**STATE OF MAINE**

**SUBSTANCE USE TESTING**

**FOR THE WORKPLACE RULE**

**10-144 CODE OF MAINE RULES**

**Chapter 265**



**Department of Health and Human Services**

**Maine Center for Disease Control and Prevention**

**11 State House Station**

**Augusta, Maine 04333-0011**

**Last Amended:** October 14, 2024

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**SECTION 1.**

**PURPOSE AND DEFINITIONS**

1. **Purpose.** This rule is intended to ensure that employees and applicants receive reliable and accurate testing and ensure that privacy rights are protected.
2. **Definitions.** Definitions in this rule are in addition to definitions in the governing statute. As used in this rule, unless otherwise indicated, the following terms have the following meanings:

**1. Applicant** means any person seeking employment from an employer. The term includes any person using an employment agency's services.

1. **Confirmed positive result** means a result of a confirmation test, as defined in Section 1(B)(7)(b) of this rule, that indicates the presence of a substance of use in accordance with the laboratory protocols at or above the cutoff level.
2. **Employee** means a person who is permitted, required or directed by any employer to engage in any employment for consideration of direct gain or profit.
3. **Employer** means any person, partnership, corporation, association or other legal entity, public or private, that employs one or more employees. The term also includes an employment agency.
4. **Negative test result** means a test result that indicates that:

a. A substance of use is not present in the tested sample; or

b. A substance of use is present in the tested sample in a concentration below the cutoff level.

1. **Non-negative test result** means a test result that indicates the presence of a substance of use in the tested sample at or above the cutoff level of the test.

1. **Substance use test** means any test procedure designed to take and analyze body fluids or materials from the body for the purpose of detecting the presence of substances of use. The term does not include tests designed to determine blood alcohol concentration levels from a sample of an individual's breath.

a. **Screening test** means an initial substance use test performed through the use of immunoassay technology*,* chromatography, mass analysis, enzymatic technology (for blood alcohol),or a test technology of similar or greater accuracy and reliability approved by the Department as specified in this rule, Section 4(H), and which is used as a preliminary step in detecting the presence of substances of use.

b. **Confirmation test** means a second substance use test performed on a separate aliquot of a specimen to identify and quantify a specific drug or drug metabolite and verify the presence of a substance of use indicated by an initial non-negative test result. A confirmation test uses gas chromatography/mass spectrometry or liquid chromatography/mass spectrometry, except that blood alcohol will be confirmed using gas chromatography.

1. **Substance of use** means any scheduled drug, alcohol or other drug, or any of their metabolites.

a. Alcohol has the same meaning as found in 28-A MRS § 2(2)

b. Drug has the same meaning as found in 32 MRS § 13702-A(11).

c.Scheduled drug has the same meaning as found in 17-A MRS § 1101(11).

**SECTION 2.**

**COLLECTION AND STORAGE OF SAMPLES**

**A.** For all testing allowed under this rule, the specimen to be collected must be the employee's or applicant's urine, oral fluids, hair or sweat, except that, as provided by 26 MRS § 683(5), employees may request that a blood sample be collected for testing for alcohol and cannabis (tetrahydrocannabinol and/or metabolites), provided that a laboratory is available to the employer or applicant which is in compliance with all other sections of this rule concerning laboratories, and which offers testing for alcohol or cannabis (tetrahydrocannabinol and/or metabolites) in compliance with this rule. If such a blood sample is requested, the employer may not test any other sample for alcohol or cannabis (tetrahydrocannabinol and/or metabolites).

1. The collection of any sample for use in a substance use test must be conducted in a medical facility and supervised by a physician licensed under 32 MRS chapter 36 or 48, or a nurse licensed under 32 MRS chapter 31. A medical facility includes a first aid station located at the work site.

2. An employer may not require an employee or applicant to remove any clothing for the purpose of collecting a urine sample, except that an employer may require that an employee or applicant leave any personal belongings other than clothing, and any unnecessary coat, jacket, or similar outer garments outside the collection area.

3. No employee or applicant may be required to provide a urine sample while being observed, directly or indirectly, by another individual.

4. Urine samples must be collected in new, clean containers manufactured for the purpose of urine collection. If the employer's policy calls for specimen assessment, the person in charge of collection, may, in the presence of the test subject, measure the temperature of the specimen no later than four minutes after voiding, measure the pH of the specimen, and evaluate the color and odor of the specimen. The container must be sealed and labeled immediately after collection and specimen assessment in a manner which will prevent or reveal tampering with the specimen. Seals must cover the cap and extend over the sides of the container and be initialed by the employee or applicant being tested. The specimen container must be clearly and indelibly labeled with the date and time of collection and the name or other identifier associated with the person from whom the specimen was obtained. Sealing and labeling must occur under the observation of the employee or applicant being tested.

5. Blood specimens, where allowed, must be collected in new vacuum-activated blood collection tubes, with such preservatives as may be specified by the testing laboratory, and must be sealed with tamperproof seals, covering the cap and extending over the sides of the container. Blood samples must be collected by a qualified person in accordance with 26 MRS §683(5)(B). Each specimen container must be clearly and indelibly labeled with the date and time of collection and the name or other identifier associated with the person from whom the specimen was obtained. Sealing and labeling must occur under the observation of the employee or applicant being tested.

6. Oral fluid specimens must be collected in new, clean containers manufactured for the purpose of oral fluid collection. The container must be sealed and labeled immediately after collection in a manner that will prevent or reveal tampering with the specimen. Seals must cover the cap and extend over the sides of the container and be initialed by the employee or applicant being tested. The specimen container must be clearly and indelibly labeled with the date and time of collection and the name or other identifier associated with the person from whom the specimen was obtained. Sealing and labeling must occur under the observation of the employee or applicant being tested.

1. Hair specimens must be collected in new, clean containers manufactured for the purpose of hair specimen collection. The container must be sealed and labeled immediately after collection in a manner that will prevent or reveal tampering with the specimen. Seals must cover the top of the container and extend over the sides of the container and be initialed by the employee or applicant being tested. The specimen container must be clearly and indelibly labeled with the date and time of collection and the name or other identifier associated with the person from whom the specimen was obtained. Sealing and labeling must occur under the observation of the employee or applicant being tested. Hair specimens must be collected using head hair, unless head hair is not available or is not at least one and a half inches long. In those cases, a urine specimen must be collected.
2. Sweat patch specimens must be collected using a patch that has been specifically manufactured for sweat specimen collection. The sweat patch must be sealed within a container and labeled immediately after collection in a manner that will prevent or reveal tampering with the specimen. Seals must cover the top of the container and extend over the sides of the container and be initialed by the employee or applicant being tested. The specimen container must be clearly and indelibly labeled with the date and time of collection and the name or other identifier associated with the person from whom the specimen was obtained. Sealing and labeling must occur under the observation of the employee or applicant being tested.

**B.** Immediately upon collection of each sample, a chain of custody record must be established for that sample, indicating the identity of each person having control over the sample and the times and dates of all transfers or other actions pertaining to the sample. If warranted due to the volume of testing, chain of custody records may be maintained in a logbook or other custody form for multiple specimens, provided the identity of each specimen can be documented.

1. Samples must be transported or shipped promptly to the testing laboratory in a secure fashion, so as to prevent tampering.

2. At the request of the employee or applicant, a portion of the sample collected, sealed, and labeled in accordance with this rule, must be segregated at the time the sample is taken for that person's own testing. This sample must be stored, and chain of custody must be maintained, as provided above. If the employer does not have the capability to store segregated samples for the necessary time period, such storage may be arranged with the licensed testing laboratory performing the employer's analyses, provided that all chain of custody and security requirements are otherwise met. Within five days after notice of the test results is given to the employee or applicant, the employee or applicant must notify the employer of the testing laboratory selected for that person's own testing. The laboratory so selected must comply with all the requirements of this rule relating to testing laboratories. The employer or the employer's laboratory must promptly send the segregated portion of the specimen to the selected laboratory, subject to the same chain of custody and security requirements as observed for the employer's specimen.

**C.** All non-negative specimens must be retained in the original containers in secure storage at appropriate temperature for preservation for at least 12 months. Should legal challenge occur, the specimen will be retained throughout the period of resolution of the challenge. All negative samples must be retained for a minimum of three days after testing.

**D.** No employer may perform any substance use test administered to any of that employer's employees. As provided by law, employers may perform screening tests on their own applicants, provided the employer's testing facility complies with the requirements in Section 4 of this rule, in accordance with required statutory employment practices within 26 MRS § 683(6).

**SECTION 3.**

**SUBSTANCES FOR WHICH TESTING IS PERMITTED**

**A.** Employers may require testing of employees and applicants for the following substances and groups of substances, as allowed for in the employer’s policy approved by the Maine Department of Labor. Except for assessing specimen integrity, no other testing is permitted. Employers must specify to the testing laboratory which substances are to be tested for in each specimen or group of specimens.

**B.** Substances or groups of substances include, but are not limited to, amphetamine/ methamphetamine, barbiturates, tetrahydrocannabinol (THC) and/or metabolites, benzodiazepines, cocaine and/or metabolites, phencyclidine, opiates and/or metabolites, methaqualone, methadone, propoxyphene, fentanyl, buprenorphine and alcohol.

1. Minimum reportable levels (cutoff levels) for the initial screening test will be established by laboratories and employers at levels (in urine, unless otherwise specified) no lower than the following:

Alcohol in blood or urine 0.02 g/100mL

Amphetamines: 500 ng/mL

Methamphetamine 500 ng/mL

MDMA 500 ng/mL

Barbiturates 300 ng/mL

Benzodiazepines 300 ng/mL

Buprenorphine 10 ng/mL

Tetrahydrocannabinol (THC)

and/or metabolites in urine 50 ng/mL

Tetrahydrocannabinol (THC)

and/or metabolites in blood 10 ng/mL

Cocaine and/or metabolites 150 ng/mL

Fentanyl 2 ng/mL

Hydrocodone 300 ng/mL

Hydromorphone 300 ng/mL

Methadone 300 ng/mL

Methaqualone 300 ng/mL

Opiates and/or metabolites: 2000 ng/mL

6-Acetylmorphine 10 ng/mL

Codeine 2000 ng/mL

Morphine 2000 ng/mL

Oxycodone 100 ng/mL

Oxymorphone 100 ng/mL

Phencyclidine 25 ng/mL

Propoxyphene 300 ng/mL

2. Threshold detection levels for confirmatory tests will be established by laboratories at levels (in urine, unless otherwise specified) no lower than the following:

Alcohol in blood or urine 0.02 g/100mL

Amphetamines: 250 ng/mL

Methamphetamine 250 ng/mL

MDA 250 ng/mL

MDEA 250 ng/mL

MDMA 250 ng/mL

Barbiturates 300 ng/mL

Benzodiazepines 200 ng/mL

Buprenorphine 5 ng/mL

Tetrahydrocannabinol (THC) and/or

metabolites in urine 15 ng/mL

Tetrahydrocannabinol (THC) and/or

metabolites in blood 10 ng/mL

Cocaine and/or metabolites 100 ng/mL

Fentanyl 0.5 ng/mL

Hydrocodone 100 ng/mL

Hydromorphone 100 ng/mL

Methadone 300 ng/mL

Methaqualone 300 ng/mL

Opiates and/or metabolites: 2000 ng/mL

6-Acetyl morphine 10 ng/mL

Codeine 2000 ng/mL

\*Morphine 2000 ng/mL

(\*A laboratory subject to this rule must apply the federal standard when the published morphine cutoff in 49 CFR Part 40 is greater than 2000 ng/mL)

Oxycodone 100 ng/mL

Oxymorphone 100 ng/mL

Phencyclidine 25 ng/mL

Propoxyphene 200 ng/mL

3. Minimum reportable levels (cutoff levels) for the initial screening test will be established by laboratories and employers at levels in hair no lower than the following:

Amphetamines 500 pg/mg

Methamphetamine 500 pg/mg

MDMA 500 pg/mg

Tetrahydrocannabinol (THC) and/or

metabolites 1 pg/mg

Cocaine and/or metabolites 500 pg/mg

Hydrocodone 200 pg/mg

Hydromorphone 200 pg/mg

Opiates and/or metabolites: 200 pg/mg

Codeine 200 pg/mg

Morphine 200 pg/mg

Oxycodone 200 pg/mg

Oxymorphone 200 pg/mg

Phencyclidine 300 pg/mg

4.Threshold detection levels for confirmatory tests will be established by laboratories at levels in hair no lower than the following:

Amphetamines: 300 ng/mg

Methamphetamine 300 pg/mg

MDA 300 pg/mg

MDEA 300 pg/mg

MDMA 300 pg/mg

Tetrahydrocannabinol (THC) and/or

metabolites 0.05 pg/mg

Cocaine 500 pg/mg

Cocaine metabolites 50 pg/mg

Hydrocodone 200 pg/mg

Hydromorphone 200 pg/mg

Opiates and/or metabolites: 200 pg/mg

6-Acetylmorphine 200 pg/mg

Codeine 200 pg/mg

Morphine 200 pg/mg

Oxycodone 200 pg/mg

Oxymorphone 200 pg/mg

Phencyclidine 300 pg/mg

5. Minimum reportable levels (cutoff levels) for the initial screening test will be established by laboratories and employers at levels in oral fluids no lower than the following:

Amphetamines 50 ng/mL

Methamphetamine 50 ng/mL

MDA 50 ng/mL

MDEA 50 ng/mL

MDMA 50 ng/mL

Cocaine and/or metabolites 15 ng/mL

Hydrocodone 30 ng/mL

Hydromorphone 30 ng/mL

Tetrahydrocannabinol (THC) and/or

metabolites 4 ng/mL

Opiates and/or metabolites: 30 ng/mL

6-Acetylmorphine 4 ng/mL

Codeine 30 ng/mL

Morphine 30 ng/mL

Oxycodone 30 ng/mL

Oxymorphone 30 ng/mL

Phencyclidine 10 ng/mL

6. Threshold detection levels for confirmatory tests will be established by laboratories at levels in oral fluid no lower than the following:

Amphetamines: 25 ng/mL

Methamphetamine 25 ng/mL

MDA 25 ng/mL

MDEA 25 ng/mL

MDMA 25 ng/mL

Cocaine and/or metabolites 8 ng/mL

Hydrocodone 15 ng/mL

Hydromorphone 15 ng/mL

Tetrahydrocannabinol (THC) and/or

metabolites 2 ng/mL

Opiates and/or metabolites: 15 ng/mL

6-Acetylmorphine 2 ng/mL

Codeine 15 ng/mL

Morphine 15 ng/mL

Oxycodone 15 ng/mL

Oxymorphone 15 ng/mL

Phencyclidine 10 ng/mL

7. Minimum reportable levels (cutoff levels) for the initial screening test will be established by laboratories and employers at levels in sweat patches no lower than the following:

Amphetamines: 25 ng/patch

Methamphetamine 25 ng/patch

MDMA 25 ng/patch

Cocaine and/or metabolites 25 ng/patch

Hydrocodone 25 ng/patch

Hydromorphone 25 ng/patch

Tetrahydrocannabinol (THC) and/or

metabolites 4 ng/patch

Opiates and/or metabolites 25 ng/patch

Codeine 25 ng/patch

Morphine 25 ng/patch

Oxycodone 25 ng/patch

Oxymorphone 25 ng/patch

Phencyclidine 20 ng/patch

8. Threshold detection levels for confirmatory tests will be established by laboratories at levels in sweat patches no lower than the following:

Amphetamines: 25 ng/patch

Methamphetamine 25 ng/patch

MDA 25 ng/patch

MDEA 25 ng/patch

MDMA 25 ng/patch

Cocaine and/or metabolites 25 ng/patch

Hydrocodone 25 ng/patch

Hydromorphone 25 ng/patch

Tetrahydrocannabinol (THC) and/or

metabolites 1 ng/patch

Opiates and/or metabolites 25 ng/patch

Codeine 25 ng/patch

Morphine 25 ng/patch

Oxycodone 25 ng/patch

Oxymorphone 25 ng/patch

Phencyclidine 20 ng/patch

**SECTION 4. TESTING LABORATORIES**

**A.** Laboratories conducting substance use testing of employees and applicants must comply with all of the following requirements, except as noted.

1. Licensure.

1. Laboratories conducting substance use testing under this rule must be licensed by the Department for such testing. Application for licensure must be made by the laboratory owner on forms prescribed by the Department and must be accompanied by a non-refundable fee, in accordance with the Schedule of Charges for Testing and Services Provided by the Maine Health and Environmental Testing Laboratory Rule (10-144 CMR Chapter 257), as provided by 22 MRS § 565.
2. A laboratory may be licensed upon application, without inspection, if the laboratory is approved by the Substance and Mental Health Services Administration’s National Laboratory Certification Program or College of American Pathologists Laboratory Accreditation Program (CAP). CAP-Forensic Drug Testing Accreditation program (FDT) is not required for an applicant under this rule; however, a laboratory holding CAP-FDT certification may be licensed without inspection.
3. The term of the license will be one year from the date of issue. Application for renewal must be received by the Department at least one month before the expiration date of the current license. Application for renewal must be accompanied by a non-refundable fee, in accordance with 10-144 CMR Chapter 257, as provided by 22 MRS § 565.
4. Laboratories must notify the Department of any changes to accreditation status, within 10 days of occurrence.

**B.** The laboratory must designate one or more certifying officer(s), who may be the director. The certifying officer(s) must be qualified in both formal training and laboratory experience, for performance and supervision of substance use testing. A certifying officer must review the standards, blanks and quality control data together with the screening and confirmation test results. Upon assurance that all results are acceptable, the certifying officer certifies the test result or results before reporting.

**C**. All laboratory reports, including the screening, confirmation and quality control data must be reviewed by a certifying officer before being certified as accurate. The report must identify the name of the laboratory, the drugs and metabolites tested for, whether the test results were negative or confirmed non-negative, and the cutoff levels for each substance.

1. Unless agreed upon by the employee or applicant, no report may show the quantity of substance detected, but only the presence or absence of that substance relative to the cutoff level.

2. No report may show that a substance was detected in a screening test, unless the presence of the substance was confirmed in the confirmatory test. Procedures must be in place to ensure that an applicant or employee's unconfirmed non-negative screening test result cannot be determined by the employer in any manner, including, but not limited to, the method of billing the employer for the tests and the time within which results are provided to the employer.

3. No substance may be reported as present if the employer requesting the testing did not request analysis for that substance.

4. Reports of samples segregated at the request of the applicant or employee for testing by a laboratory selected by the applicant or employee must be provided to both the employer and the applicant or employee.

**D.**  A laboratory aggrieved by any decision of the Department regarding approval has the rights of appeal specified in the Maine Administrative Procedure Act, 5 MRS ch. 375, and the Administrative Hearings Regulations, 10-144 CMR chapter 1.

**SECTION 5.**

**CONFIDENTIALITY**

**A.** Unless the employee or applicant consents, all test results and any information acquired by an employer in the testing process is confidential and may not be released to any person other than the employee or applicant who was tested, a Medical Review Officer, any authorized personnel of the employer, and a provider of rehabilitation or treatment services. This requirement applies to personnel of all laboratories, as well as to employers. This paragraph does not prevent:

1. The release of this information when required or permitted by State or federal law, including release under 26 MRS § 683 (8)(D); or

2. The use of this information in any grievance procedure, administrative hearing or civil action relating to the imposition of the test or the use of test results.

**B.** Notwithstanding any other law, the results of any substance use test required, requested, or suggested by any employer may not be used in any criminal proceeding, as provided by 26 MRS § 685(3)(B).

**SECTION 6**.

**INTERDEPARTMENTAL COMMUNICATION**

The Department will inform the Department of Labor of any changes proposed or made in this rule, to ensure necessary coordination between the rules of both departments.

**STATUTORY AUTHORITY AND HISTORY**

STATUTORY AUTHORITY: 26 MRS §§ 683(11) and 687 (1)

EFFECTIVE DATE:

November 1, 1989

AMENDED:

April 27, 1990 - Section C(4) (EMERGENCY)

July 1, 1990 - Section C(4)

EFFECTIVE DATE (ELECTRONIC CONVERSION):

May 5, 1996

AMENDED:

September 18, 1999 - Section C (EMERGENCY - expires December 17, 1999)

December 17, 1999

NON-SUBSTANTIVE CORRECTIONS:

March 12, 2000 - restored missing language in C, D(8)

AMENDED:

December 6, 2004 - filing 2004-554

November 1, 2011 – filing 2011-370

November 1, 2023-filing 2023-196

October 14, 2024-filing 2024-234 (Technical amendment on October 17, 2024 to correct effective date information and add filing number information in rule history section, as well as to delete filing number information from cover page)