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Official Response from the International Paruresis Association

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Regarding:

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

ACTION: Notice of proposed rulemaking

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

Bill Howell is fighting for his job. Bill lost his job last year with the Southeastern Pennsylvania Transportation Authority (SEPTA) because he was subject to random urine tests under US Department of Transportation (DOT) rules. “I was an exemplary employee without a blemish on my record for 32 years. I think I may have been affected by medication that I was on, but for some reason, I just couldn’t go that day.” SEPTA summarily dismissed Bill. After a year of fighting for another test opportunity with the help of his union, Bill secured a second chance. “I knew that my livelihood, my pension, everything was riding on my ability to pee. Again, I just couldn't do it.” Bill remains unemployed today.

Bill and many others, especially those who suffer from Paruresis or shy bladder syndrome, have been terminated, forced to attend drug treatment programs, and endured humiliating circumstances all because they could not provide a urine sample. These victims were not drug users; they just couldn’t prove it under current testing rules. No sample meant they were assumed guilty.

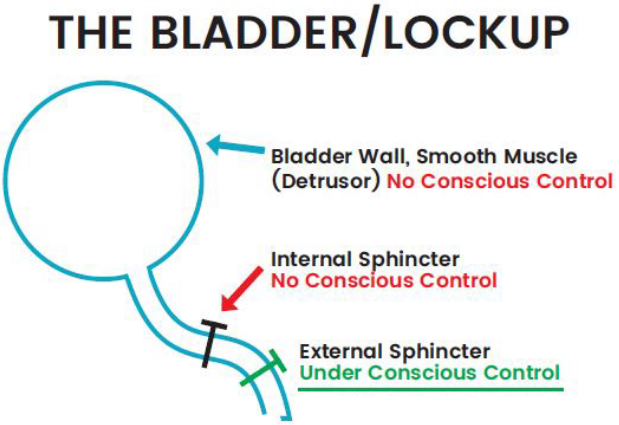
The International Paruresis Association is thankful that the science of oral fluid drug testing and the regulatory environment have improved for making these rules changes. **We applaud the US Department of Transportation for thoughtfully considering the positive impacts of the oral**

fluid testing option. You have well captured the potential savings in cost reduction, employer flexibility, and the improvements to avoid potential cheating. We support your efforts, and in this document share our expertise learned after 26 years of working with hundreds of Paruresis sufferers who have been negatively affected by the rules as currently written and implemented.

Dr. Steven Soifer, Ph.D., LCSW-C, is the co-founder of the International Paruresis Association. He is the primary author of "The Secret Social Phobia: Shy Bladder Syndrome (Paruresis)." He has traveled the world helping sufferers of Paruresis. "We have been working since 1996 for fair and equitable treatment of people in this situation. The comment period is a watershed moment for employee rights. We support the need for workplace drug testing. However, employees who can't provide a urine sample are considered guilty and then must fight a system that is geared against them. These new rules, if developed appropriately, will solve that problem. Giving employees the upfront right to choose oral fluid testing – which is three times more accurate than urine testing – will save countless procedural man hours, agency money, and resources, not to mention just be the right thing to do to ensure individual rights to privacy and due process."

In Bill Howell's case and in countless others, claims of "shy bladder" are met with incredulity by Medical Review Officers (MRO). Bill was told, in effect, by his MRO, "Paruresis is made up." Here are the facts:

Paruresis is a social phobia outlined in the DSM-V (Diagnostic and Statistical Manual of Mental Disorders, fifth edition), under the category 300.23 (F40.10). According to a National Co-Morbidity Study, an estimated 7% of the US population suffers from this illness. The United States Equal Employment Opportunity Commission (EEOC) provided an opinion in 2011 that Paruresis qualifies as a disability under Americans with Disabilities Act as Amended (ADAAA) definitions. For Paruresis sufferers and for usually unaffected people under extreme stress, their failure to provide a urine sample is not a refusal (as current forms dictate the situation be classified), but simply a psychological and physical impossibility to provide a sample despite their fervent wish to do so. This chart outlines, in a simplified fashion, the mechanism of Paruresis.



	Bladder Wall	Internal Sphincter	External Sphincter
Normal Need To Go	Squeezes	Open	Closed
Normal Peeing	Squeezes	Open	Open
Under Threat	Relaxes	Closed	N/A

If you knew you HAD TO perform a physical act in order to keep your job, would you understandably be anxious about it? Mr. Howell's anxiety is now so severe that it is psychologically impossible to comply under current testing conditions. His situation is not unique.

It is important to talk about the self-selecting nature of urine drug-testing policy and people with paruresis. Whenever a person with paruresis knows he or she will be subjected to a urine drug test, the person is likely to decline working for that employer, or to choose another career where drug tests aren't required. Here's an example: An airline pilot needs good vision, quick reflexes, technical knowledge, and a talent for flying an aircraft. What's missing from this job description is the ability to urinate into a cup in front of an observer. That skill isn't needed in order to fly an aircraft. A pilot could prove one's drug-free status through many alternative test procedures if regulations allowed them. The sad thing is that most people with paruresis won't even apply for flight school because they know they can't get through the drug test once they graduate.

Since people with paruresis often select themselves out of certain careers, people involved in drug testing seldom encounter a person with it. The natural conclusion of a person who's never encountered someone with shy bladder is that the problem doesn't exist, or a person claiming it might be trying to evade a drug test because he or she is a drug user.

The IPA is not dismissing the significance of drug testing. It is especially important to ensure the safety of the American transportation system. Rather, we are advocating for the implementation of a policy which meets the need of organizations and its affected individuals. With today's shortage of employees, the DOT is impacting its operations by terminating exemplary employees for this situation.

The Substance Abuse and Mental Health Services Administration (SAMHSA) has recognized the need for an alternative and published its final Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid on Oct. 25, 2019, in the Federal Register. We applaud the DOT for looking to reconcile its procedures with SAMSHA. These rules "revise the requirement to **collect only a urine specimen**, which has existed since the Guidelines were first published in 1988." (Federal Register, 10/25/2019, 57574)

The importance of these new rules cannot be overstated. The DOT is the bellwether agency for drug testing not only in the federal government, but across the private sector as well. As systems are put in place to comply with DOT rules, they are then used for most facilities and programs in US workplaces – and they establish how testing facilities maintain compliance. **It is essential that we get these rules right for fairness for all employees.**

(more . . .)

Comments in Summary

1. **The new rules as written, still imply the "option"** of oral testing rests with the employer. (11156, ¶ 1; 11158, ¶ 3; 11170, ¶ 1; 11171, ¶ 3) It is essential that your effort to "harmonize" the rules (11156, ¶ 1) clarifies this confusion. Otherwise, it will remain "business" as usual with currently ingrained and flawed processes.

2. **Oral testing will be adequate** to test for the presence of illegal substances in all circumstances based on your published window of detection (Federal Register 2/8/2022, 11159) and on the comments included in 84 FR 57544: "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…'"

3. If oral testing can be selected **upfront** without requiring any justification, employees' constitutional privacy rights will be protected. The IPA can provide countless examples of how livelihoods have been negatively affected by the current rules and processes.

4. The Federal Government will see significant hard and soft cost savings by implementing this change. We applaud the Department's summaries on potential improvement of new rules on cost reduction, flexibility, cheating reduction, and privacy rights. However, if the change remains optional, the savings and benefits will not be realized.

5. On the matter of Medical Review Officer and Substance Abuse Professional training. It is essential that training for these professionals include the recognized social phobia of "Paruresis." (Subpart G, 11165, last paragraph)

Our comments to background items

Page number and paragraph noted of your text in italics. Our emphases in **bold**.

11157 ¶6

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.* [highlights added for emphasis]

This statement is counter to the direction of the SAMHSA regulations which explicitly state that these rules "**revise the requirement to collect only a urine specimen**, which has existed since

the Guidelines were first published in 1988." (Federal Register, 10/25/2019, 57574). If the DOT continues to only allow but not require the option by employees to select oral testing upfront without cause, the status quo will continue. The wheel of government turns slowly, and without an obligation on the part of employers, nothing will change.

11157 ¶6 CONTINUED

Specifically, we are seeking comments as to whether there are circumstances where either urine or oral fluid should be mandatory.

In consultation with our oral fluid drug testing industry experts, as noted in the SAMHSA guidelines ("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 FR57554)), and in reviewing the data you have provided within this document, we support the case that oral fluid testing can suffice within the needs of the program as dictated by Code of Federal Regulations and Executive Order 12564. Given the fact that studies suggest the positivity rate for oral fluid testing is three times higher than urine testing, no one who is trying to "cheat" the testing requirements would choose oral fluid as their specimen of choice. People suffering from Paruresis or the unexpected "lock-up" would gladly choose oral fluid testing.

11158 ¶ 3

*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.*

We bring attention to the inference that the inclusion of oral fluid specimen testing will remain as an option to employers. Without a clear oral fluid mandate, change will be minimal at best and the estimated cost and procedural savings will not be realized.

11158 ¶ 6

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 note that beyond the hard cost savings associated with the processing of the specimens, the change to an upfront ability to request oral fluid testing will result in significant additional savings. Please see our comments below regarding page 11170 ¶ 6.

11158 ¶ 8

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.***

The International Paruresis Association and its more than 5,000 members and followers are grateful for this recognition of the issues we have attempted to bring forth over the past 26 years. We appreciate the identification of the wasted time and effort on all parts when an alternative test is not made available for an employee. It is important to accept that Paruresis suffers have been desperate to have any alternative test and their medical and psychological diagnoses recognized by the DOT. We have hundreds of documented cases of employees being humiliated, harassed, dismissed, disenfranchised, and shamed by this process.

We've shared the case of Bill Howell above with his permission; he unfortunately has not gotten his job back. Chris Knudson, an employee of the Los Angeles County Metropolitan Transportation Authority (Metro) spent four years navigating the labyrinth of DOT drug testing in order to be reemployed. Because of his Paruresis, his path back to work was arduous – a path that included losing back pay and other negative financial ramifications. "Not being able to pee for the mandated tests was traumatic. Thankfully, I've improved my Paruresis over that time through graduated exposure and relaxation techniques in order to get my job back, but my time being suspended and unemployed could have been drastically shortened with the oral fluid option." Chris is not on drugs – he simply could not provide a urine sample when he urgently wanted to.

MROs don't understand what Paruresis is and how it works. Medical doctors do not know the specific language that MROs are looking for to accept a diagnosis of Paruresis. Urologists can

only say that there is nothing physically wrong. Their diagnosis must be paired with a psychologist or therapist's diagnosis of the social anxiety disorder of Paruresis (see the appropriate diagnosis steps in our comments on 11165 ¶ 1 – Subpart G below). MROs require a "documented history" of shy bladder syndrome; this history oftentimes is not available as it has never been shared with medical professionals before. By definition, people with Paruresis are ashamed and embarrassed by their condition and may not have shared it with anyone. Even people who do not experience the severe end of the spectrum can have a "lock up" out-of-the-blue. No amount of water over any amount of time can "force" a person to urinate if the cause is not in their control (see prior chart). We urge the DOT to provide an alternative that is free of a process of disclosure, medical examination, or review. Some people can't urinate in front of others on demand. We implore the DOT to provide a solution that ensures privacy rights and dignity. It just so happens that this solution can also save the government time and money.

We interject here a comment on the state of collection/testing facilities. The staff at these facilities are overworked – at agency run sites, employer sites, or contracted provider locations. This situation results in a "hurry up" mentality and adds an important stress factor for many suffering from Paruresis that people are "waiting on them." Although someone in the shy bladder protocol may be given a three-hour window, the time period to produce the sample is limited. The collection instructions say, "The collector may set a reasonable time limit for the employee to be inside the bathroom and this time frame should be explained to the employee."[1] Yet technicians have begun knocking on doors after one-, two-, or three-minute time periods; the implementation is inconsistent. We have first-hand reports that collectors require the bathroom or stall doors to be "open a crack." The collection environment is fraught with minefields for the shy bladder sufferer.

11158 ¶ 10

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., preemployment, random, etc.). Instead, we are proposing to offer employers the flexibility in the type of specimen they collect.*

Again, we bring attention to the inference that the inclusion of oral fluid specimen testing will remain as an option to employers. Without a clear oral fluid mandate, change will be minimal at best and the estimated cost and procedural savings will not be realized. While this section highlights the benefits of oral fluid testing in a post-accident or reasonable cause scenario, the foundational message is employers will have the option to provide an oral fluid test.

11159 ¶ 1

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

[1] https://www.transportation.gov/sites/dot.gov/files/docs/resources/partners/drug-and-alcohol-testing/2567/urine-specimen-collection-guidelines-january-2018.pdf

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.

Our reading of the chart you have sourced, indicates that using oral fluid testing, drug use can be detected within one day for all categories listed. Except for marijuana, all can be detected within two days. This detection window should suffice, especially for the testing needs of pre-employment and random screening. This section continues:

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 preemployment, 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.*

We encourage the department to avoid the "urine is best because we've always done it that way" mindset. Based on the detection data provided, multiple oral tests can be given across the same period as the urine detection window and capture the same savings. In addition, intermittent drug use does not occur in a vacuum; drug testing should be just one part of a management program that also includes performance reviews, one-on-one and team meetings and other standard management best practices that can identify chronic drug use behaviors – which can then be supplemented by oral testing. [Although this NPRM has specifically noted discussion of hair specimen testing as out of bounds, we note it here as a future method to meet this "longer window of detection" need.]

11160 ¶ 5

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.

We strongly object to this amendment. The currently mandated use of urine testing is itself problematic without adding this additional stressor for most employees.

11165 ¶ 1 (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.

It is essential that MROs and Substance Abuse Professionals receive training on the recognized social phobia of "Paruresis." The sad truth is that, according to our 2020 survey of urologists, only about 1 in 10 themselves receive training on Paruresis and much less so for general practitioners. There have been cases when employees have brought forth the appropriate diagnoses, yet the MRO dismissed these facts ruling in favor of their own judgement without due process. Additionally, the requirement that there be a "documented history" is also unfair as a "lock up" can occur to anyone at any time.

The appropriate method of diagnosing Paruresis is as follows (per Dan Rocker, LCSW, MA):

1. The employee goes to a urologist who reports that there is no physiological reason for the inability to provide a sample.
2. The employee is referred to a licensed therapist with expertise in social anxiety disorders.
3. The practitioner diagnoses Paruresis.

In the case of a "failed" test, the practitioner would recommend the minimal accommodation of switching from a urine-based to an oral fluid-based test.

Currently, after a failed sample, the employee has just **five** days to receive a diagnosis. And, as noted above, the appropriate way to diagnose Paruresis involves coordination between two providers. In this health system environment, getting appointments in the short five-day time frame with the appropriate professionals can be problematic. Adopting new rules that put the oral fluid testing option **upfront** eliminates all of these subsequent MRO processes.

Additionally, we reiterate that we have hundreds of documented cases of employees being humiliated, harassed, dismissed, disenfranchised, and shamed by this process. It would also be a waste of time and a source of humiliation if the employee was forced to go through the 3-hour "shy bladder" protocol before being given the oral fluid option. Putting the option upfront will logically eliminate extra effort at the outset.

11167 RE: § 40.193 ¶ 1

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)…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 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.*

It is our recommendation that the new rules explicitly state the upfront choice of oral fluid testing. The overall language of the new rules still imply that urine testing will be the continued method and that employers will have the option to provide the oral method. We envision a situation where workplace drug testing at the DOT continues as is. Employees must go through the same "shy bladder" protocol and only then be given the oral fluid test. Potentially, employers could read these rules as indicating that an employee must go through the entire MRO process before being identified as having "shy bladder," and then and only then being given the oral fluid test. Therefore:

WE EMPHATICALLY IMPLORE THE DOT TO MAKE CLEAR THE UPFRONT CHOICE OF ORAL FLUID TESTING BY EMPLOYEES WITHOUT JUSTIFICATION.

11168 RE: 40.210 ¶ 2

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?*

Again, this language relies heavily on the decision-making of the employer or its agent. The more logical process would be to allow the employee to choose the most accommodating test for that individual. **The rules must be clear on how this will play out.** Will it be: Employee arrives for urine test; employee must go through the three-hour process, then be given the oral choice IF the employer and its agent decide it's okay?

Or, most simply as we propose: Employee arrives. Employee has the choice of oral fluid or urine testing. Employee chooses oral fluid. Test complete. Why should it be more complicated than that?

11169 VI. Regulatory Analyses and Notices RE: 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 [employers] 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.*

We provide the text of paragraph one of this section as we wholeheartedly agree and support its content. However, we caution the Department, as we have elsewhere above, in that the subsequent paragraph regarding the implementation of these changes implies 1. The employee will first have to attempt a urine specimen (three-hour window). And 2. An MRO will be involved in some capacity even if it does not involve arranging an evaluation. The hoped-for benefit of enhanced flexibility is therefore undermined. We advise the simplicity of allowing the employee the upfront choice of test type.

11170 ¶ 1

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.*

You have made the case elsewhere in this document of the improved logistics and cost savings potentially achieved by using the oral fluid option. **Why not mandate oral fluid as the preferred option now while we have this opportunity?** Additionally, this text implies that urine will remain the "go to" testing method and oral will only be selected in case of a "problematic" situation. If that is the case, you must clarify how that process will operate.

11170 ¶ 6

From 2018 MIS dates, 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.

You've made your own case for placing oral fluid as the preferred testing option. Giving employees the right to choose their method is a time and money saving accommodation that can be easily given. What is the cutoff in savings for allowing this option? If the DOT saves $1 million? $10 million?

We respectfully request to allow employees the upfront right to choose the drug test specimen type they desire. It is a simple and logical solution. For the overwhelming majority of employees, they aren't on drugs and just want to get back to work. Employers want their teams tackling today's issues, not running a gauntlet of procedures. So, the thought of the reviewer may be, "What's the big deal?" "How many people are we talking about that are affected by shy bladder?" "How much money will we save?"

Yes, the number of employees who may be impacted may be small and the money savings may be small, but each person is a human being. We all want to be given our right to privacy and to due process. Denying that to one person is something that a citizen of the United States should not have to abide. We know that oral fluid testing works. We know that it will be a money saving option. Let employees choose.

11170 Versatility in Detection ¶ 1

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.

Why? In the previous sections, you have laid out a 15-page case on why oral fluid testing is better than urine testing. This paragraph is the equivalent of saying, "We're going to authorize the option of the postal service using trucks to deliver the mail, but we expect horseback to remain the established and reliable component of mail delivery." If you change the rules to move to oral fluid testing, the processes and the underlying industry will move with you. It's a win for all.

11171 Costs and Benefits ¶ 6

*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.*

We emphatically concur.

Our comments on the proposed language by section

Subpart E – [Amended] § 40.61 What are the preliminary steps in the drug testing collection process?

1. Ask the employee which specimen type they would like collected.

11182 RE: § 40.191(5) and (7)

*(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));... (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).*

We recommend that this language specifically include the immediate option of switching to the alternate approved method. If a sample cannot be collected by either approved method, then a required medical evaluation would be needed. We anticipate the failure of someone to provide either a urine OR oral fluid sample to be extremely limited. [The addition of hair sample testing in the future would bring this occurrence to zero probability.]

11183 RE: §40.193 (c) thru (i)

*(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.) ...*

(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: …

(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: …

(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. …*

(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.

For the purposes of this specific discussion, (11183 RE: §40.193 (c) thru(i)), let us assume that a urine test is required (whether by lack of options provided, a determination that urine testing is required in a specific case, or other reason). In this case, we point out as we have in page 8 here, that achieving an appointment with a qualified medical practitioner (in fact, two as is medically appropriate for proper Paruresis diagnosis) is difficult to obtain in this health care environment. We recommend a period of at least 15 business days be allowed.

Secondly, we ask you to review our comments on page 8 as well regarding the proper diagnosis of Paruresis. We question the training and expertise of an MRO in "overruling" the determinations of licensed medical and therapeutic professionals that an employee has Paruresis. We have documented cases of this occurring.

Lastly, the language of "unsupported assertions of 'situational anxiety'" have been used to detriment of employees in these cases. The US Centers for Disease Control and Prevention reported on April 2, 2021, "During August 2020–February 2021, the percentage of adults with recent symptoms of an anxiety or a depressive disorder increased from 36.4% to 41.5%, and the percentage of those reporting an unmet mental health care need increased from 9.2% to 11.7%." (Retrieved March 17, 2021; https://www.cdc.gov/mmwr/volumes/70/wr/mm7013e2.htm#:~:text=During%20August%202020%E2%80%93February%202021,from%209.2%25%20to%2011.7%25.) More than 4 in 10 Americans suffer from these disorders. The situational anxiety of taking a drug test to secure or retain employment must be considered. Having the immediate option to switch to an alternative test must be provided without MRO intervention or justification. [Using this language will also support any future adoption of hair specimen testing which will be unaffected by situational anxiety.]

11184 § 40.210

§ 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.

We propose this edited version for this section:

*Both urine and oral fluid specimens are authorized for collection and testing under this part. An employer ~~can~~ **shall** 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~~ **shall** 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~~ the **alternate approved** specimen type **shall** be ~~chosen~~ **used** 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.*

In Summary

The current system is **flawed**. Employees have been unfairly treated not because they were on drugs, but only because they could not produce a urine sample.

The adoption of the oral fluid testing option is a must for **ensuring due process and individual rights** not only for US Department of Transportation employees, but for all employees whose organizations look to the blueprint of your testing guidelines.

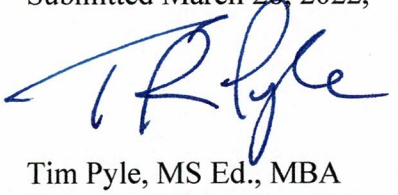
Logic dictates – and human dignity demands – that the best option is to allow the choice by the employee at the beginning of the collection procedure of oral fluid or urine specimen test.

While the gross number of employees affected by the current "shy bladder protocol" seems small, **each of those employees is a human being** and deserves to be treated fairly.

We applaud the DOT for revising these procedures to meet the demands of Americans' safety and the needs of individuals.

The International Paruresis Association and our experts are available for consultation at your convenience.

Submitted March 28, 2022,



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EIN #06-1509744