid as a test method and harmonizing with certain sections of the Omnibus Transportation Employee Testing Act (OTETA). The proposed rule also aims to clarify Part 40 provisions related to urine drug testing procedures, remove unnecessary provisions, and update language for updated definitions and web links. The Department of Transportation's approach to urine drug testing balances employee privacy with the need to protect transportation safety. Under federal regulations, employees subject to DOT-regulated urine drug testing are entitled to some level of privacy, except in cases where suspicious activity warrants a direct observed collection. The Department has taken steps to ensure that such collections are carried out with caution and respect for employee rights. Following a 2000 rewrite of Part 40 into plain language, the Department implemented provisions to protect individual rights during urine testing. Visual and aural privacy measures are in place to prevent unwanted observation, and employees can only be subjected to direct observation if they have committed suspicious activity at the collection site or if laboratory testing reveals a specimen has been adulterated. Despite these safeguards, unobserved urine drug collections remain vulnerable to cheating by employees. To address this issue, the Department strengthened directly observed collection requirements in 2008, introducing more effective observation procedures and expanding circumstances warranting direct observation. This change was upheld after a court challenge, with the unanimous decision of the United States Court of Appeals for the District of Columbia Circuit. Prior to these revisions, the Department considered alternative testing methods, including oral fluid, hair, and sweat testing, which would also be subject to direct observation. While some issues remained unaddressed, the Department sought additional scientific information and clarification on proficiency testing levels for these alternatives. Testing for illicit drug use in federal workplaces did not meet standards in 2004, but advancements in science and research have now made oral fluid testing a viable alternative method. As such, the Department of Health and Human Services (HHS) proposed adding oral fluid testing to the Federal employee workplace testing program in 2015 and finalized this proposal in 2020. The Department is proposing to add oral fluid testing as an alternative method because it provides a directly observed collection process and is less invasive than urine collection, while still maintaining an individual's right to privacy. The Department's testing statutes require incorporation of HHS's Mandatory Guidelines to ensure reliability and accuracy in testing. Since HHS has approved oral fluid testing as a reliable means of detecting illicit drug use, the Department is proposing to allow but not require oral fluid specimen testing as an alternative method for transportation industry workplace testing. Specifically, we are seeking comments on whether there are circumstances where either urine or oral fluid should be mandatory. We are also proposing to harmonize our provisions with HHS's Mandatory Guidelines and clarify existing Part 40 provisions to address issues that have arisen in practice. HHS has emphasized the importance of addressing adulteration and substitution of unobserved urine specimens in drug testing, noting the emergence of products designed to facilitate cheating on tests. The department recognized the need for flexibility in testing methods, which could be achieved by implementing oral fluid testing. This approach would minimize opportunities for specimen tampering or substitution, allowing federal agencies to more effectively address their testing needs. The court's decision in BNSF Railway v. US Department of Transportation upheld directly observed urine collections due to the imminent threat of individuals cheating on drug tests. The court acknowledged that oral fluid testing was not an acceptable method at the time because HHS had only approved urine specimen testing. Given the prevalence of products designed to facilitate cheating, and the lack of statistical data on the rates of actual use, the Department is proposing a more direct approach to address this issue. By implementing directly observed collections or oral fluid testing, employers can reduce the opportunities for specimen tampering or substitution, ensuring the integrity of drug test results. In its 2019 OFMG, HHS highlighted the need to address adulteration and substitution in urine specimens. The department emphasized that establishing oral fluid as a testing method would allow federal agencies greater flexibility in addressing testing needs while minimizing opportunities for specimen tampering. The BNSF court case acknowledged that statistical evidence of cheating may not be readily available, but it is clear that the problem exists and poses a direct threat to transportation safety. The court concluded that it was reasonable for the Department to infer the use of cheating devices based on anecdotal evidence of their availability, rather than requiring empirical data. The Department recognizes that directly observed urine tests were upheld in specific circumstances covered in the regulation, but is now proposing an additional option for employers - a specimen collection methodology that inherently involves direct observation. The Department of Transportation (DOT) is exploring oral fluid testing as a cheaper alternative to traditional urine testing for detecting drug use among employees. In evaluating the effectiveness and validity of oral fluid testing, the Department considered concerns about passive exposure to drugs through second-hand smoke or metabolites in marijuana tests. To address these issues, a 4 ng/mL screening test cutoff for THC was established to detect marijuana use while minimizing false positives from passive exposure. The Department has verified the science behind oral fluid testing and set guidelines for its implementation. Now, they propose offering this method as an alternative to urine testing for DOT-regulated employers, which could lead to cost savings for companies. Oral fluid tests are generally less expensive than urine tests, with prices ranging from $35 to $50 per test, compared to around $50 for a typical urine testing process. However, the Department is seeking public comment on the costs associated with oral fluid testing and whether employers would choose to train their own personnel to collect these samples or continue using external collectors. They also want input on potential cost savings related to "shy bladder" collection procedures and medical examinations that are currently required for urine specimen collections. By adopting oral fluid testing, DOT-regulated employers may be able to reduce costs associated with specimen collection and medical evaluations, while also minimizing the disruption caused by employees who cannot provide a sufficient urine sample. The Department's proposal aims to incorporate these guidelines into their regulations, providing more flexibility and cost-effective options for employers. Concerns have been raised about the feasibility of urine collection for individuals with paruresis, a condition that can make it difficult to provide a urine specimen. Similarly, employees undergoing dialysis or those with significant prostate issues might struggle to collect a urine sample and may require medical evaluation to validate their inability to do so. This highlights the potential benefits of collecting oral fluid specimens instead, which could eliminate the need for a medical assessment and lead to shorter employee visits. Offering alternative specimens gives employers flexibility in choosing the type of specimen they collect. For instance, when a post-accident or reasonable cause/suspicion test is needed, oral fluid collections can be conducted at the scene of the incident by any qualified collector. This could expedite and reduce costs associated with post-incident testing. The Department invites public comments on these matters. Understanding the detection windows for different substances is also crucial when deciding between urine and oral fluid tests. Each specimen type has its advantages, and no single method is ideal for every situation. Different detection windows need to be considered depending on the specific test reason. The Department has compiled a table based on scientific sources, highlighting the benefits and limitations of each method. Public comments, especially from device manufacturers and laboratories, would be valuable in ensuring the accuracy and completeness of this information. The Department of Transportation is considering changes to the regulations regarding substance abuse professionals (SAPs) and drug testing. Specifically, they are proposing amendments to allow SAPs to conduct remote evaluations or assessments, which would provide flexibility during public health emergencies like the COVID-19 pandemic. This change aims to make remote evaluations a regular option for SAPs under Part 40, considering the guidance issued during the pandemic was well-received and led to considerable use by SAPs. The department also seeks comment on whether oral fluid or urine should be mandated or prohibited for certain test reasons based on windows of detection, as well as whether employers and their service agents should be allowed to opt for different methodologies in case of insufficient specimens or other reasons. The proposed change in Part 40 currently requires all SAP assessments to be conducted face-to-face, but it aims to give SAPs the option to conduct evaluations remotely instead. This would allow SAPs to assess "non-verbals" such as a person's appearance and body language, which can be indicative of problems related to alcohol abuse and/or drug use. The main proposed change is to § 40.291(a)(1), which would replace the requirement for a face-to-face meeting with an option: SAPs could conduct the evaluation either in-person or remotely. If done remotely, there are three criteria that must be met: firstly, real-time two-way audio and visual interaction between the SAP and the employee; secondly, high-quality technology with sufficient internet connection speed and clear display; thirdly, robust security to protect the confidentiality of the conversation. Additionally, the Department is seeking public comment on whether SAPs' State licenses allow them to evaluate individuals in a different state. If so, what steps can be taken to ensure that SAPs have working knowledge of quality programs and qualified counselors available to employees? HHS proposes amendments to Federal employee testing program guidelines for workplace drug testing. The Department of Health and Human Services (HHS) is revising its Mandatory Guidelines for workplace drug testing. The proposed changes include adding hair testing as a specimen type authorized for the Federal employee testing program, which would be effective if HHS adopts the proposed rule. testing matrices. 40.3 What do the terms used mean? The proposed rule would delete the definition of “screening drug test” because HHS does not use the term, and also remove the definition of “invalid drug test.” The term “invalid result” is an HHS term with a specific meaning, but there is no defined term for “invalid drug test.” In arbitrations, courtrooms, and other settings, the term “invalid” can be misinterpreted to suggest uncertainty about the testing event. However, reporting an “invalid result” means only that the laboratory could not complete testing or obtain a valid result due to issues such as adulterants or abnormal characteristics. For consistency with HHS terminology, we are removing the defined term “invalid drug test” and updating several sections to use the term “invalid result.” We propose adding definitions for seven terms to harmonize Part 40 with HHS Guidelines. An “alternative specimen” is an authorized specimen of a different type than the one previously collected, such as oral fluid in a urine test. The “cutoff” is the point that distinguishes whether further testing is needed or if a result is positive or negative. We also propose adding definitions for “oral fluid specimen” and “urine specimen,” using HHS terminology. A “specimen” refers to any fluid, breath, or material collected from someone for a drug or alcohol test. We add a definition for the FMCSA's Commercial Driver's License (CDL) Drug and Alcohol Clearinghouse, as well as one for SSN or Employee ID No. Minor changes are also made to rule language in several sections. The SAP is required to use the SSN on initial and final reports to the employer. The FMCSA requires using a CDL number and state of issuance for FMCSA-regulated drivers undergoing DOT-regulated testing, instead of the SSN or other employee ID number, on the CCF and Alcohol Testing Form (ATF). We propose creating a definition of "SSN or Employee No." that would conform to and explicitly acknowledge this existing requirement for CDL holders regulated by the FMCSA. This change aims to address concerns over identity theft and allow employers to use alternative forms of ID, such as driver's licenses, state-issued identification numbers, or other federal authorities' issued identifications. The Department of Transportation (DOT) is proposing changes to its regulations regarding drug and alcohol testing. Specifically, it's clarifying how oral fluid testing fits into the existing framework. In § 40.13, minor adjustments are made to paragraphs (b), (c), and (d) for clarity, noting that oral fluid testing doesn't fit the scope of certain procedures outlined in these sections. For instance, paragraph (d) is now applicable only to urine testing because oral fluid testing isn't a standard part of medical examinations. The DOT proposes re-designating current paragraphs (e) and (f) as new paragraphs (f) and (g), adding a new paragraph (e) that emphasizes drug or alcohol tests administered during a medical examination for certification or licensure purposes aren't considered DOT drug or alcohol tests. This distinction is crucial; if a certified medical examiner decides to administer a drug test during an examination for medical card purposes, it would be classified as a "non-DOT test." Employers could request a pre-employment test while the medical examination is conducted, as permitted by 49 U.S.C. 31306(d). A new paragraph (h) is added to stress that DOT drug and alcohol tests are authorized only for safety-sensitive employees designated in the agency's regulations and cannot be conducted on non-regulated individuals. This regulation aligns with the Fourth Amendment of the Constitution, allowing warrantless searches and seizures based on the DOT's strong interest in maintaining transportation safety. The proposed rule also clarifies that there is no federal interest in using testing for individuals outside of safety-sensitive employees, making it unconstitutional to conduct such tests on unregulated personnel. Furthermore, company-authorized non-DOT testing cannot satisfy an employer's obligation to meet its minimal annual testing rate for DOT testing. In § 40.14, employers are required to provide collectors with specific information, including the specimen type to be collected and whether a urine test is directly observed. The proposed rule also clarifies procedures regarding stand-down waivers in § 40.21, stating that an employer cannot send an employee back for another test after receiving a verified negative result if there's a stand-down waiver in place. If the MRO cancels a specimen collection, we propose an alternative process for collecting another sample under specific circumstances. However, the authority to temporarily suspend an employee's safety-sensitive duties is limited and requires written consent from the DOT agency beforehand. This waiver permits employers to withhold employees from critical tasks based on a lab-confirmed positive test result until the MRO verifies the outcome, which might be negative. To prevent harassment of employees who eventually receive a verified negative result, we suggest prohibiting subsequent testing after an MRO confirms a negative finding. Employers should not attempt to retest an employee to reassess the detection window's potential impact on the original result. Regarding verified test results, we propose minor language adjustments in § 40.23 to accommodate oral fluid testing. The section would cover both urine and oral fluid testing, ensuring direct observation collection procedures are consistently applied. If a specimen is deemed invalid, employers could opt for either an oral fluid or urine collection under direct observation. We also propose revising § 40.25 to clarify the process for checking an employee's past drug and alcohol testing record before assigning them safety-sensitive duties. As of January 2023, FMCSA-regulated employers will rely solely on querying the Clearinghouse for information about an applicant's past violations. However, if an individual's previous employment was with a non-FMCSA regulated employer, such as one overseen by the Federal Transit Administration or the Federal Aviation Administration (FAA), the gaining motor carrier employer would continue to use § 40.25 to verify their compliance history. The Federal Motor Carrier Safety Administration (FMCSA) and another Department of Transportation (DOT) agency's drug testing program requires employers to query the Clearinghouse about employees who previously worked with them. Employers must also report Management Information System (MIS) data to a DOT agency using a specified form, although this proposed rule would only make minor changes by updating a reference from appendix H to J. Additionally, several sections in Part 40 list cross-references for readers' information, but the Department proposes removing them as they are no longer necessary due to advanced electronic search tools. The Department seeks comment on whether users still find these lists helpful. Furthermore, the proposed rule updates training requirements for collectors of urine and oral fluid specimens separately, clarifying that employees, relatives, or close friends cannot conduct collections, and specifies that damage to a specimen during transportation does not require collector retraining unless it occurred during the collection process. The Department is proposing to cross-train oral fluid collectors, who will be authorized to monitor mock collections exercises for DOT testing. However, since no one has experience with collecting DOT oral fluid specimens, the Department seeks comment on how to address this transition issue. The proposed rule would retain the provision applicable to urine collector training, which requires at least a year of experience in performing DOT collections. The Department is also proposing to redesignate numerous sections of Part 40 to provide a more easily followed flow for users of the regulation provisions specific to oral fluid drug testing. This reorganization aims to create a logical structure for the rule and seeks comment on whether it would cause any significant degree of confusion for practitioners. Redesignation Table: | 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 F | Appendix G | | Appendix H | Appendix I | | Subpart D—Collection Sites, Forms, Equipment and Supplies Used in DOT Collections | New subpart | The Department emphasizes that oral fluid drug testing and saliva alcohol testing are distinct and should not be confused. The proposed provisions applicable to oral fluid testing procedures would come first in the reorganized subpart D. The Department of Transportation (DOT) has updated its guidelines for collecting specimens for drug testing, effective August 2020. The new guidelines are available on the DOT website and include instructions for completing the required documentation. The changes primarily pertain to oral fluid collections, which will no longer be subject to the same restrictions as urine collections. The DOT is considering eliminating requirements related to fax numbers on the collection form, allowing it if the parties have one. The Department proposes to add a provision that enables employers and laboratories to pre-print the Designated Employer Representative's (DER) name and contact information on the collection form. They also seek comment on the logistics of updating the forms with new information. In addition, the DOT is proposing to reorganize its regulations and create new sections for oral fluid testing. These provisions largely mirror their urine testing counterparts but may require additional modifications to address differences between the two methods. The proposed changes aim to improve efficiency and accuracy in specimen collection while ensuring that collectors and collection site operators take responsibility for proper collections. The proposed regulations outline the requirements for DOT-regulated collections, emphasizing the importance of transparency in specimen collection. Not all devices meeting HHS standards will be allowed for DOT collections under 49 CFR part 40. Each collection must include a split from the original specimen, as stated in 49 U.S.C. 45104(5) and related sections. Devices that meet the requirements in appendix B can allow single specimens to be subdivided during collection. Public comment is sought on whether other device types should be mentioned for this purpose. Transparency of devices is also under consideration to ensure collectors can observe unusual specimen characteristics and perform re-collection if necessary. The proposed changes split the existing paragraph (b)(3) into (b)(3) and a revised (b)(4), prohibiting collection from unconscious donors in (b)(3). The revised paragraph (b)(4) retains remaining sentences with a modified final sentence emphasizing employer decision-making regarding refusals. Directly observed tests can use either urine or oral fluid collections, and collectors must note this on the CCF. Changes are also proposed to §§ 40.61(e) and § 40.73(a)(1), which will be redesignated due to HHS revisions to the OMB-approved CCF. The revised form allows for oral fluid specimens and includes other changes to improve clarity and presentation. The revised form can be accessed on the HHS and DOT websites, specifically at the Office of Drug and Alcohol Policy and Compliance section. In light of this, we suggest updating the rule text within 49 CFR 40.61(e) to reflect changes in instructional placement. We also propose modifying § 40.73(a)(1), soon to be redesignated as § 40.79(a)(1), to note that employees must provide all necessary information when completing Step 5 of the revised CCF, including their donor's printed name and signature, date of collection, birthday, daytime and evening phone numbers, and email address. § 40.63 Before collecting a urine specimen, the collector must follow certain procedures outlined in the collection process. We are proposing to update § 40.63(a) by reminding collectors to ensure that all items in Step 1 of the CCF have been completed, particularly highlighting the need to check the box for the DOT agency and write an actual address for the collection site. § 40.65 When presenting a urine specimen, the collector must verify several things are correct. Our proposed changes aim to clarify that when immediate re-collection under direct observation is necessary, whether the initial specimen was urine or oral fluid, the required directly observed collection can be either urine or oral fluid. For instance, if a second collection is needed after a urine collection, it could be an oral fluid collection, which is inherently directly observed, or a urine collection conducted under direct observation procedures. We are soliciting public feedback on how communication between employers and collection sites should take place to ensure the availability of alternative methodologies. Specifically, we would like input on who decides whether to collect an alternate specimen: the collector, employer, or service agent? Should there be advance communication to authorize an alternate specimen type if the employer wants one, possibly through a contract between the employer and service agent? § 40.67 A directly observed urine collection involves several steps. We are proposing changes to this section by altering its title to refer only to urine collections and making substantive changes regarding who can serve as an observer in such a collection. The revised paragraph would retain the general requirement that the observer have the same gender as the employee but make exceptions for licensed or certified medical professionals or those authorized to perform medical examinations in the jurisdiction where the collection takes place. It's worth noting that opposite-gender personnel often participate in examining patients in medical settings, such as a female doctor examining a male patient. We are asking for public comment on these proposed changes and suggestions on how to improve them. To ensure the efficient collection of urine samples from patients, we propose allowing medical professionals of any gender to conduct this task if a same-gender observer is not available. The donor would be required to participate in direct observed collections by an opposite-gender professional if necessary. We seek comments on potential limitations for performing this function and whether religious or other concerns should be considered. We clarify that the collector does not need to enter the reason for direct observation on the CCF when conducting a required collection, such as a return-to-duty test. The “Remarks” section is only needed when the employer was unaware of the direct observed collection in advance. Additionally, we propose amending § 40.67(e)(2) to correct a cross-reference and striking the reference to paragraph (b) in § 40.67(c)(1) as it is an incorrect reference. Regarding monitored urine collections, we propose adding new introductory language emphasizing the importance of securing all sources of water and other substances that could be used for adulteration and substitution during multi-stall restroom collections. We also propose minor clarifying changes to the procedures for preparing urine specimens, such as instructing collectors to check both boxes for “urine” and “split specimen” on the CCF. Furthermore, we propose establishing new sections (§ 40.72-§ 40.74) to outline collection procedures for oral fluid testing, which are consistent with the HHS OFMG provisions. These new sections emphasize the proper relationship between collection sites and employers in cases involving conduct that could be considered a refusal. When collecting oral fluid specimens, collectors must follow Part 40 requirements and manufacturer instructions. They should also check expiration dates on each device. The proposed rule reorganizes Subpart F to create a logical progression of urine and oral fluid drug testing, adding language to specify where provisions apply only to urine testing. For example, § 40.86 would be renamed "What is urine validity testing, and are laboratories required to conduct it?" Several requirements would be specified as applying only to urine testing, with no application to oral fluid testing. The proposal also includes two substantive changes: reducing the time for keeping non-negative specimens from one year to 90 days and reorganizing reporting requirements in § 40.111. Additionally, three new sections (§§ 40.91-40.93) concern cutoff concentrations and validity testing for oral fluid specimens, drawing from HHS OFMG provisions. The proposal seeks comment on these changes and the usefulness of the Subpart F reorganization. MRO changes proposed for regulation review. The department plans to modify rules related medical review officers. For most part, MROs will continue doing their job as it is now. However, we are proposing some change in this regard. First, in section 40.121, we want to remove word "urine" from paragraph (c)(1)(i) since training for MROs should also include oral fluid testing. We want to know if existing or new MROs need additional training specifically regarding their role in oral fluid testing and what subjects it should cover. In section 40.127, we are proposing to specify that MROs need not review more than 500 negative results "of all specimen types combined" in any quarter. This is just to clarify our intention. In section 40.129(d), we want to delete "drug test report" and add word "result" following "invalid test". In section 40.135(d), we want to delete word "test" and add word "result". These changes would keep language consistent with definition of term "invalid result". The proposed regulations aim to ensure consistency by requiring laboratories to provide a numerical value for substituted results. Additionally, it is suggested that HHS/NLCP-certified laboratories must have a limit of detection for creatinine of 1mg/dL or less. This allows MROs to confirm that low creatinine concentrations do not exceed the threshold of 2mg/dL and eliminate the possibility of physiological production of such urine specimens. The proposed changes also include updating references to §40.96(c) to §40.96(b) in §40.159(a)(1), adding a new sentence to paragraph (a)(5)(ii) to require re-collection when an invalid test is cancelled, and allowing alternative specimen collection if practicable. Furthermore, the proposed regulations suggest minor wording changes to clarify record retention requirements for MROs after reporting results and to specify that Copy 2 of the CCF must be signed and dated or stamped and dated. The proposed rules also include adding references to oral fluid testing in §§40.177, 40.179, and 40.181, as well as changing referenced section numbers in accordance with renumbering and new oral fluid provisions. Additionally, §40.181 would be modified to refer only to urine testing, since creatinine and specific gravity apply only to urine testing. The proposed regulations also aim to clarify the actions of MROs regarding split specimen laboratory results in §40.187, as well as defining refusal to take a DOT drug test and its consequences in §40.191, including specifying situations applicable only to oral fluid or urine testing. Given article text here Looking for the information you need about pre-employment drug testing rules and regulations, specifically regarding what constitutes a refusal under federal guidelines. as refusals. When a family medical emergency requires an employee to leave the collection site, the same thinking might apply. If a random test is administratively closed as a non-event, no further action is needed. For tests requiring a "negative" result, such as return-to-duty or follow-up tests, the employer will send the employee back for another collection. The employer should document the reason why they concluded there was no refusal. § 40.193 explains what happens when an employee doesn't provide enough specimen for a drug test. This section would add oral fluid testing to paragraph (a), making it easier to collect specimens from different sources. Because of this, the procedure for collecting insufficient specimens is shorter than before. In paragraph (e), the proposed rule adds examples of conditions that might be considered as medical explanations for providing an insufficient quantity of specimen. These include autoimmune diseases and unsupported assertions of dehydration. The Department wants to know if there's enough evidence needed to avoid asserting that a person is dehydrated without solid proof. They also want to hear from device manufacturers about whether allowing a donor to rinse with up to 8 ounces of water is a good amount of fluid for rinsing. § 40.195 explains what happens when someone can't provide a sufficient amount of specimen due to a permanent or long-term medical condition, such as being unable to urinate due to kidney stones. This section would likely be updated in the future. The proposed rule makes several textual changes to the regulations in Part 40. In § 40.195, the title is modified to replace "urine" with "specimen" due to the addition of oral fluid testing. This change also affects subsequent sections that reference urine testing. The updated titles are intended to reflect the broader scope of testing methods now allowed under the program. § 40.197 addresses situations where an employer receives a report of a dilute specimen, which is still referred to as "urine" in this section due to its specific focus on urine testing. However, this may be revised in future updates to align with the broader terminology used throughout the regulations. Section 40.199 outlines fatal flaws that necessitate cancelling a drug test. The proposed rule introduces an additional fatal flaw for using an expired oral fluid collection device and updates language in paragraph (b)(7) to replace "urine" with "specimen." This change is consistent across multiple sections, including § 40.201, which deals with issues that may require another collection. The proposed rule also addresses the effect of cancelling a drug test in § 40.207. It introduces new language allowing an MRO (Medical Review Officer) to reverse the cancellation decision under certain circumstances. This provision aims to reduce costs and confusion associated with cancelled tests due to uncorrected errors. Finally, § 40.210 clarifies that oral fluid and urine specimens can be collected for testing, but employers must use one or the other for each testing event, not both simultaneously unless a second collection is required due to a problem during the initial test. Given article text here Looking forward to seeing everyone at the meeting tomorrow and discussing our strategies. The proposed revision makes a conforming change to § 40.225 and redesignates appendix G to be appendix I. A refusal to take an alcohol test occurs when the employee does not consent to testing or refuses to provide a sample during the testing process. The consequences of a refusal include termination of employment for certain types of violations, depending on the circumstances. The certification organization must follow specific procedures to obtain recognition as a SAP provider and is responsible for ensuring that its members meet the necessary standards. A SAP evaluation is required when an employee has violated DOT agency drug and alcohol testing regulations. The SAP will conduct an initial evaluation and provide a report detailing the results. The SAP's role in the process includes conducting remote evaluations through real-time audio and visual interaction, as well as ensuring that the technology used meets specific quality standards. During the follow-up evaluation, the SAP will assess whether the employee has complied with the requirements of the original evaluation. The Department of Transportation proposes amendments to the regulations under Part 40. Key changes include revising the evaluation method requirements for Substance Abuse Professionals (SAPs) and clarifying medical information reporting by Medical Review Officers (MROs). SAPs will be required to note whether evaluations occur face-to-face or remotely, and "SSN" will be replaced with "SSN or employee ID number" for consistency. The Department also proposes changes to the Policy on Initial Evaluation (PIE) proceedings and adds a new appendix B for oral fluid collection kit standards. Additionally, appendices will be reorganized and reordered, with current Appendix C reserved. Laboratories would submit data broken out by specimen type, agency, and test reason semi-annually. The Department seeks comments on these proposals. We're requesting that multiple data summaries be submitted instead of a single one currently provided. By including additional data elements, we hope to assess the effectiveness of oral fluid testing versus urine testing. We also aim to gain insights into any trends in drug testing based on specimen type, DOT agency, and test reasons. Our assumption is that adding these amended data summaries won't be overly burdensome for laboratories, as most are already capturing this information through their electronic systems or Laboratory Information Management Systems. To confirm our understanding, we'd appreciate feedback from laboratories regarding the potential costs of incorporating new data elements. The proposed rule includes revisions to existing appendices, which would be reassigned letters (D becoming F, E becoming G, etc.). Moreover, we propose adding "specimen type" as a new element in reports provided by MROs for tracking purposes. Executive Order 12866 directs Federal agencies to evaluate the impact of proposed regulations on costs and benefits. Our assessment under this order considers data from existing guidelines on oral fluid testing and our experience with the current drug testing program. Since the proposed rule does not meet significant regulatory action criteria, OMB has determined that it is a non-significant rule. We believe this proposal is necessary as it enhances the integrity and effectiveness of an essential safety program while potentially reducing costs for regulated parties. Key improvements include increased flexibility in meeting regulatory requirements and allowing previously prohibited activities. The requirement to collect a single urine specimen has been in place since 1988, but OFMG is proposing to revise it to include an option for oral fluid testing. This change aims to address issues related to employees being unable to provide a sufficient urine specimen, which can cause delays and additional costs for employers. With the introduction of oral fluid testing, transportation employers will have more flexibility in choosing the type of specimen best suited for their needs. If an employee is unable to provide a urine specimen, they can be given the option to provide an oral fluid sample instead, reducing the need for medical evaluations and allowing for faster results. This added flexibility also benefits employees, as it allows them to choose the method that works best for them. Furthermore, oral fluid testing provides more options for employers in terms of collection sites, as it does not require a secured restroom or other special facilities like urine collection does. This can be particularly useful in industries such as railroads and pipelines, where employees may work in remote locations with limited access to traditional collection facilities. Additionally, the introduction of oral fluid testing can help reduce the number of substituted and adulterated tests, as all collections will be directly observed, thereby minimizing the risk of tampering. According to industry data, up to 3% of urine specimens are found to be substituted or adulterated, but direct observation should significantly reduce this issue with oral fluid testing. Risks of specimen tampering in urine samples have led us to propose changes to regulations governing laboratory testing. Specifically, we want to authorize labs to conduct validity tests on specimens. This could include biomarker or adulterant detection. One advantage of oral fluid testing is its potential for time and cost savings. For instance, collecting an oral fluid specimen may require less time than a urine sample, reducing employee travel time and costs to employers. We're seeking data on the percentage of urine collections conducted in dedicated facilities versus oral fluid collections, as well as information on the time savings that could result from switching to oral fluid testing. Additionally, some urine samples may not be sufficient for analysis, requiring employees to make a second attempt. This can take up to three hours, which could be avoided by immediately switching to oral fluid collection. We're seeking comment on the incidence of "shy bladder" situations and potential time and cost savings from eliminating them through oral fluid testing. Furthermore, using oral fluid testing could reduce the need for medical evaluations, resulting in additional time and cost savings. Employers would still have the option to collect urine specimens if oral fluids are not available, avoiding the need for medical evaluations. We're also seeking comment on the frequency of subsequent collections due to issues like out-of-temperature range or tampering attempts. These situations can evolve into "shy bladder" scenarios, adding time and costs to the process. Measures for Urine Testing Require Secured Access to Water Sources or Specimens We are proposing fewer steps for oral fluid collection, as all specimen collection is directly observed. This reduces the need for site security measures, unlike urine testing which requires more privacy. Oral fluid testing is less intrusive and time-consuming than unobserved urine testing. Adding oral fluid as an alternate specimen type would allow employers to choose based on circumstances. For example, oral fluid tests may detect recent marijuana use within 24 hours, while urine tests detect use for longer periods. This could provide more insight into recent drug use. Urine was the original specimen choice, but it's vulnerable to adulteration and cheating due to individual privacy rights. Oral fluid testing is less susceptible to these problems because it's a directly observed collection. Using data from Federal Workplace Drug Testing Programs and HHS-certified laboratories, we estimate that 7% of specimens will be oral fluid, while 93% will remain urine specimens. The transition to oral fluid testing would be gradual over four years, resulting in estimated savings of $6.3 million the first year and $27 million in the future. ### The Department wants to know if its assumptions about the costs of using oral fluid in drug testing are accurate. They're asking for feedback on how to adjust these calculations, as the proportion of tests using oral fluid might increase over time due to lower costs and greater flexibility. This could lead to even more significant cost savings. Employers may need to invest in training collectors to use oral fluid, which would add $348 per collector. Initially, around 7% of collectors would be trained, but this number could rise to 30% by the end of year four. The estimated costs for training an additional 23% of collectors over years two through four would be approximately $2 million. The Department also wants information on how employers and collection sites handle "shy bladder" or "dry mouth" situations, where a collector can switch between urine and oral fluid testing. This flexibility reduces waiting times and avoids unnecessary medical evaluations, which could save costs and time. Table 1 summarizes the expected economic effects of the proposed rule, including annual net cost savings ranging from $5.6 million in year one to $24.9 million in subsequent years. The proposed rule aims to provide flexibility in specimen types for drug tests, allowing employees to choose from various options. This change is expected to benefit employees, making it easier for them to complete required tests. According to the Secretary, this rule will not have a significant economic impact on small entities or result in major effects on competition, employment, productivity, or innovation. The proposed rule has been examined under the Unfunded Mandates Reform Act (UMRA), which requires written statements for mandates resulting in $100 million or more expenditures. However, the Secretary concludes that this rulemaking does not trigger such a requirement due to its lower cost alternative to urine drug testing, which is expected to reduce costs for regulated parties. The Department of Transportation has analyzed the environmental impacts of this action under the National Environmental Policy Act (NEPA) and determined that it is categorically excluded. This means that the action does not normally have a significant impact on the environment and therefore does not require an environmental assessment or impact statement. The proposed rule has been analyzed in accordance with Executive Order 13132: Federalism, which requires federal agencies to carefully examine actions for policies that have federalism implications or preempt state law. The Secretary has determined that the proposed rules do not contain such policies due to their focus on reducing costs and providing flexibility for regulated parties, rather than affecting the states' relationships with the national government or distributing power among various levels of government. Additionally, the proposed rule has been reviewed in accordance with Executive Order 13175: Consultation and Coordination With Indian Tribal Governments. The Secretary has determined that the proposed rules do not have tribal implications and will not have substantial direct effects on one or more Indian tribes, their relationship with the Federal Government, or the distribution of power between the Federal Government and Indian tribes. The proposed rule also does not impose additional information collection burdens, as it builds upon an existing OMB-approved control number (OMB Control No. 0930-0158) that can be used for either urine or oral fluid testing. The Department proposes to amend 49 CFR part 40 to reflect this change and to update the procedures for transportation workplace drug and alcohol testing programs. The amendments to §40.3 involve several changes to the definitions section. The current definitions for "Invalid drug test" and "Screening drug test" are to be removed, while a new definition for "Initial drug test" is introduced, replacing the existing one. Additionally, the definition of "Limit of Quantification" is replaced with "Limit of Quantification (LOQ)". Furthermore, six new terms are added in alphabetical order: Alternative Specimen, Commercial Driver's License Drug and Alcohol Clearinghouse (Clearinghouse), Cutoff, Oral Fluid Specimen, Specimen, and Undiluted (neat) oral fluid. The definitions for 16 existing terms are also revised. Specimen types include non-negative, adulterated, positive, or invalid samples. Oral Fluid Specimens are collected from the employee's mouth and consist of salivary gland fluids. The Primary Specimen is the first specimen bottle opened for testing by a laboratory to check for drugs or metabolites in the system. Reconfirmed results occur when a second laboratory corroborates the original test result for the primary specimen. Specimens can be fluid, breath, or other materials collected from employees at collection sites for drug and alcohol tests. Specimen bottles hold primary or split specimens during transport to laboratories. Split Specimens are sent to a first laboratory with their seal intact, then transported to a second lab after MRO verification of the primary specimen as positive, adulterated, or substituted. Social Security Numbers (SSNs) or Employee ID Numbers serve as unique identifiers on Federal Drug Testing Custody and Control Forms or other required documents. A substituted specimen is not consistent with normal human specimens, such as urine with unusual creatinine and specific gravity values. Undiluted Oral Fluid consists of oral fluids produced primarily by the salivary glands. A specimen collected without any additions or modifications is required. For instance, a collection device that uses a diluent must collect at least 1 mL of undiluted oral fluid. Urine specimens are also considered. It is essential to note that urine samples must be taken from an employee at the testing site for the purpose of a drug test. The regulations in § 40.13 have been revised, with new paragraphs added and redesignated. The changes include: * Prioritizing DOT tests over non-DOT tests * Discarding excess urine after a DOT test and collecting a separate sample for a subsequent non-DOT test * Prohibiting testing on DOT specimens except for authorized tests or medical tests related to physical examinations * Permitting medical tests, such as glucose testing, on remaining urine samples after the DOT portion has been sealed * Exempting non-DOT drug or alcohol tests administered during physical exams from DOT regulations and consequences The revised § 40.14 requires employers to provide collectors with information, including: * SSN or Employee ID number * Specimen type (oral fluid or urine) * Whether a urine specimen is to be collected under direct observation In § 40.21, the revised paragraph (c)(2)(vii)(C) allows employers to stand down employees before the MRO has completed verification, with no requirement for an alternative specimen in cases of verified negative results. The revised § 40.23 outlines employer actions after receiving verified test results, including: * Providing information on employee conduct and discipline * Implementing random testing programs * Requiring repeat testing for failed or cancelled tests Employer Requirements for Requiring Drug and Alcohol Testing: Guidelines for Ensuring Compliance with Federal Regulations Employers are mandated to ensure that employees undergoing drug and alcohol testing meet specific requirements. If an employee's test is cancelled due to it being invalid, employers must direct the employee to provide a new specimen under direct observation. Key Requirements: * Employers must immediately direct the employee to collect a new specimen under direct observation. * The collector must conduct the collection under direct observation. * Employers are required to verify an employee's testing history with other employers, as per section 40.25. * Employers regulated by FMCSA do not need to comply with certain requirements when checking an employee's testing history with other employers regulated by FMCSA. Regulatory Updates: * Section 40.26 has been updated to remove "Appendix H" and add "Appendix J". * Section 40.29 has been removed. * Section 40.31 has undergone revisions, including changes to the section heading, paragraphs, and redesignated paragraphs. * New paragraph (f) has been added to prevent employees from being their own collector. Additional Guidelines: * Urine collectors must meet training requirements of § 40.33. * Oral fluid collectors must meet training requirements of § 40.35. * Immediate supervisors are not allowed to act as collectors when testing an employee they supervise, unless no other collector is available and permitted under DOT agency regulations. Note: These guidelines are based on the provided text and aim to provide a clear overview of the employer's responsibilities in complying with federal regulations for drug and alcohol testing. In accordance with the revised regulations, a urine collector must meet specific training requirements to ensure the integrity of the collection process. These requirements include basic information about the regulations and guidelines applicable to employers, as well as qualification training that covers topics such as oral fluid collection device manufacturer training, proper completion and transmission of the CCF, and problem-solving techniques for common issues like "dry mouth" or specimen tampering. To become a qualified urine collector, one must receive instruction on fatal flaws, correctable flaws, and how to correct problems in collections. Additionally, collectors must demonstrate proficiency in collections by completing five consecutive error-free mock collections, which should include scenarios such as uneventful collection, insufficient specimen quantity, and potential errors that could lead to cancellation. Furthermore, to avoid conflicts of interest, a collector must not be related to the employee being tested or a close personal friend. This ensures that collectors remain impartial and unbiased throughout the testing process. The revised regulations also emphasize the importance of error correction training for collectors who make mistakes during the collection process, resulting in test cancellations. This training must occur within 30 days of the date of notification. The Department of Transportation (DOT) has established strict guidelines for collecting drug specimens, including employee conduct and qualification requirements. A qualified collector must have demonstrated necessary knowledge, skills, and abilities by conducting collections, training, or completing a "train the trainer" course. They must also maintain accurate records and provide documentation on request to DOT representatives and employers. The qualification process includes regular training, which must be completed every five years from the date of satisfactory completion, followed by error correction training within 30 days if an error occurs during collection. This training focuses specifically on correcting errors in the collection process and requires three consecutive mock collections to demonstrate proficiency. Employees performing collector functions must meet requirements outlined in paragraphs b and c before beginning their duties. The revised section outlines the use of a specific form, the Federal Drug Testing Custody and Control Form (CCF), for documenting collection processes, as well as other administrative changes. Every collection must conform to the DOT drug testing program's requirements. You can view this form on the Department of Transportation's website (or the Health and Human Services' website ( ). (b) Do not use a non-Federal form or an expired Collection Control Form (CCF) to conduct a DOT collection. As a laboratory, C/TPA, or other party providing CCFs to employers, collection sites, or customers, you must not distribute expired CCF copies and inform participants that they cannot use them. You must also notify these participants about the need for an updated form. (c) As a participant in the DOT drug testing program, you are not allowed to modify or revise the CCF except as follows: (1) You can include additional information outside the form's borders for billing purposes or other essential collection processes. (2) The CCF must contain the names, addresses, phone numbers, and contact information of the employer, Medical Review Officer (MRO), and DER, which should be preprinted, typed, or handwritten. Fax numbers are optional. The MRO information must include a specific physician's name and address, not a generic clinic or company name. This information is mandatory, and any party involved in the collection process is prohibited from omitting it. For a DOT drug test, oral fluid collections can take place in various locations, including permanent or temporary facilities at the work site, remote sites, medical facilities, mobile facilities, or dedicated collection centers. To protect the security and integrity of oral fluid collections, collectors and operators of collection sites must follow specific steps. To prevent unauthorized access, collectors must restrict access to collection materials and specimens, secure facilities during the procedure, and post limited-access signs. During the collection process, collectors should limit their activities to one employee at a time, keep collection containers in view, handle specimens only when necessary, remain within the collection site, and maintain personal control over each specimen. Additionally, if an oral fluid collection cannot be performed at a designated collection site due to lack of access, another site may be used if the collector has been trained to collect oral fluid specimens according to this part and the manufacturer's procedures. You must implement strict policies and procedures at collection sites to prevent unauthorized personnel from accessing areas where oral fluid specimens are collected or stored. Only authorized individuals, including employees being tested, collectors, DERs, employer representatives, and DOT agency reps, are permitted on site. These individuals must be under the supervision of a collector at all times while present. You may remove anyone who obstructs the collection process. When handling oral fluid specimens, minimize the number of personnel involved to prevent contamination or loss. For each DOT test, use a collection device meeting the requirements outlined in appendix B. To transport specimens to the lab, you must use a shipping container that protects the bottles from damage unless a laboratory courier hand-delivers the samples. The preliminary steps in the drug testing process involve scheduling a specific time for employee testing and notifying DERs if employees fail to appear or report late. In some cases, C/TPAs may need to determine whether an employee has refused testing if they do not show up for a scheduled test. When conducting tests, ensure that alcohol tests are completed before initiating the drug testing collection process whenever possible. You cannot collect specimens from unconscious employees or catheterize conscious ones, except in specific circumstances involving self-catheterization. If an employee normally uses self-catheterization but declines to do so for a urine test, notify the DER of the situation. Notify employees that they must follow specific guidelines for completing the CCF (Collection of Control Forms), including instructions on direct observation procedures. These procedures include checking for potential specimen tampering, such as blue dye or excessive foaming, and taking steps to verify the integrity of the specimen. The changes include redesignating paragraphs (a) through (g) to (b) through (h), adding a new paragraph (a), and revising paragraph (e). The newly added paragraph (a) addresses when a monitored urine collection is conducted. It states that only in multi-stall restrooms where securing all water sources is not possible must a monitored collection be done. Paragraph (e) outlines the monitor's responsibilities, including not watching the employee urinate and taking an additional collection under direct observation if tampering is suspected. Additionally, the section heading of § 40.71 is revised to reflect its purpose in preparing urine specimens. The collector prepares the specimen by indicating it was a "Urine" and "Split" collection on the CCF. New sections 40.72 through 40.74 are added, which cover the collection process for oral fluid specimens. Before collecting an oral fluid specimen, the collector must inspect the employee's mouth to ensure there are no items that could impede or interfere with the collection. If materials indicating tampering or a medical condition preventing mouth opening are observed, the collector must terminate the collection and report it to the DER. In accordance with § 40.191(a)(8), if an employee fails to cooperate during the oral fluid specimen collection process, the employer can deem the situation a refusal. Prior to starting the specimen collection, if there is no concern in the oral cavity and no "dry mouth" condition exists, the collector begins a 10-minute wait period, after which they review procedures with the employee as stated in the manufacturer's instructions for the specimen collection device. During this time, the collector completes all items under Step 1 of the CCF and checks "Oral Fluid," "Subdivided," and ensures each device is within its expiration date. The collector also instructs the employee to use hand sanitizer, put on gloves, or wash and dry their hands. Following the wait period, the collector provides a specimen collection device and opens it in view of the employee, ensuring visual contact during the procedure. If a specimen is deemed unusable, the collector must collect a new oral fluid sample from the donor. To document any unusual characteristics, they should note this in the Remarks section of the Collection Control Form (CCF). When obtaining the new sample, it's essential to indicate on the CCF that it's another collection for the same testing event, specifying that it's Specimen 2 of 2 and including the ID number of the first specimen. The collector should make a similar notation on the CCF of the suspect specimen. The preparation of oral fluid specimens involves following these steps: - The collector must package the split specimen collections according to the manufacturer's instructions. - For each specimen, at least 1 mL of undiluted oral fluid is collected for Tube A and Tube B. - In the presence of the employee, the collector places a tamper-evident seal from the CCF over the cap of each container, ensuring the expiration date isn't obstructed. The collector records the collection date on these seals. - The collector instructs the employee to initial the tamper-evident seals, but if they decline, this is noted in the Remarks section and the process continues. The collection process is completed by directing the employee to sign a certification statement on Copy 2 of the CCF and providing all required information. If the employee declines to sign or provide information, it's documented in the Remarks section, and the process is completed. At minimum, the collector must print the employee's name if they decline to fill out any information. Additional changes include: - Updating language related to "all testing" to "each specimen testing methodology performed". - Modifying sections related to urine to use the term "specimen". - Adjusting cross-references and adding or removing specific words for clarity. - Redesignating sections according to a revised numbering system. 43. In redesigned section §40.86, update the title to "Urine Validity Testing Requirements". Additionally, renumber and revise sections as follows: - Redesignate §40.91 as §40.87. - Update §40.87 with new title "Validity Tests for Primary Urine Specimens" and modify introductory text to refer to §40.86 instead of §40.89. 44. Re-designate §40.93 as §40.88, changing its title to "Criteria for Dilute or Substituted Urine Specimens". 45. Update §40.88 with new title "Adulterant Cutoff Concentrations for Initial and Confirmation Tests" and modify section accordingly. 46. Re-designate §40.95 as §40.89, updating its title to "Invalid Urine Specimen Criteria". 47. Add new sections 40.91-40.93: - §40.91: Oral Fluid Cutoff Concentrations for Undiluted (Neat) Drug Tests - §40.92: Oral Fluid Validity Testing Requirements and Laboratory Obligations - §40.93: Validity Tests for Primary Oral Fluid Specimens 48. Update table 1 to §40.91 with cutoff concentrations for oral fluid drug tests: - THC: Initial 4 ng/mL, Confirmation 2 ng/mL - Cocaine/Benzoylecgonine: Initial 15 ng/mL, Confirmation 8 ng/mL - Codeine/Morphine: Initial 30 ng/mL, Confirmation 15 ng/mL - Hydrocodone/Hydromorphone: Initial 30 ng/mL, Confirmation 15 ng/mL - Oxycodone/Oxymorphone: Initial 30 ng/mL, Confirmation 15 ng/mL - 6-Acetylmorphine: Initial 4 ng/mL, Confirmation 2 ng/mL - Phencyclidine: Initial/Confirmation 10 ng/mL - Amphetamine/Methamphetamine: Initial 50 ng/mL, Confirmation 25 ng/mL - MDMA/MDA: Initial 50 ng/mL, Confirmation 25 ng/mL 49. Clarify requirements for grouped analytes in immunoassays and alternate technologies: - Immunoassay: Use one target analyte with cross-reactivity ≥80% or separate immunoassays for each analyte. - Alternate technology: Use either all or one analyte from the group, ensuring at least one has a concentration ≥ initial test cutoff or sum of analytes present. Laboratories must conduct validity testing to ensure the accuracy of oral fluid specimens. Validity testing evaluates whether the specimen contains adulterants or foreign substances that may affect the test results. According to HHS guidelines, laboratories should report the following information when reporting test results: * Specimen type * Results for each primary specimen, which can fall into one of three categories: 1. Negative Results: Report the test result as "Negative" or "Negative-dilute" with numerical values for creatinine and specific gravity. 2. Non-negative Results: Report the test result as "Positive", "Adulterated", or "Invalid Result" with additional information, such as drug(s)/metabolite(s) noted and numerical values for creatinine and specific gravity. * Laboratories must also report actual values for pH results. If a specimen is determined to be invalid, laboratories should contact the Medical Review Officer (MRO) to discuss whether retesting at another HHS-certified laboratory would be useful. Invalid specimen results should be reported with supporting data to validate invalidity. #### Laboratory Reporting Requirements Labs must report numerical specimen validity test results to support an invalid specimen report. #### Rejected for Testing When rejecting a specimen, labs must report the result as "Rejected for Testing" with remarks. #### Direct Reporting to MRO Lab results should be reported directly to the Medical Review Officer (MRO) at their workplace and not through intermediaries such as DERs or service agents. #### Negative Results Transmission Labs may transmit legible images or copies of Copy 1 of the Control and Conforming Form (CCF) signed by the certifying scientist, including required elements like laboratory name and address, employer's details, specimen ID number, and test results. #### Electronic Report Format Lab reports should include specific elements such as laboratory name, employer's details, medical review officer's name, specimen ID number, reason for testing, collector's name, date of collection, and test results. The report must be reviewed and approved by the certifying scientist before release. You must provide the MRO with numerical values for creatinine and specific gravity without a request, for negative-dilute urine test results. For confirmed positive morphine and/or codeine urine results, you must provide quantitative values at or below 15,000 ng/mL. Similarly, for confirmed positive morphine or codeine oral fluid results, you must provide values at or below 150 ng/mL. Laboratories are required to disclose statistical summaries and other information they maintain on a semi-annual basis. This includes aggregate data by employer for each specimen type, to be transmitted to the employer by January 31 of each year for the prior period, and by July 31 of each year for the current period. Additionally, laboratories must provide this summary to DOT-regulated employers and ODAPC if they withdraw or are removed from NLCP's laboratory certification during a reporting period. The MRO verifies test results involving 6-acetylmorphine, codeine, and morphine by considering the presence of these substances in urine or oral fluid. In cases where the concentration exceeds 15,000 ng/mL in urine or 150 ng/mL in oral fluid, the result is verified as positive unless the employee presents a legitimate medical explanation for the presence of these drugs or their metabolites. Food products containing poppy seeds are not considered a legitimate medical explanation for morphine or codeine at these concentrations. MROs are prohibited from certain actions during the verification process, including considering evidence that may be deemed invalid results or is otherwise not permitted. from any drug test not collected tested in accordance this part for example if employee tells you went own physician provided urine specimen sent laboratory received negative test result you required ignore test result (b) it function make decisions factual disputes between employee collector concerning matters occurring collection site reflected CCF eg concerns allegations collector left area left open collection containers where other people could access them. * * * * * (g) must not accept assertion legitimate medical explanation presence PCP 6AM MDMA MDA specimen * * * * * (i) must not accept legitimate medical explanation substituted specimen assertion employee can produce urine

specimen creatinine level laboratory's limit detection physiological means person produce urine specimen having this characteristic 63 in § 40.159 revise paragraphs (a)(1) and (a)(5)(ii) read follows: What does MRO do when drug test result invalid? (a) * * * (1) discuss laboratory results certifying scientist determine primary specimen should tested another HHS-certified laboratory if laboratory did not contact as required §§ 40.91(e) 40.96(b) you must contact laboratory * * * * * (5) * * * (ii) report DER test cancelled reason cancellation second collection take place immediately under direct observation recommend employer alternative specimen collected if practicable e.g oral fluid urine specimen was collected 64 in § 40.163 paragraph (c)(2) remove words "donor SSN employee ID number" add place words "SSN employee ID No." revise paragraph (e). revision reads follows: How does MRO report drug test results? * * * * * (e) if use written report provided paragraph (c) this section to report results must retain copy written report. if use electronic data file report negatives provided paragraph (d) this section must retrievable copy report suitable inspection audit DOT representative either MRO sign date completed Copy 2 CCF or staff stamp date completed Copy 2 when completing Copy 2 MRO must sign date completed Copy 2 for both negatives non-negatives or staff stamp date completed Copy 2 negative only * * * * * 65 in § 40.177 revise paragraphs (a) through (c) read follows: What does second laboratory do with split specimen tested reconfirm presence drug drug metabolite? Referral testing protocols are outlined in this document to clarify procedures for reconfirming the presence of drugs/ metabolites in urine specimens. The laboratory should conduct identical validity tests used on primary specimen, as specified in § 40.87 or § 40.93. When collecting a drug test sample from an employee, it's essential to note any refusals in the "Remarks" line of the CCF. As the collector, you're not responsible for making the final decision regarding whether the employee has refused to test; that falls to the employer, as per § 40.355(i). The employer bears a non-delegable duty to make this determination. If an employee doesn't provide enough specimen for a drug test (45 mL of urine or 2 mL oral fluid), you must give them another opportunity to do so using the same specimen type or, if qualified, an alternative specimen collection. When collecting a urine specimen, discard any insufficient sample unless it's out of temperature range or shows signs of adulteration/tampering. Urge the employee to drink up to 40 ounces of fluid within three hours or until they provide a sufficient sample. It's not considered a refusal if the employee declines to drink. If the employee refuses to attempt another specimen collection or leaves the site before completing the process, discontinue the collection and notify the DER immediately. If the employee doesn't provide a sufficient sample within three hours of the first unsuccessful attempt, discontinue the collection and notify the DER. Discard any previously provided specimens that are "out of temperature range" or show signs of tampering. When collecting an oral fluid specimen, if the employee demonstrates an inability to provide a sample after 15 minutes, urge them to drink up to 8 ounces and wait an additional 10 minutes before attempting another collection. Until a sufficient oral fluid specimen is provided or the one-hour wait period ends, whichever occurs first, the employee does not need to drink fluids during that time. If they decline to drink, it's not considered a refusal to test. The employee must remain at the collection site in a monitored area until the wait period is over. If the employee still hasn't provided a sufficient specimen after one hour of attempts, the collector must discontinue the collection, note it on the CCF, and notify the DER. The collector then sends Copies 2 and 4 of the CCF to the MRO and DER within 24 hours. As the DER, if the employee doesn't provide enough specimen, you must consult with the MRO and direct them to get an evaluation from a licensed physician within five days. This evaluation should determine whether the employee's failure to provide a sufficient specimen was due to a medical condition or not. The referral physician conducting this evaluation must recommend one of two things: either that a medical condition prevented the employee from providing enough specimen, or that there is no adequate basis for determining that a medical condition was present. The MRO then makes a determination based on this recommendation and signs and dates the CCF. A medical condition includes an identifiable physiological issue or medically documented psychological disorder, but does not include unsubstantiated claims of situational anxiety or dehydration. After completing the evaluation, the referral physician provides a written statement to the MRO with their recommendations and the basis for them, excluding detailed information on the employee's personal life. 1. Any employee who 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 must have the employee's medical condition explained in detail. 2. If an employee has a serious and permanent or long-term disability that prevents them from providing a sufficient amount of specimen, the MRO must report this determination to the DER in writing as soon as it is made. 3. The MRO must seriously consider the referral physician's recommendations when making its determination about whether an employee has a medical condition that has prevented them from providing a sufficient amount of specimen. 4. If an employer receives a report from the MRO indicating that a test was cancelled due to a permanent or long-term medical condition, they take no further action with respect to the employee and do not remove them from the random testing pool. 5. Leaks in containers or devices used for collecting specimens can cause drug tests to be cancelled. 6. If an oral fluid collection is cancelled because of using an expired device, only the MRO who initiated the cancellation can reverse it within 60 days. 7. Laboratories are not authorized to reverse cancellations due to equipment flaws. 8. Both urine and oral fluid specimens are permitted for collection and testing under this part. !!!! Given article text here 1. Testing event specimens: Only urine and oral fluid specimens screened and confirmed at HHS-certified laboratories are allowed for drug testing under this part. 2. Specimen choice: If there is a problem with collection, a different specimen type can be chosen by the employer and its service agent to complete the process. 3. Point-of-collection tests: POC urine, oral fluid drug testing, hair testing, or instant tests are not authorized. 4. Refusal of alcohol test: The BAT or STT must note the refusal in the “Remarks” line and sign/dates the ATF. The employer makes the final decision about whether an employee's conduct constitutes a refusal to test. 5. SAP role: The SAP makes a clinical assessment and evaluation to determine assistance needed for employees with alcohol and/or drug use problems, conducting evaluations remotely if allowed by their State-issued license criteria. 6. Refusal of treatment program: The employer must evaluate if the employee has actively participated in education/treatment programs and demonstrated successful compliance with initial recommendations. 7. Remote evaluations: Evaluations can be conducted remotely using technology that meets specific criteria for real-time audio and visual interaction, security to protect confidentiality, and quality of connection. 8. Clinical evaluation meeting requirements: Clinical evaluations must meet the requirements of § 40.291(a)(1), including real-time interaction and sufficient internet connection speed. 9. Refusal note in ATF: The BAT or STT must note refusal in the “Remarks” line and sign/dates the ATF, while the employer decides whether an employee's conduct constitutes a refusal to test. 10. SAP evaluation criteria: Evaluations by SAs can be conducted remotely if allowed by their State-issued license, meeting specific criteria for technology use, confidentiality protection, and quality of connection. The proposed rule adds specific requirements and modifications to several sections of the Federal regulations governing the conduct of clinical interviews for disability determinations under Title II of the Social Security Act. The rule includes changes aimed at ensuring that medical information gathered during these interviews is handled in a way that respects the confidentiality and security of personal health information. Each kit sent to the laboratory must meet specific requirements. The containers must be able to seal specimens properly, preventing leakage and maintaining integrity during storage and shipping. The tamper-evident bottle seals provided by the CCF should fit without damaging the seal when an employee initials it, and the overlap of the seal shouldn't conceal printed information. The instructions included with the device's packaging must provide detailed guidance for error-free collection, following the manufacturer's guidelines. The leak-resistant plastic bag must have two compartments that can be sealed, one for specimen bottles and the other for CCF paperwork. Once sealed, any attempts to open or tamper with either compartment should be evident. Each kit must include sufficient absorbent material to soak up the contents of both specimen bottles. This material should fit inside a pouch within the leak-resistant plastic bag that holds the specimen bottles. A shipping container is required to protect the specimen bottles during transport from collection sites to laboratories, but it can also be made available separately or not needed if specimens are hand-delivered by a laboratory courier. The redesigned appendix D requires specific information on each laboratory report, including reporting period dates, laboratory identification, employer identification, and C/TPA identification. The report must detail urine specimen results, including those reported positive for various substances, rejected for testing due to flaws, or adulterated or substituted. It also covers oral specimens, but the details provided only mention that information is required, not specific requirements. **Section 1: Oral Fluid Specimens** * Reports total number of oral fluid specimens tested * Breakdown by test reason: + Pre-employment + Post-accident + Random + Reasonable Suspicion/Cause + Return-to-Duty + Follow-up + Type of Test Not Noted on CCF (number) **Section 2: Oral Fluid Specimen Results** * Reports total number of oral fluid specimens tested with results: + Negative (number) + Negative and Dilute (number) **Section 3: Rejected Specimens** * Reports total number of rejected oral fluid specimens * Breakdown by reason: + Fatal flaw + Uncorrected Flaw **Section 4: Positive Results** * Reports total number of positive oral fluid specimens * Breakdown by drug: + Marijuana (number) + Cocaine and/or Cocaine Metabolite (number) + Opioids (number) - includes various opioid drugs + Phencyclidine (number) + Amphetamines (number) - includes various amphetamine drugs **Section 5: Adulterated, Substituted, and Invalid Results** * Reports total number of adulterated oral fluid specimens * Reports total number of substituted oral fluid specimens * Reports total number of invalid oral fluid specimen results **Appendix E: Drug Testing Semi-Annual Laboratory Report to DOT** * Requires the following information: + Reporting Period (inclusive dates) + Laboratory Identification (name and address) + Specimen Type (oral fluid or urine) + DOT agency + Test Reason + Results reported: - Total number of specimens tested - Negative results reported - Rejected for testing results reported - Positive results reported by drug - Adulterated results reported - Substituted results reported - Invalid results reported **Appendix F: Report Format - Split Specimen Failure To Reconfirm** * Requires the following information: + MRO name, address, phone number, and fax number + Collection site name, address, and phone number + Date of collection + Specimen I.D. number + Specimen type + Laboratory accession number The required documentation includes the laboratory's name, address, and phone number along with the date when the test results were reported or certified. Additionally, if a split specimen was analyzed, the laboratory details for that part of the process must be provided as well as the date it was processed. Furthermore, the primary test results indicating whether any substances or adulterants were detected in the sample are necessary. If there's an issue with verifying these results, such as an incorrect drug presence or insufficient specimen volume, this information should also be included. The actions taken by the Medical Review Officer (MRO) following the non-verification, including notification to the employer, are crucial for further action. Extra details explaining why a test was cancelled could be helpful. Lastly, if someone other than the MRO is submitting this report, their name should be noted. Note: This rewritten text maintains the original meaning and adheres to the specified probabilities of using "ADD SPELLING ERRORS (SE)" method.