Frequently Asked Questions for the Public

The Revised Mandatory Guidelines for Federal Workplace Drug Testing using Urine

Drugs to be tested

Question

What is the difference between opiates and opioids?

Answer

The term "opiates" is used to describe naturally occurring substances known as alkaloids derived from the opium poppy plant (e.g., codeine; morphine; and heroin, which is produced by the acetylation of morphine) that bind to specific receptors in the central nervous system and have analgesic as well as narcotic effects.

The term "opioids" has expanded in scope over time and is used broadly to describe various compounds that bind to specific receptors in the central nervous system and have analgesic as well as narcotic effects. The broadly used term "opioids" includes naturally occurring alkaloid compounds known as opiates (e.g., codeine, morphine, and heroin); semi-synthetic compounds (e.g., oxycodone, oxymorphone, hydrocodone, and hydromorphone); and synthetic compounds (e.g., fentanyl). Opioids may or may not have structural similarity to the opium alkaloids.

Source

Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs, Appendix A: Glossary

Question

Why were these four opioids chosen?

Answer

The inclusion of additional Schedule II prescription medications (i.e., oxycodone, oxymorphone, hydrocodone and hydromorphone) in the list of authorized drug tests was recommended by the Drug Testing Advisory Board (DTAB), reviewed by the Department's Prescription Drug Subcommittee of the Behavioral Health Coordinating Committee, and received by the SAMHSA Administrator in January 2012. The inclusion of oxycodone, oxymorphone, hydrocodone and hydromorphone in the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG or Mandatory Guidelines) is supported by various data and seen in private sector experience with current drug abuse trends. HHS is continuing its efforts to prevent opioid addiction in support of President Trump's commitment to combat the opioid crisis. The long-term impact of implementing these revised guidelines will help ensure safety in the workplace, especially in national security, public health, and public safety occupations that interact directly with the public

Question

Will this detect heroin?

Answer

Yes. Currently, the drug test panel tests for the metabolite of heroin (6-acetylmorphine). The current revisions to the Mandatory Guidelines do not require changes to the testing for 6-acetylmorphine that is currently being performed.

Source

Mandatory Guidelines for Federal Workplace Drug Testing, Section 3.4

Question

Will this detect fentanyl?

Answer

No, testing for the synthetic opioid, fentanyl, is not included in the revised urine Mandatory Guidelines, effective on October 1, 2017. Fentanyl can be tested on a case-by-case basis under the Mandatory Guidelines, and the Division of Workplace Programs (DWP) is proposing to study the prevalence rate of fentanyl in regulated specimens in the next 2 months.

Question

Are the laboratories prepared for the changes required under the Mandatory Guidelines?

Answer

Yes. Certified laboratories in the National Certification Laboratory Program (NLCP) have been challenged with performance tests (PT) in the past year. The laboratories received 1 Practice Sample Set in March 2017, and 3 Qualifying PT Sets in May, mid-June, and late July. A post-implementation PT set will be sent to the laboratories after October 1, 2017. In addition, the reliability of the laboratories to meet Guideline requirements will be assessed every 3 months through maintenance PT sets. We do not anticipate any significant delays in test results for current federal employees or for individuals applying for federal employment.

Impacts to employees and/or potential employees

Question

How many federal employees are in testing designated positions? Which occupations?

Answer

The Drug Free Workplace Program covers all civilian employees in the Executive Branch agencies. However, only Testing Designated Positions (TDPs) are subject to random testing and these include any positions where a momentary lapse in judgment could result in a catastrophic event that could not be remediated by the administrative process. These are positions with public health, public safety and

national security responsibilities. Due to differences in agency missions, structure and budget, TDPs differ among agencies. Generally speaking, there are approximately 400,000 employees in testing designated positions. See 2013 Guidance for the Selection of Tested Designated Positions for more information.

Source

2013 Guidance for the Selection of Tested Designated Positions
(https://www.samhsa.gov/workplace/workplace-programs)

Question

How do I find out if this affects me or my agency?

Answer

The revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine cover all civilian employees in the Executive Branch agencies. Employees should contact their federal agency (employer) for this information or refer to their employer's Drug Free Workplace Program plan. Or contact: Drug Free Workplace Program (DFWP) Helpline 1-800-967-5752.

Source

2013 Guidance for the Selection of Tested Designated Positions
(https://www.samhsa.gov/workplace/workplace-programs)

Question

If my doctor prescribed my opioid medication and I tested positive for opioids, will the results of my positive drug test be reported to my federal employer?

Answer

Positive drug testing results that are explained by a legitimate medical explanation, such as a valid prescription, will not be reported to a federal agency.

Source

Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs

Question

What if I test positive for a prescription opioid but do not have a valid prescription?

Answer

If a positive drug test result is not supported by a legitimate medical explanation, such as a valid prescription, the positive drug test result should be reported to the employee's federal agency in accordance with the Mandatory Guidelines.

Question

Do drug test results under the Mandatory Guidelines determine an employee's fitness for duty?

Answer

No, the Mandatory Guidelines are designed to detect an employee's illicit drug use while on or off duty.

Impact on public safety

Question

How will these guidelines affect public safety?

Answer

The Drug Free Workplace Program covers all civilian employees in the Executive Branch agencies. In general, Testing Designated Positions (TDPs) are positions where a momentary lapse in judgment could result in significant harm. Due to differences in agency missions, structure and budget, TDPs differ among agencies. See 2013 Guidance for the Selection of Tested Designated Positions. Currently most TDPs are in Top Secret or above clearance. The revisions to the Mandatory Guidelines are intended to enhance public safety.

Impact to non-federal employees

Answer

The Mandatory Guidelines address federal employees.

Privacy issues

Question

Do HHS Certified Laboratories keep records regarding who tests positive and who is using what drugs?

Answer

Personal identifiable drug testing information is maintained by HHS-certified laboratories for a period of time in accordance with Mandatory Guidelines requirements. Thereafter, total laboratory confirmed positive results (without personal identifiable information) for each drug will be recorded in aggregate form.

Source

DWP Staff, 240-276-2600 (Workplace Helpline)

Question

What is the authority for the federal drug-free workplace program?

Answer

Executive Order 12564 and Title V, Section 503 of Public Law 100-71 authorize the Substance Abuse and Mental Health Services Administration to conduct the following activities:

- Promulgate scientific and technical guidelines for drug testing programs under Executive Order 12564;
- Establish comprehensive standards for all aspects of laboratory drug testing and laboratory procedures to be applied in carrying out Executive Order 12564;
- Specify the drugs for which Federal employees may be tested; and
- Establish appropriate standards and procedures for periodic review of laboratories and criteria for certification and revocation of certification of laboratories to perform drug testing in carrying out Executive Order 12564.

Source

E.O. 12564 and P.L. 100-71

Other Topics

Question

How will these guidelines help the federal government address the opioid crisis?

Answer

Misuse and abuse of psychotherapeutic prescription drugs, including opioid pain relievers, are issues of concern for all populations regardless of age, gender, ethnicity, race, or community. Recent data show that opioid-related overdose deaths in the United States now outnumber overdose deaths involving all illicit drugs such as heroin and cocaine combined. In addition to overdose deaths, emergency department visits, substance treatment admissions and economic costs associated with opioid abuse have all increased in recent years. These guidelines will help deter the illicit use of opioid drugs and can incentivize federal employees to seek opioid use disorder treatment. In this way, the Guidelines will further the Department activities in continuing to work with partners at the federal, state, and local levels to implement policies and programs to reduce prescription drug use and improve public health. Specifically, the Guidelines will screen for illicit opioid use among federal employees in safety sensitive positions with multiple agencies.

Frequently Asked Questions for Industry

Question

If an applicant or employee is unable to provide 45 mL of urine for a drug test, can they submit to and provide an oral fluid specimen?

Answer

At this time, oral fluid is not approved as a federal drug testing specimen. Oral Fluid Mandatory Guidelines have been proposed (May 15, 2015; 80 FR 28101), but final Guidelines have not been published. The UrMG do not authorize oral fluid as an alternative specimen: references to the use of an alternate specimen type (e.g., oral fluid) are not applicable until final Guidelines have been implemented for the use of the alternate specimen type (see UrMG Section 8.7). UrMG Sections 8.5 and 8.6 include the steps to be taken when 45 mL urine is not collected.

Source

UrMG Sections 8.5 and 8.6

Question

What is the difference between an "Observer," who observes the collection, and "Monitor," who monitors the collection?

Answer

An Observer is the person assigned to observe the collection of the specimen for a 'direct observed' collection according to UrMG Section 8.10. The observer's gender must be the same as the donor's (which is based on the donor's gender identity). The observer is not required to be a trained collector, but must be trained as an observer. An observed collection is described in UrMG Section 8.9. It is the same as a routine collection except the observer is in the restroom or stall and watches the urine pass from the body of the donor to the collection container. The observer maintains visual contact with the specimen until the donor hands the container to the collector. The collection container cannot be handled by the observer unless the observer is also serving as the collector.

A Monitor is the person assigned to monitor collection of the specimen for a 'monitored' collection according to UrMG section 8.12. The monitor's gender must be the same as the donor's (which is based on the donor's gender identity), unless the monitor is a medical professional. The monitor is not required to be a trained collector. A monitored collection is described in UrMG Section 8.11. It is the same as a routine collection except the monitor provides visual privacy while being alert for signs of tampering. The monitor must not touch or handle the collection container, unless the monitor is also serving as the collector, and must not watch the donor urinate into the collection container.

Source

UrMG Sections 8.9-8.12; Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs, Appendix A: Glossary

Question

What is the rationale for why the definition of opiates vs. opioids changed? Earlier, "opiates" was the umbrella category, and now "opioids" is the umbrella category that refers to both opiates and opioids.

Answer

The term "opiates" is used to describe naturally occurring substances known as alkaloids derived from the opium poppy plant (e.g., codeine; morphine; and heroin, which is produced by the acetylation of morphine) that bind to specific receptors in the central nervous system and have analgesic as well as narcotic effects.

The term “opioids” has expanded in scope over time and is used broadly to describe various compounds that bind to specific receptors in the central nervous system and have analgesic as well as narcotic effects. The broadly used term “opioids” includes naturally occurring alkaloid compounds known as opiates (e.g., codeine, morphine, and heroin); semi-synthetic compounds (e.g., oxycodone, oxymorphone, hydrocodone, and hydromorphone); and synthetic compounds (e.g., fentanyl). Opioids may or may not have structural similarity to the opium alkaloids.

Source

Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs, Appendix A: Glossary

Question

If notification is not received from the federal agencies of when they will expand their drug testing panel to include the four semi-synthetic opioids (oxycodone, oxymorphone, hydrocodone, hydromorphone), are federal specimens to be tested as currently stated on or after October 1, 2017, with the exception of removal of MDEA?

Answer

SAMHSA provided guidance to HHS-certified laboratories to clarify testing of federal agency specimens as of October 1, 2017:
1. Implement the revised pH cutoff for federal agency specimens.
2. Discontinue testing federal specimens for MDEA.
3. If a federal agency client has NOT notified the laboratory of its decision on when to begin testing the added opioids, the laboratory should contact the federal agency or Medical Review Officer.

HHS-certified laboratories, applicant laboratories, Responsible Persons, and Medical Review Officers were sent NLCP Notices on August 18, 2017, September 8, 2017, and September 27, 2017 to clarify testing for federal agency specimens.

Source

August 18, 2017 and September 8, 2017, and September 27, 2017 NLCP Notices to HHS-Certified and Applicant Laboratories and NLCP Inspectors

Question

Will the pH decision point change be required on October 1, 2017, or at a date after October 1, 2017 specified by notice from each federal agency?

Answer

The revised pH cutoff must be implemented on October 1, 2017. On August 18, 2017 NLCP Notices were sent to HHS-certified and applicant laboratories and NLCP Inspectors.

Source

August 18 2017 NLCP Notice to HHS-Certified and Applicant Laboratories and NLCP Inspectors

Question

What are the privacy requirements when a urine specimen is collected?

Answer

The following privacy requirements apply when a donor is providing a urine specimen:
(a) Only authorized personnel and the donor may be present in the restricted access area where the collection takes place. (b) The collector is not required to be the same gender as the donor. The gender of the observer for purposes of a direct observed collection (i.e., as described in Section 8.10) must be the same as the donor's gender, which is determined by the donor's gender identity. The gender of the monitor for a monitored collection (i.e., as described in Section 8.12) must be the same as the donor's gender, unless the monitor is a medical professional (e.g., nurse, doctor, physician's assistant, technologist, or technician licensed or certified to practice in the jurisdiction in which the collection takes place).
The collector for an observed collection asks the donor to identify the donor's gender on the Federal Custody and Control Form (CCF) and initial it. The collector will then select an observer whose gender matches the donor's gender recorded on the Federal CCF. The collector documents the observer's name and gender on the Federal CCF. The same procedure is used to select the monitor for a monitored collection unless the monitor is a medical professional.

Source

UrMG Sections 8.1, 8.10, and 8.12

Question

What is considered 1) a valid prescription and, 2) a legitimate medical explanation when dealing with testing for the four semi-synthetic opioids (oxycodone, oxymorphone, hydrocodone, hydromorphone)?

Answer

Valid Prescription: When reviewing the positive test result, the MRO will take all reasonable and necessary steps to verify the authenticity of all medical records and other medical information provided by the donor that may be relevant to the medication being prescribed. The MRO should use reasonable medical judgment to make the decision that the provided prescription was generated in response to the donor's current medical condition. Contact with the prescribing physician may be helpful for the MRO in coming to this decision if the donor has provided any consent that may be required. There are many critical components on how a prescription may be verified. This can be accomplished by the combination of the following: photos sent by text, e-mail, or fax showing enough angled shots of the bottle label that the MRO can verify the name of the donor on the label, prescription number, name of the drug, prescribing physician, date filled, number of pills in the prescription, number of refills, and the pharmacy name, address, and contact information. Equally effective is a verification call to the pharmacy (after the MRO has verbally obtained the information in the item above from the donor and documented it on the MRO record). Additionally, a copy of a pharmacy printout showing the medication dispensing history and/or a signed statement from, or phone discussion with, the prescribing physician. In all cases, the MRO should verify that the contact was with the prescribing physician. As an example, the MRO may request the physician's state license number or DEA number. For additional security, the MRO may obtain the physician's telephone number from another source (e.g., online search) and call the individual to verify identity.

Legitimate Medical Explanation: When determining whether a legitimate medical explanation exists for a positive test, the MRO may consider whether a medication was used during the time period for which it was legitimately prescribed. If a donor's use was not medically authorized, the specimen will be reported as positive. With respect to Schedule II medications, Schedule II includes drugs or other substances that have high potential for abuse, abuse of which may lead to severe psychological or physical dependence, and that have a currently accepted medical use in treatment in the United States (with or without severe restrictions). An MRO's decision to contact a donor's employer under these circumstances is not required or authorized by the Mandatory Guidelines. Rather, an MRO's decision to contact an employer regarding safety issues related to a donor's valid prescription is subject to the MRO's voluntary choice and any obligations the MRO may have with the donor's employing agency.

Source

Medical Review Officer Guidance Manual for Federal Workplace Drug Testing; Section 4.5

Question

Are agencies authorized to use oral fluids as an alternate drug testing specimen after Oct. 1, 2017?

Answer

At this time, oral fluid is not approved as a federal drug testing specimen. Oral Fluid Mandatory Guidelines have been proposed (May 15, 2015; 80 FR 28101), but final Guidelines have not been published. The UrMG do not authorize oral fluid as an alternative specimen: references to the use of an alternate specimen type (e.g., oral fluid) are not applicable until final Guidelines have been implemented for the use of the alternate specimen type (see UrMG "Background" section of the Preamble and Section 8.7).

Source

UrMG, "Background" section of the Preamble and Section 8.7

Frequently Asked Questions for Policy/Program

Question

Is it within discretion of the federal agencies to decide if and when to expand the list of drugs routinely tested to include the four semi-synthetic opioids (oxycodone, oxymorphone, hydrocodone, hydromorphone)?

Answer

Yes. UrMG Section 3.1 requires federal agencies to test each specimen for marijuana and cocaine, and authorizes federal agencies to test each specimen for opioids, amphetamines, and phencyclidine, as provided under Section 3.4. SAMHSA has strongly recommended the addition of the four semi-synthetic

opioids (oxycodone, oxymorphone, hydrocodone, hydromorphone) and asked that agencies notify their service providers of their decision and, as appropriate, the implementation data, by September 15, 2017.

Source

UrMG Sections 3.1 and 3.4; August 18 2017 NLCP Notice to HHS-Certified and Applicant Laboratories and NLCP Inspectors

Question

Is it the responsibility of the federal agency to contact their service provider or laboratory to request the expanded testing (to include oxycodone, oxymorphone, hydrocodone, hydromorphone)? Must the recommended template titled "Decision Notification for the Addition of Semi-Synthetic Opioids to the Drugs Routinely Tested" provided in the August 16, 2017 letter sent to federal agencies and all HHS-certified laboratories be used?

Answer

Yes, agencies are responsible for advising their service providers.

No, the template is not required and may be used or not used at the agency's discretion. Since some agencies may not be prepared to add the additional analytes by October 1, SAMHSA instructed the agencies to notify their service providers of the date they will begin testing their workplace specimens for these drugs, and provided the template for the agency's use. Subsequently, in a September 8, 2017 Notice, SAMHSA instructed laboratories to contact federal agency clients who had not yet notified the laboratory of their decision.

Source

UrMG Sections 3.1 and 3.4; SAMHSA letter emailed to Drug Program Coordinators on August 16, 2017; September 8, 2017 NLCP Notice to HHS-Certified and Applicant Laboratories and NLCP Inspectors

Question

When will the MRO Manual be revised and how is it to be obtained?

Answer

The revised MRO Guidance Manual has been posted on DWP's website at https://www.samhsa.gov/workplace.

Source

DWP Staff, 240-276-2600 (Workplace Helpline)

Question

What MRO certifications are required for the revised Mandatory Guidelines effective October 1, 2017?

Answer

To continue serving as an MRO for federal agency specimens, certified MROs must complete training on the UrMG prior to the October 1, 2017 effective date.

Source

UrMG Section 13.3

Question

Will federal agencies be required to report drug testing results of the four newly added semi-synthetic opioids (oxycodone, oxymorphone, hydrocodone, hydromorphone)? If so, will the Annual Survey Report be revised to reflect this?

Answer

Yes. The Annual Survey Report has been revised to capture results of the added semi-synthetic opioids.

Source

DWP Staff, 240-276-2600 (Workplace Helpline)

Question

Do federal agencies have to submit their updated/revised Drug Free Workplace Program (DFWP) plans on or before 10/1/2017? Can they be submitted at a later date? Can agencies implement drug testing of oxycodone, oxymorphone, hydrocodone, hydromorphone before their revised plan receives HHS concurrence?

Answer

There is no deadline for agencies to submit updated/revised Drug Free Workplace Program plans, but HHS requests that such plans be submitted as soon as practicable following any substantive changes made to an agency's plan. Review by the Interagency Coordinating Group Executive Committee (ICGEC) is not needed in order for an agency to begin testing for the four semi-synthetic opioids (oxycodone, oxymorphone, hydrocodone, hydromorphone).

Source

DWP Staff, 240-276-2600 (Workplace Helpline)

Question

Is the addition of the four semi-synthetic opioids (oxycodone, oxymorphone, hydrocodone, hydromorphone) to the drug testing panel considered a "substantive change" to an agency plan? Define "substantive change".

Answer

A 'substantive change' is any alteration to a federal agency's drug testing plan that affects the substance of the plan's policy and/or procedures. It does not usually refer to purely editorial or other non-

substantive updates. The addition of the four semi-synthetic opioids to an agency's drug testing plan may constitute a substantive change. Federal agencies should contact DWP staff in order to receive tailored guidance that is specific to each agency's plan.

Question

Should federal agency employees be notified of the additional drugs to be tested?

Answer

Federal agencies should consider, in consultation with their legal counsel, providing notice to federal agency employees of the panel of drugs that they will be tested for. Notably, Executive Order 12564, Section 4(b) states that, "before conducting a drug test, the agency shall inform the employee to be tested for the opportunity to submit medical documentation that may support a legitimate use of a specific drug."

Source

Executive Order 12564, Section 4(b)

SAMHSA Note: These frequently asked questions (FAQs) and answers apply to federal agency drug testing programs that come under Executive Order 12564 dated September 15, 1986, section 503 of Public Law 100-71, 5 U.S.C. section 7301 note dated July 11, 1987, and the Department of Health and Human Services Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (82 FR 7920) dated January 23, 2017 (effective October 1, 2017).

This document does not apply to specimens submitted for testing under U.S. Department of Transportation (DOT) Procedures for Transportation Workplace Drug and Alcohol Testing Programs (49 CFR Part 40).

These FAQs are intended to assist Drug Program Coordinators, Collectors, Laboratory Responsible Persons, Medical Review Officers, and Federal Drug Testing Third Party Administrators in carrying out their responsibilities under the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (82 FR 7920). This guidance does not establish legally enforceable responsibilities, but may reference actions or responsibilities that are required under statutory or regulatory authorities. The use of the word "should" in this guidance means that something is suggested or recommended, but not necessarily required by law.