

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration Mandatory Guidelines for Federal Workplace Drug Testing Programs

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), HHS.

ACTION: Notice of the mandatory guidelines proposed by the Secretary of Health and Human Services. [FR Doc. 2015-11523 Filed: 5/13/2015 04:15 pm; Publication Date: 5/15/2015]

Benefits of Oral Fluid Drug Testing as noted in FR Doc. 2015-11523

The federal agencies choosing to use oral fluid in their drug testing program may see many benefits including:

- A reduction in time of the collection process, which means productivity for federal agencies related to the drug free workplace program is expected to improve. The savings generated for the Federal Government would be roughly \$400,000 to \$1.2 million a year, or \$38 to \$114 per test
- An observed collection method leading to reductions in rejected, invalid, substituted, and adulterated specimens. Additionally, the collector need not be the same gender as the donor
- An effective tool in post-accident testing identifying the parent or active drug, which may indicate recent administration of the drug and be advantageous when assessing whether the drug contributed to an observed behavior. With the legalization of marijuana and the continued opioid crisis, keeping the workplace safe with an effective testing tool is critical.

Need for regulation

Enhances Flexibility

The proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) will provide flexibility to address workplace drug testing needs of federal agencies while continuing to promulgate established standards to ensure the full reliability and accuracy of drug test results.

Enhances Versatility

Medical conditions exist that may prevent a federal employee or applicant from providing sufficient urine drug test. When the OFMG are implemented, in the event that an individual is unable to provide a urine specimen, the federal agency may authorize the collection of an oral fluid specimen. This will reduce both the need to reschedule collections and the need for the Medical Review Officer (MRO) to arrange a medical evaluation of a donor's inability to provide a specimen.

Urine collection requires use of a specialized collection facility, secured restrooms, the same gender, and other special requirements. Oral fluid may be collected in various settings. It is expected that many oral fluid collections will occur at or near the workplace, and not at a dedicated collection site, thereby reducing the amount of time away from the workplace.

Decreases Invalid Tests

A major challenge to urine drug testing has been the proliferation of commercial products used to adulterate or substitute a donor's urine specimen. Due to individual privacy rights, most urine

collections are unobserved, allowing the opportunity to use such products. As the Department has established requirements and laboratories have developed procedures to control for adulterated and substituted specimens, manufacturers have developed new products to avoid detection. Current research indicates that some current substitution products are indistinguishable from human urine. The use of these products is expected to continue.

Oral fluid collections will occur under observation, which should substantially lessen the risks of specimen substitution and adulteration that has been associated with urine specimen collections, most of which are unobserved. All oral fluid specimens will be tested for either albumin or immunoglobulin G (IgG) to identify invalid specimens.

Saves Time

Administrative data indicates it takes, on average; about 4 hours from the start of the notification of the drug test to the actual time a donor reports back to the worksite. Since oral fluid collection does not have the same privacy concerns as urine collection, onsite collections are likely, thereby reducing the time a donor is away from the worksite. The Department estimates the time savings to be between 1 and 3 hours. This range reflects uncertainty around the location of the collection. The lower bound represents an estimate of time savings if the collection was conducted at an offsite location. The upper bound estimate represents the time savings if the collection was conducted at the employee's workplace, and thus incorporates travel time savings. The lower bound represents an estimate of time savings if the collection was conducted at an offsite location. The upper bound estimate represents the time savings if the collection was conducted at the employee's workplace, and thus incorporates travel time savings.

Using OPM's estimate for the average annual salary of Federal employees converted to an hourly wage, the savings generated for the Federal Government would be roughly \$400,000 to \$1.2 million a year, or \$38 to \$114 per test.

Versatility in Detection

The time course of drugs and metabolites differs between oral fluid and urine, resulting in some differences in analytes and detection times. Oral fluid tests generally are positive as soon as the drug is absorbed into the body. In contrast, urine tests that are based solely on detection of a metabolite are dependent upon the rate and extent of metabolite formation. Thus, oral fluid may permit more interpretative insight into recent drug use drug-induced effects that may be present shortly before or at the time the specimen is collected. A federal agency may select the specimen type for collection based on the circumstances of the test. For example, in situations where drug use at the work-site is suspected, the testing of oral fluid may show the presence of an active drug, which may indicate recent administration of the drug and be advantageous when assessing whether the drug contributed to an observed behavior.

Time Horizon of this Analysis

The transition to the testing of oral fluids will be gradual and steady over the course of four years, when it should plateau. By this time, it is expected that oral fluid tests will account for 25-30% of all regulated drug testing. This estimate is based on the non-regulated sector's time course of the testing of oral fluid and urine in the past four years.

Highlights from the Quest Drug Testing Index, May 2018

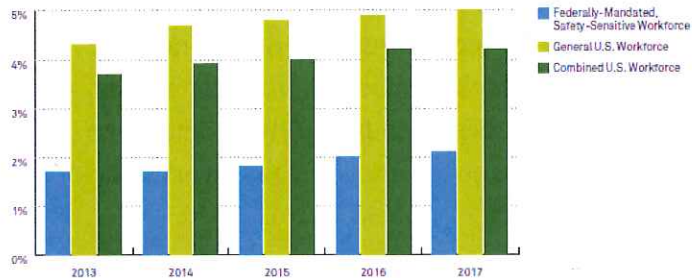
<https://www.questdiagnostics.com/home/physicians/health-trends/drug-testing>

Oral Fluid positivity rates are more than double those found with urine, as illustrated by the charts noted in the Drug Testing Index.

Urine Drug Positivity Rates:

Positivity Rates by Testing Category

Urine Drug Tests

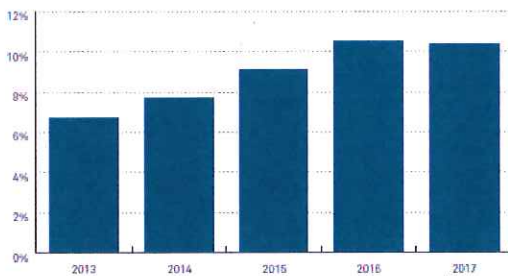


Testing Category	2013	2014	2015	2016	2017
Federally-Mandated, Safety-Sensitive Workforce	1.7%	1.7%	1.8%	2.0%	2.1%
General U.S. Workforce	4.3%	4.7%	4.8%	4.9%	5.0%
Combined U.S. Workforce	3.7%	3.9%	4.0%	4.2%	4.2%

Oral Fluid Drug Positivity Rates:

Positivity Rates by Testing Category

Oral Fluid Drug Tests – For General U.S. Workforce



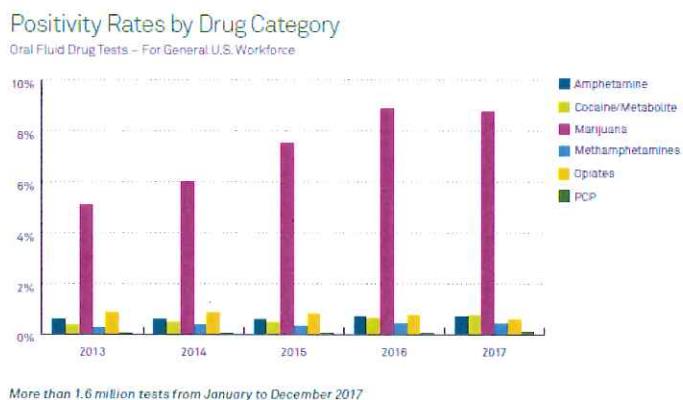
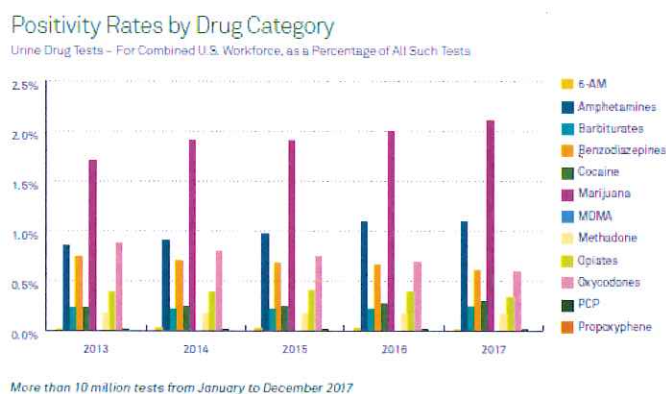
More than 1.6 million tests from January to December 2017

Testing Category	2013	2014	2015	2016	2017
General U.S. Workforce	6.7%	7.7%	9.1%	10.5%	10.4%

The legalization of marijuana is having an impact on positivity rates:

Increases in positivity rates for marijuana in the general U.S. workforce were most striking in states that have enacted recreational use statutes since 2016. Those states include: Nevada (43%), Massachusetts (14%) and California (11%). These three states also saw significant increases in marijuana positivity in federally-mandated, safety-sensitive workers: Nevada (39%), California (20%), and Massachusetts (11%). Federally-mandated, safety-sensitive workers include pilots, rail, bus and truck drivers, and workers in nuclear power plants, for whom routine drug testing is required by the DOT. “These increases are similar to the increases we observed after recreational marijuana use statutes were passed in Washington and Colorado,” said Dr. Sample. “While it is too early to tell if this is a trend, our data suggests that the recreational use of marijuana is spilling into the workforce, including among individuals most responsible for keeping our communities safe. We encourage policy analysts to track these trends closely to determine whether a correlation between the state legalization of marijuana and increased workforce drug use, as suggested by our data, bears out in other research.”

Further investigation into positivity rates reveals that oral fluid positivity rates for marijuana are 4 times higher than urine positivity rates (8.5% vs. 2%).



Oral fluid is not subject to dilution and adulteration tactics employed when using urine testing – this improves ability to detect true positives improving safety in the workplace

- The US GAO report entitled “DRUG TESTING - Undercover Tests Reveal Significant Vulnerabilities in DOT’s Drug Testing Program” shows significant vulnerabilities in DOT Drug Testing Program. For example, 75 percent of the urine collection sites GAO tested failed to restrict access to items that could be used to adulterate or dilute the specimen, meaning that running water, soap, or air freshener was available in the bathroom during the test. GAO investigators used adulterants at four of the collection sites and substitute synthetic urine at another four sites without being caught by site collectors—demonstrating that these products could easily be brought into a collection site and used during a test.

Oral fluid collection is a more dignified and donor friendly method which has driven employers who previously would not perform urine testing to establish drug testing program improving safety in the workplace. Additionally, Oral fluid collection accommodates individuals with medical conditions such as dialysis and paruresis (can’t urinate on demand).

Oral fluid detects recent use of all drugs better than urine and therefore potential impairment in the most critical positions in all transportation modals, manufacturing, production, distribution, warehousing, and more.

- Oral fluid is generated primarily by excretion of saliva, a fluid that originates from the blood. Thus, saliva contains, in real time, whatever drug/metabolite is present in the bloodstream. Hair and urine specimens collected shortly after drug use may test negative. For hair, there is an approximate week of “lag” time before drug appears because of the time required for the newly formed hair in the follicle to grow to the surface of the skin. Delays in appearance of drug/metabolite of 4-8 hours in urine may occur for a number of reasons. Tests that are targeted for metabolites may be negative initially because of required time for liver enzymes to convert sufficient amounts of drug to metabolite. For example, formation of THC-carboxy acid in sufficient amounts to register “positive” in urine may take several hours. In a study of smoked marijuana, Niedbala et al. reported that it took an average of 4 hours after use for individuals to produce a positive urine specimen by GC/MS at a 15 ng/mL cutoff concentration. In stark contrast, all individuals were positive by oral fluid testing for THC immediately after drug use. Hence, an individual tested within a few hours of use will test positive for THC in oral fluid but negative for THC-carboxy acid in urine.
- According to the most recent data published by Quest Diagnostics (Quest Drug Testing Index: <http://www.questdiagnostics.com/home/physicians/health-trends/drug-testing.html>) ***Detection of Recent Usage of Marijuana Continues to Increase Significantly in Oral Fluid Testing*** - In addition to urine drug tests for marijuana, Quest also provides oral fluid testing, and for the second consecutive year, DTI data showed a marked increase in marijuana detection in oral fluid. Oral fluid positivity rates for marijuana climbed 27 percent (5.1% vs. 4.0%) in 2013 compared to 2012 after a dramatic increase of 48 percent (4.0% vs. 2.7%) in 2012 compared to 2011. While the trend of higher positivity rates may be partially attributed to an uptick in marijuana use among testing subjects, other variables including observed collections associated with oral fluid testing.

There are 24 states plus the District of Columbia that have legalized marijuana for medicinal purposes and 4 states plus the District of Columbia that have legalized marijuana for recreational purposes.

- There are challenges with traditional urine drug testing when it comes to testing for marijuana. Key among these challenges is the window of detection, as mentioned above. Employers still have the right to drug test to ensure a safe working environment, but it becomes very confusing how to approach drug testing in states where it is legal to ingest marijuana. Oral fluid testing is testing ideal for reasonable suspicion and post-accident drug testing, as well as random testing. A lab-based oral fluid test for marijuana will only detect, and thus reveal, the presence of THC in the donor for 24 hours or less from the time the person used the drug. This is critically important when you consider the fact that a person remains under the influence of marijuana for many hours after the high has worn off according to numerous reports.
- Oral fluid testing is available to employers who are not subjected to mandated testing, but not currently for those subject to mandated testing. Once the Federal Register is updated to include the ability to test with oral fluids, employers will have the same ability to detect recent use that employers in the non-mandated sector have today. Until that time, urine continues to be the only testing methodology and creates issues as to understanding how long ago the person actually ingested marijuana and whether they are under the influence or not.