What does Joint Commission require if urine drug screens are performed in a behavioral health care facility?

Any examples are for illustrative purposes only.

All organizations that perform urine drug testing must obtain the federally required CLIA^ license and abide by applicable Joint Commission standards. This is required even if the organization uses the test as a screen and then refers the sample to another laboratory for confirmatory testing. To determine which CLIA license is appropriate, it is first necessary to know the test complexity assigned by the FDA for the test system being used, which may be either waived^^, moderate, or high, based upon several factors. The test complexity may be obtained by

contacting the manufacturer or locating the information in the package insert or checking the FDA web database.

The level of complexity then determines which CLIA license is required and the subsequent criteria which apply for various aspects of testing, such as inspection, personnel qualifications, and quality control. These requirements apply both to organizations that choose to provide the testing and to those organizations that are required to provide the testing by law and regulation. For clarity, the Joint Commission standards do not require organizations to perform urine drug testing.

For a urine drug test classified as waived, the following applies:

- The organization must have a current Certificate of Waiver (COW) obtained from their state CLIA office.
- The testing is surveyed under the waived testing standards in the PC chapter (PC.16.10 to PC.16.60) of the Comprehensive Accreditation Manual for Behavioral Health Care (CAMBHC).
- The testing is reviewed during the organization's routine triennial survey.

For moderately complex urine drug testing, the requirements are different:

- The organization must have a current license for moderate complexity testing obtained from their state CLIA office.

- The CLIA license must have the following specialty/subspecialty listing: Chemistry/Toxicology.
- The testing is surveyed under the standards in the Comprehensive Accreditation Manual for Laboratories and Point-of-Care Testing (CAMLAB), which are more stringent than the waived testing standards.
- The testing is reviewed during a biennial survey, which is separate from the organizational triennial survey.

For moderately complex testing, organization's must fill out a separate application to request a biennial laboratory survey. Alternatively, an allowance from this requirement may be granted on a case by case basis under Joint Commission's "One Test Rule". An organization may formally request an exemption from the Joint Commission laboratory survey if it is performing only one moderately complex laboratory test and the organization can provide evidence of a state CLIA inspection every two years.

^Clinical Laboratory Improvement Act, a section of the federal Center for Medicare & Medicaid Services (CMS) regulations
^^Note: A test designated as CLIA waived does not mean it is CLIA exempt.

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