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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Chapter 1

Mandatory Guidelines for Federal Workplace Drug Testing Programs—Authorized Testing Panels

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services (HHS)

ACTION: Issuance of authorized drug testing panels.

SUMMARY: The Department of Health and Human Services (''HHS'' or ''Department'') herein publishes the panels of Schedule I and II drugs and biomarkers authorized for testing in Federal workplace drug testing programs. The Department has revised the drug testing panels for both urine and oral fluid, and revised required nomenclature for laboratory and Medical Review Officer Reports.

DATES: The authorized drug testing panels and required report nomenclature are effective July 7, 2025.

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SUPPLEMENTARY INFORMATION: The drug testing panels in this Notification specify the analytes and cutoffs for Federal agency workplace drug testing specimens and the nomenclature (*i.e.,* analyte names and abbreviations) that must be used to report Federal workplace drug test results, in accordance with Subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG, 88 FR 70768) and the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG, 88 FR 70814). Section 3.4 of Subpart C calls upon the Secretary of HHS (Secretary) to ''publish the drug and biomarker test analytes and cutoffs (*i.e.,* the 'drug testing panel' and 'biomarker testing panel') for initial and confirmatory drug and biomarker tests in the **Federal Register** each year,'' and make them available on the internet at *http://www.samhsa.gov/workplace.* Section 3.4 of the UrMG and the OFMG also requires HHS-certified laboratories, instrumented initial test facilities (IITFs, urine only), and Medical Review Officers (MROs) to use the nomenclature (*i.e.,* analyte names and abbreviations) published with the drug and biomarker testing panels to report Federal workplace drug test results.

This **Federal Register** Notification (FRN) contains only the drug testing panel because, to date, HHS has not approved any biomarker tests for use with Federal workplace drug testing specimens. The drug testing panels in Section 3.4 of the UrMG and OFMG will remain in effect until July 7, 2025.

Background

HHS, by the authority of section 503 of Public Law 100–71, 5 U.S.C., and Executive Order 12564, establishes the scientific and technical guidelines for Federal workplace drug testing programs and establishes standards for certification of laboratories engaged in drug testing for Federal agencies. In addition, the Department specifies the drugs and biomarkers for which Federal employees may be tested. To facilitate timely analyte and cutoff changes based on the state of the science, the Department publishes the HHS authorized drug and biomarker testing panels separately from the Mandatory Guidelines.

Analyte changes are based on a thorough review of relevant information, including drug prevalence estimates, the current state of the science, laboratory capabilities, costs associated with the change, and benefits of the change to Federal agencies. To identify panel changes needed, the Department solicits review and input from subject matter experts such as Responsible Persons (RPs) of HHS-certified laboratories, Medical Review Officers (MROs), research scientists, and manufacturers of collection devices and/or immunoassay kits, as well as Federal partners such as the Department of Transportation (DOT), the Food and Drug Administration (FDA), the Department of Defense (DOD), and the Drug Enforcement Administration (DEA). The Department also seeks public comment to inform decisions related to analyte changes.

Using this process for recommending changes to the analyte table, the Department proposed the removal of methylenedioxyamphetamine (MDA) and methylenedioxymethamphetamine (MDMA) and the addition of fentanyl in the notice for the December 5, 2023, Drug Testing Advisory Board (DTAB) meeting published in the November 17, 2023, **Federal Register**. The meeting notice included supporting information for the proposed changes and a request for public comment, along with the January 4, 2024, due date for public comments and the methods for comment submission. During the December 5th, 2023, DTAB meeting, the Department presented the basis for the proposed changes including technical and scientific support.

The Department received and reviewed 176 comments from 118 commenters. All comments were reviewed and taken into consideration in the preparation of draft final drug testing panels. During the DTAB meeting on March 5, 2024, the Department presented a summary of the public comments, along with additional supporting information for the proposed changes including workplace testing prevalence information, cost estimates and areas of agreement and concerns The comments are available for public view on the SAMHSA website at *https://www.samhsa.gov/meetings/dtab-meeting-december-2023* and *https://www.samhsa.gov/meetings/dtab-meeting-march-2024.* During the June 4–5, 2024, DTAB meeting, the Department provided updated information on fentanyl positivity in workplace testing (urine and oral fluid). DTAB members agreed with the proposed changes.

The Department continued to assess the proposed testing panel changes and as described below, has decided not to remove MDMA and MDA from the urine and oral fluid drug testing panels at this time.

Summary of Public Comments and HHS's Response

The following provides the basis for the changes to nomenclature and the drug testing panel. The issues and concerns raised in public comments and HHS responses are set forth under each topic.

Nomenclature

For consistency and to avoid misinterpretation of test results, the UrMG and OFMG require HHS-certified test facilities and MROs to report results using the nomenclature (*i.e.,* analyte names and abbreviations) in the drug and biomarker testing panels published in the **Federal Register**.

The drug testing panel includes revised abbreviations for marijuana test analytes, consistent with current scientific nomenclature. The Department previously used the abbreviation THC for Δ-9-tetrahydrocannabinol and THCA for Δ-9-tetrahydrocannabinol-9-carboxylic acid. The new abbreviations are Δ9THC in place of THC and Δ9THCC in place of THCA. Including ''Δ9'' in these abbreviations distinguishes them from other compounds (*e.g.,* Δ-8-tetrahydrocannabinol-9-carboxylic acid and Δ-8-tetrahydrocannabinol). The revised abbreviation Δ9THCC also distinguishes this marijuana metabolite from Δ9-tetrahydrocannabinolic acid, a non-psychoactive cannabinoid in the cannabis plant that is also commonly abbreviated as THCA. This plant compound is an important precursor integral to the growth, definition, and production of legal hemp as defined by the US Department of Agriculture (USDA).[1] [2]

Drug Testing Panel

Note: *Oral fluid cutoffs in the authorized drug testing panel are based on undiluted (neat) oral fluid.*

Removed Drugs: Methylenedioxyamphetamine (MDA) and Methylenedioxymethamphetamine (MDMA)

The Department proposed to remove MDA and MDMA from the drug testing panel because the number of positive specimens reported by HHS-certified laboratories did not seem to support testing all specimens for MDA and MDMA in Federal workplace drug testing programs. Information provided to the Department through the National Laboratory Certification Program (NLCP) in 2024 shows the MDMA positivity rate for the past three years (2021–2023) has been at or below 0.002% and a review of the results indicates that >25% of the positive specimens are likely agency blind samples. A further review of the NLCP data shows that almost 40% of MDMA positive urine specimens are also positive for another drug to include amphetamines (7%), benzoylecgonine (9%) and THC (21%), indicating that these specimens would be identified as drug positive by other means. MDMA accounts for only 0.28% of the drugs identified in exhibits submitted to crime laboratories. Tablets sold as MDMA on the street often do not contain MDMA and instead contain another phenethylamine compound such as dipentylone.[3] [4] In addition, the NLCP information shows that MDA has a significantly lower positivity rate (0.00008% of tested specimens) than MDMA, with only six specimens identified as containing MDA without MDMA in 2023, and both analytes have lower positivity rates than phencyclidine (PCP). While PCP has an overall positivity rate nearly as low as MDMA, there are regional differences in the positivity of PCP in federally regulated and general workplace drug testing populations with some areas of the country having much higher rates, so the Department has determined that PCP remains a regulated test analyte.[5]

A total of 10 commenters addressed the removal of MDMA and MDA from the testing panel. Of these, four agreed with removal of these drugs, while six disagreed.

Four commenters who disagreed noted that, because drug testing deters use, MDMA and MDA use may increase after removal from the panel. Another commenter who disagreed with removal stated that growing interest in MDMA use for post-traumatic stress disorder and anxiety may lead to increased MDMA use. This commenter also noted that the National Survey on Drug Use and Health (NSDUH) showed adults' self-reported use of MDMA (*i.e.,* Ecstasy) was higher than for phencyclidine (PCP).[6] A commenter who agreed with removal noted that SAMHSA might consider removing MDA and keeping MDMA on the testing panel with amphetamine and methamphetamine, based on current amphetamines immunoassay cross-reactivity to MDMA.

Three commenters stated that MDMA/MDA positivity rates in DOT-regulated programs have remained steady over time. One of these agreed with removal and had no safety concerns, while the other two commenters cited this as a reason for continuing to test these drugs.

The Department considered all comments and has decided that the removal of MDMA and MDA from the urine and oral fluid drug testing panels requires further study, and therefore, MDMA/MDA will not be removed from the drug testing panels at this time. The Department will continue to monitor MDMA/MDA prevalence and will engage with the DTAB and continue to assess the costs and benefits of removing one or both analytes in the future.

Added Drugs: Fentanyl and Norfentanyl

After declaring the opioid crisis, a public health emergency in 2017, former President Trump signed the SUPPORT for Patients and Communities Act (SUPPORT Act) into law on October 24, 2018. Section 8105 of the Fighting Opioid Abuse in Transportation Act,

included in the SUPPORT Act, required the Secretary to determine whether it is justified, based on the reliability and cost-effectiveness of testing, to revise the Mandatory Guidelines for Federal Workplace Drug Testing Programs to include fentanyl.[7] Section 8105 additionally required the Secretary to consider whether to include any other drugs or other substances listed in Schedule I and II of Controlled Substances Act (CSA).[8] Norfentanyl is a metabolite of fentanyl. Because it is also an immediate precursor used in the illicit manufacture of fentanyl, it is a Schedule II substance under the CSA.

Fentanyl was considered for inclusion in the proposed Mandatory Guidelines of May 2015. At that time, fentanyl was primarily found as a mixture with heroin. Because the heroin metabolite 6-acetylmorphine was already included in the Mandatory Guidelines, it was decided that the addition of fentanyl was not needed to identify fentanyl use. However, the illicit drug market and epidemiological data on drug use and overdose have changed since that time: fentanyl, primarily illicitly made fentanyl, is involved in a large percentage of overdose deaths in the United States and is therefore an important public safety concern.[9] [10] Furthermore, illicitly made fentanyl is increasingly used as a stand-alone substance among people who use drugs, not in conjunction with heroin and other substances.[3] According to the National Forensic Laboratory Information System (NFLIS) 2022 Annual Report, fentanyl was the 3rd most frequently identified drug and accounted for 13.81% of all drugs reported by forensic laboratories.

The Department conducted studies to determine the prevalence of fentanyl in regulated drug testing specimens and examined the current state of the technology available to HHS-certified laboratories for initial and confirmatory testing of fentanyl and norfentanyl. A review of the literature was conducted to identify peer-reviewed publications that reported concentrations of fentanyl and/or norfentanyl in urine and oral fluid, to determine whether the current initial and confirmatory test technologies available in HHS-certified laboratories are appropriate for testing for fentanyl and/or norfentanyl and to assist in decisions regarding appropriate cutoff concentrations.

Fentanyl Prevalence

When the Department assessed fentanyl prevalence, two HHS-certified laboratories offered urine testing for fentanyl upon request of a Federal agency or an MRO. Data from the NLCP included six laboratory-reported positive test results from 52 requests for fentanyl testing from January 1, 2017, through December 31, 2022. Three of the specimens were also positive for at least one other drug: two specimens were positive for Δ9THCC, and one was positive for other opioids (*i.e.,* hydrocodone, hydromorphone) in addition to fentanyl.

The Department also gathered information through a query of HHS-certified laboratories that perform fentanyl and norfentanyl testing (urine and/or oral fluid) for non-regulated clients (*e.g.,* workplace testing, compliance testing of healthcare providers) and through pulse testing studies (*i.e.,* retesting several deidentified federally regulated urine specimens using the laboratory's fentanyl and norfentanyl testing procedures). Based on information from non-regulated workplace drug testing and the pulse testing studies, it is estimated that approximately 0.27–0.37% of submitted Federal workplace urine specimens will screen positive during initial testing and 0.1 to 0.3% will confirm positive for fentanyl and/or its primary metabolite norfentanyl. Additionally, a recent pulse testing study showed that norfentanyl was 36% more prevalent than 6-acetylmorphine in specimens with a positive opiate initial test.

Of the total 118 commenters, 115 supported the addition of fentanyl to the authorized drug testing panels. Most commenters noted the prevalence of fentanyl use and overdoses, based on their professional or personal experience, and the threat to workplace and public safety, particularly in transportation industries. Of the three individuals who disagreed: one incorrectly stated that fentanyl would be detected and reported using current opioid tests for Federal agency urine specimens; one incorrectly indicated that fentanyl would only be detected within a few hours of use; and the third disagreed with any additional Federal regulations for truck drivers.

The Department considered all comments and has added fentanyl to the urine and oral fluid drug testing panels and added its metabolite norfentanyl to the urine drug testing panel. Until the effective date of the new drug testing panel, fentanyl and/or norfentanyl can be analyzed under the Mandatory Guidelines only upon request of a Federal agency for a reasonable suspicion or post-accident specimen or routinely with a waiver from the Secretary (in accordance with Section 3.2 of the UrMG and OFMG). A detailed discussion is provided below.

Fentanyl Analyte Selection and Cutoff Determination—Urine

Information provided by HHS-certified laboratories in 2023 indicated that a majority (84%) of the laboratories analyzed non-regulated workplace specimens for fentanyl and/or norfentanyl, and that all had the ability to analyze urine specimens for fentanyl with sufficiently sensitive detection limits using commercially available immunoassay kits and confirmatory test instrumentation commonly used in HHS-certified laboratories. The laboratories' initial test cutoffs ranged from 0.5 to 2 ng/mL for fentanyl and confirmatory test cutoffs for fentanyl and norfentanyl ranged from 0.5 to 2 ng/mL for fentanyl and 0.5 to 5 ng/mL for norfentanyl.

Fentanyl and norfentanyl prevalence and concentrations appear to vary considerably depending on the population studied and the applied cutoff. Laboratory data from non-regulated workplace drug testing are around 1% fentanyl positivity in urine. The median, mean and max fentanyl concentrations were 12.6 ng/mL, 257.5 ng/mL and 36,199 ng/mL, respectively. Norfentanyl concentrations were reported to be around 4 times higher than those of fentanyl.[11] A recent pulse testing study on regulated urine workplace specimens showed that norfentanyl concentrations were 5.5 times higher than fentanyl concentrations (median, Q1–Q3, 2.5–13.3 times higher).[12] The median fentanyl and norfentanyl concentrations were 159 and 1,521 ng/mL, respectively. In a large study of 1 million urine specimens conducted by healthcare professionals for routine care, the positivity rate for fentanyl was 1.4% (13,770 specimens) using cutoffs of 2 ng/mL for fentanyl and 8 ng/mL for norfentanyl.[13] Using immunoassay screening and a GC–MS confirmatory test cutoff of 1 ng/mL, fentanyl was positive in 4.2% (458 specimens) of specimens among patients being treated for pain conditions.[14] The median, mean, and range of fentanyl concentrations were 23 ng/mL, 87 ng/mL, and 1 to 2382 ng/mL, respectively. Another study of patients with chronic pain demonstrated that norfentanyl can be an important component of identifying people who use fentanyl when urine is the specimen matrix.[15] The authors showed that including norfentanyl increased the number of positive specimens by 42% over analyzing for fentanyl alone. The fentanyl median, mean and range concentrations were 22 ng/ml, 59.2 ng/mL, and 0.5 to 596 ng/mL, respectively.

Norfentanyl median, mean and range concentrations were 25.5 ng/mL, 134 ng/mL, and 0.5 to 1,772 ng/ml, respectively. A study of 77,018 urine specimens from patients treated with fentanyl using a transdermal patch reported median and mean fentanyl concentration of 37 and 88 ng/mL.[16] When comparing doses of 12 and 100 µg/h, the mean fentanyl concentration increased from 32 to 137 ng/mL, and the norfentanyl mean concentration increased from 176 to 695 ng/mL, illustrating the dose-response relationships.

Based on this information, the Department originally proposed a 1 ng/mL initial test cutoff for both fentanyl and norfentanyl in urine, with a 0.5 ng/mL confirmatory test cutoff for both analytes.

Ten commenters disagreed with adding norfentanyl as an initial test analyte for urine. Nine of these specifically disagreed with norfentanyl as an initial test analyte, noting that no current FDA-cleared immunoassay has sufficient cross-reactivity for fentanyl and norfentanyl to meet the program requirement for grouped analytes (*i.e.,* at least 80% cross-reactivity to the non-target analyte). One commenter suggested that the Department lower the cross-reactivity requirement to 5%, noting that norfentanyl is often at higher concentrations than fentanyl. One suggested including fentanyl as the initial test analyte and norfentanyl only as a confirmatory test analyte, noting it is a Schedule II drug because it is used in the synthesis of fentanyl, and is not a pharmacologically active metabolite or a separate drug of misuse.

Nine commenters addressed the proposed 1 ng/mL fentanyl initial test cutoff for urine. Of these, one agreed with the fentanyl cutoff, noting that current FDA-cleared immunoassays used for initial testing can meet this cutoff. Eight commenters disagreed, stating that a 1 ng/mL cutoff is beyond the limits of traditional immunoassay technologies, and that laboratories would not be able to meet the UrMG requirement for initial test controls targeted at 25% above and below the cutoff. One commenter suggested a lower cutoff (0.75 ng/mL) but did not provide supporting information. The Department notes that there is a commercial immunoassay at this cutoff.

Regarding the proposed confirmatory test analytes and cutoffs, one commenter agreed with testing both fentanyl and norfentanyl using the proposed 0.5 ng/mL cutoff. Two other commenters agreed with norfentanyl as a confirmatory test analyte but disagreed with the proposed cutoff. One of these commenters provided 2022–2023 data from non-regulated drug testing showing that only 1.6% of specimens had results below 1.0 ng/mL, while more than 50% had results above 100 ng/mL for fentanyl and above 1000 ng/mL for norfentanyl. The commenter did not indicate the initial test cutoff(s) used for these specimens. An initial test cutoff of 1 or 2 ng/mL could explain the low percentage of confirmatory test results below 1 ng/mL.

One commenter disagreed with the proposed fentanyl cutoffs for both initial and confirmatory testing, stating the cutoffs were too low and would present legal challenges due to long elimination times in urine following fentanyl use. The commenter noted that there are no controlled studies in the literature on this topic. Concerns were based on a laboratory's reports of six cases involving norfentanyl >0.5 ng/mL for at least one month after self-reported cessation of fentanyl use, and two other studies indicating possible long elimination time based on positive results after self-reported cessation of fentanyl use by individuals with opioid use disorder.[17]

The Department considered all comments. Regarding initial test analyte selection, the Department agrees with commenters that, at the time of this writing, most commercial immunoassays for fentanyl in urine are calibrated to fentanyl and exhibit little cross-reactivity to norfentanyl. The Department is aware of one immunoassay for fentanyl that has 5–7% cross-reactivity to norfentanyl and another immunoassay for norfentanyl in urine with a 5 ng/mL cutoff (*i.e.,* above the cutoff specified in the drug testing panel). As detailed above, HHS-certified laboratory test information, the pulse testing study, and review of fentanyl and norfentanyl concentrations from other tested populations demonstrate the importance of testing for norfentanyl.

To facilitate implementation of fentanyl testing into Federal workplace drug testing programs, the Department has decided to include only fentanyl (not norfentanyl) as the sole initial test analyte for urine at a cutoff of 1 ng/mL and require a fentanyl immunoassay initial test to exhibit at least 5% cross-reactivity for norfentanyl. The Department also increased the proposed 0.5 ng/mL confirmatory test cutoffs to 1 ng/mL for both fentanyl and norfentanyl. These changes are consistent with the current initial and confirmatory test technologies already available in HHS-certified laboratories and detailed in the current scientific literature.

Fentanyl Analyte Selection and Cutoff Determination—Oral Fluid

Information provided by HHS-certified urine laboratories in 2023 indicated that 43% offered oral fluid testing to non-regulated workplace clients and that 71% of these laboratories offered testing for fentanyl. These laboratories indicated they had the ability to analyze oral fluid specimens for fentanyl with sufficiently sensitive detection limits using commercially available immunoassay kits and confirmatory test instrumentation commonly used in HHS-certified laboratories. The laboratories' initial test cutoffs ranged from 1 to 4 ng/mL for fentanyl and confirmatory test cutoffs for fentanyl ranged from 0.5 to 1 ng/mL for fentanyl.

Fentanyl has been detected in oral fluid in non-regulated workplace drug testing, patients receiving pain management, overdose cases, and driving under the influence of drugs (DUID) cases. Laboratory data from non-regulated workplace drug testing show around 4% fentanyl positivity in oral fluid. The median, mean and max fentanyl concentrations were 8.6 ng/mL, 55.7 ng/mL and 17,409 ng/mL, respectively.[11] The median norfentanyl concentration was 4.5 ng/mL. For DUID testing, cutoffs of 1 ng/mL for the initial test and 0.5 ng/mL for the confirmatory test have been recommended for fentanyl in oral fluid.[18] In a study of people arrested for DUID, 59% of oral fluid specimens had concentrations above 20 ng/mL.[19] In a large study, oral fluid specimens were collected from 6,441 patients receiving pain care and screened by immunoassay (1 ng/mL fentanyl cutoff) and confirmed by LC–MS/MS.[20] Of the collected specimens, 6.9% screened positive (443 specimens) and 98.4% of those (436 specimens) were confirmed positive. The fentanyl, median, mean, and range concentrations were, 6.6, 49.8, and 0.2 to 5,341.3 ng/mL, respectively. For the 148 confirmed positive norfentanyl specimens, the norfentanyl median, mean, and range concentrations were 1.6, 4.7, and 0.5 to 125 ng/mL, respectively. In a study of patients treated with buprenorphine, the prevalence of fentanyl in oral fluid was 2.9% (n=146) with a median concentration of 1.3 ng/mL (Q1–Q3, 0.4–10.4).[21] In a study of patients wearing fentanyl patches (n=162), the median fentanyl concentration was around 5 ng/mL, range 0.012–38.4 ng/mL.[22]

Based on this information and review of the scientific literature, the Department originally proposed fentanyl as the only analyte for oral

fluid, with a 1 ng/mL initial test cutoff and a 0.5 ng/mL confirmatory test cutoff.

Three commenters disagreed with testing fentanyl in oral fluid noting that, because there are no FDA-cleared immunoassays meeting program requirements, inclusion of fentanyl would delay implementation of oral fluid into Federal workplace drug testing programs. One of these commenters raised concern that the added burden and cost to develop and implement an alternate technology initial test (*e.g.,* LC–MS/MS) would deter some laboratories from applying for oral fluid certification. Another commenter noted that, unless the regulatory process is streamlined, HHS will not be able to respond quickly to changes in drug use.

One commenter agreed with the proposed 1 ng/mL fentanyl initial test cutoff for oral fluid, while 10 commenters disagreed. Most commenters were concerned that the cutoff was too low, stating that oral fluid collection devices containing a buffer (*i.e.,* diluting the oral fluid) would not be able to meet program analytical requirements (*e.g.,* controls at 25% above and below the initial test cutoff). Many of the commenters indicated that a higher cutoff is supported by drug test results. One commenter suggested raising the cutoff: suggesting that the Department select a cutoff between 2 and 4 ng/mL. Two commenters requested research supporting the proposed 1 ng/mL initial test cutoff and 0.5 confirmatory test cutoff. This information is provided above. One commenter recommended a lower initial test cutoff (0.75 ng/mL) and a higher confirmatory cutoff (5 ng/mL), with no scientific support.

The Department has considered all comments and has decided to increase the initial test cutoff to 4 ng/mL and the confirmatory test cutoff for fentanyl to 1 ng/mL. Based on information provided by the public, review of the scientific literature, and current methods and technologies used for oral fluid drug testing, the Department has determined that these fentanyl cutoffs are appropriate for initial and confirmatory tests.

Revised Criteria for Grouped Analytes Using an Alternate Technology Initial Drug Test

The Department defines grouped initial test analytes as two or more analytes that are in the same drug class and have the same initial drug test cutoff. Footnote 1 of the drug testing panel specifies requirements for initial tests using immunoassay and those using an alternate technology (*e.g.,* liquid chromatography-tandem mass spectrometry, LC–MS/MS). The Department has revised Footnote 1 of the Section 3.4 tables in the UrMG and OFMG to include more specific and updated criteria for alternate technology initial drug tests, based on current technology and program experience.

For a technology other than immunoassay that measures a response from the entire group without differentiating between analytes (*e.g.,* an activity-based assay, a mass spectrometric assay that does not differentiate isobaric compounds), the laboratory must compare the result to the initial test cutoff. In the case of an alternate technology that differentiates and quantifies each analyte in the group, the laboratory must compare each analyte's result to the confirmatory test cutoff and reflex specimens with a positive initial test result to confirmatory testing.

Biomarker Testing Panel

Section 3.4 of the UrMG and OFMG call upon the Secretary to add biomarkers to the biomarker testing panel; however, at the time of this writing, no biomarkers have been approved for Federal workplace drug testing. The Department will review and approve biomarkers based on laboratory data and support from the scientific and medical literature and add them to the biomarker testing panel in a subsequent FRN.

A biomarker is defined in Section 1.5 of the UrMG and OFMG as ''an endogenous substance used to validate a biological specimen''. While creatinine in urine meets this definition, it is not sufficient as a sole analyte. The UrMG include requirements for testing both creatinine and specific gravity to report a specimen as dilute, invalid, or substituted.

Costs and Benefits

HHS-certified test facilities and MROs will incur initial costs for administrative and programming changes for the addition of fentanyl and/or norfentanyl.

Laboratories that already offer fentanyl and norfentanyl testing and use the same cutoff(s) for their non-regulated clients may experience some savings compared to laboratories that do not test for these analytes. Estimated costs for testing for fentanyl range from $0.23 to $5.00 (for initial testing) and $8.00 to $25.00 (for confirmatory testing) per specimen tested. Total laboratory costs for fentanyl confirmatory testing of Federal employee specimens are estimated to range from $577–$4,750. Based on the number of tests performed on Federal employees, the added cost for fentanyl confirmatory testing will be $0.0152 to $0.125 per submitted specimen, and the total cost for adding fentanyl will range from $9,317 to $194,750, based on these estimates.

MROs may experience increased costs when an agency chooses to test their federal job applicants and employees for the added analytes, as fentanyl analytes are expected to have high positivity rates and, in addition, fentanyl is a Schedule II drug with approved therapeutic uses requiring the MRO to review potential medical explanations. Additional costs for testing and MRO review will be incorporated into the overall costs for the Federal agency submitting the specimen to the laboratory. Added costs to MROs would be expected to shift to Federal agencies over time, as existing contracts expire, and new contract terms are negotiated.

Currently, the Department does not require HHS-certified test facilities to implement authorized biomarker tests. Each laboratory and IITF should conduct their own cost analysis when deciding whether to offer biomarker testing to federally regulated clients. The Department will consider costs when deciding whether to require all certified test facilities to test for a specific biomarker.

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Report Nomenclature—Urine

Urine	
Abbreviation	Analyte
Δ9THCC	Δ-9-tetrahydrocannabinol-9-carboxylic acid.
BZE	Benzoylecgonine.
COD	Codeine.
MOR	Morphine.
HYC	Hydrocodone.
HYM	Hydromorphone.
OXYC	Oxycodone.
OXYM	Oxymorphone.
6-AM	6-Acetylmorphine.
PCP	Phencyclidine.
FENT	Fentanyl.
NFENT	Norfentanyl.
AMP	Amphetamine.
MAMP	Methamphetamine.
MDMA	Methylenedioxymethamphetamine.
MDA	Methylenedioxyamphetamine.

HHS Drug Testing Panel—Urine

Initial test analyte	Initial test cutoff [1]	Confirmatory test analyte	Confirmatory test cutoff
Marijuana metabolite (Δ9THCC)	50 ng/mL.	Δ9THCC	15 ng/mL.
Cocaine metabolite (Benzoylecgonine)	150 ng/mL.[2]	Benzoylecgonine	100 ng/mL.
Codeine/Morphine	2,000 ng/mL.	Codeine	2,000 ng/mL.
		Morphine	4,000 ng/mL.
Hydrocodone/Hydromorphone	300 ng/mL.	Hydrocodone	100 ng/mL.
		Hydromorphone	100 ng/mL.
Oxycodone/Oxymorphone	100 ng/mL.	Oxycodone	100 ng/mL.
		Oxymorphone	100 ng/mL.
6-Acetylmorphine	10 ng/mL.	6-Acetylmorphine	10 ng/mL.
Phencyclidine	25 ng/mL.	Phencyclidine	25 ng/mL.
Fentanyl [3]	1 ng/mL.	Fentanyl	1 ng/mL.
		Norfentanyl	1 ng/mL.
Amphetamine/Methamphetamine	500 ng/mL.	Amphetamine	250 ng/mL.
		Methamphetamine	250 ng/mL.
MDMA/MDA	500 ng/mL.	Methylenedioxymethamphetamine	250 ng/mL.
		Methylenedioxyamphetamine	250 ng/mL.

[1] *For grouped analytes* (*i.e.,* two or more analytes that are in the same drug class and have the same initial test cutoff):
Immunoassay: The test must be calibrated with one analyte from the group identified as the target analyte. The cross-reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.

Alternate technology: Either one analyte or all analytes from the group must be used for calibration, depending on the technology. For a technology that measures a response from the entire group without differentiating between analytes (*e.g.,* an activity-based assay, a mass spectrometric assay that does not differentiate isobaric compounds), the laboratory must compare the result to the initial test cutoff. In the case of an alternate technology that differentiates and quantifies each analyte in the group, the laboratory must compare each analyte's result to the confirmatory test cutoff and reflex specimens with a positive initial test result to confirmatory testing.

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

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

HHS Biomarker Testing Panel—Urine

SAMHSA has not yet authorized routine testing for any biomarker in urine. HHS-certified laboratories and instrumented initial test facilities (IITFs) may request authorization to test Federal agency specimens for a biomarker upon Medical Review Officer (MRO) request by submitting supporting documentation and assay validation records to the National Laboratory Certification Program (NLCP) for SAMHSA review and approval.

REPORT NOMENCLATURE—ORAL FLUID

Oral fluid	
Abbreviation	Analyte
Δ9THC	Δ-9-tetrahydrocannabinol.
COC	Cocaine.
BZE	Benzoylecgonine.
COD	Codeine.
MOR	Morphine.
HYC	Hydrocodone.
HYM	Hydromorphone.
OXYC	Oxycodone.
OXYM	Oxymorphone.
6-AM	6-Acetylmorphine.
PCP	Phencyclidine.
FENT	Fentanyl.
AMP	Amphetamine.
MAMP	Methamphetamine.
MDMA	Methylenedioxymethamphetamine.
MDA	Methylenedioxyamphetamine.

HHS DRUG TESTING PANEL—ORAL FLUID

HHS drug testing panel—undiluted (neat) oral fluid			
Initial test analyte	Initial test cutoff [1]	Confirmatory test analyte	Confirmatory test cutoff
Marijuana (Δ9THC)	4 ng/mL.	Δ9THC	2 ng/mL.
Cocaine/Benzoylecgonine	15 ng/mL.	Cocaine	8 ng/mL.
		Benzoylecgonine	8 ng/mL.
Codeine/Morphine	30 ng/mL.	Codeine	15 ng/mL.
		Morphine	15 ng/mL.
Hydrocodone/Hydromorphone	30 ng/mL.	Hydrocodone	15 ng/mL.
		Hydromorphone	15 ng/mL.
Oxycodone/Oxymorphone	30 ng/mL.	Oxycodone	15 ng/mL.
		Oxymorphone	15 ng/mL.
6-Acetylmorphine	4 ng/mL.[2]	6-Acetylmorphine	2 ng/mL.
Phencyclidine	10 ng/mL.	Phencyclidine	10 ng/mL.
Fentanyl	4 ng/mL.	Fentanyl	1 ng/mL.
Amphetamine/Methamphetamine	50 ng/mL.	Amphetamine	25 ng/mL.
		Methamphetamine	25 ng/mL.
MDMA/MDA	50 ng/mL.	Methylenedioxymethamphetamine	25 ng/mL.
		Methylenedioxyamphetamine	25 ng/mL.

[1] *For grouped analytes* (*i.e.,* two or more analytes that are in the same drug class and have the same initial test cutoff):

Immunoassay: The test must be calibrated with one analyte from the group identified as the target analyte. The cross reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.

Alternate technology: Either one analyte or all analytes from the group must be used for calibration, depending on the technology. For a technology that measures a response from the entire group without differentiating between analytes (e.g., an activity-based assay, a mass spectrometric assay that does not differentiate isobaric compounds), the laboratory must compare the result to the initial test cutoff. In the case of an alternate technology that differentiates and quantifies each analyte in the group, the laboratory must compare each analyte's result to the confirmatory test cutoff and reflex specimens with a positive initial test result to confirmatory testing.

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

HHS Biomarker Testing Panel—Oral Fluid

SAMHSA has not yet authorized routine testing for any biomarker in oral fluid. HHS-certified laboratories may request authorization to test Federal agency specimens for a biomarker by submitting supporting documentation and assay validation records to the National Laboratory Certification Program (NLCP) for SAMHSA review and approval. Authorized biomarker test cutoffs for oral fluid will be based on undiluted (neat) oral fluid.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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