MEDICATIONS FOR OPIOID USE DISORDER

Point of Care Testing in Primary Care

mosaic GROUP

The purpose of this tool is to help you and your practice become familiar with best practices for point-of-care testing (POCT) for urine toxicology screening and hCG testing related to the initiation and maintenance of medications for opioid use disorder (MOUD).

It offers crucial information for those interested in providing POCT on-site and obtaining CLIA-waived lab status, which is a federal requirement when offering such testing.

While POCT can be advantageous for initiating and maintaining patients on MOUD, it is not mandatory. Many practices choose to use traditional, send-out lab testing and send specimens to external laboratories as needed.

It is important to note that CLIA-waived POCT urine toxicology testing is a screening test and all unexpected or contested results should be sent for confirmation testing. Regardless of methodology, toxicology testing results should be considered one of several elements used in clinical decision-making.

POCT is inexpensive, simple to perform, and provides qualitative positive or negative results. Additionally, POCT can provide immediate insight into substances used including amphetamines, cocaine, benzodiazepines, many opioids, buprenorphine and THC depending on the choice of test used.

A listing of all waived tests can be found on the FDA website's list of waived analytes: https://www.cdc.gov/labquality/waived-tests.html.

POCT can be used in a primary care setting for patients initiating or maintaining MOUD as:

- Part of the initial assessment of a patient being evaluated for and treatment of opioid use disorder (OUD).
- A tool to objectively assess illicit substance and medication intake to prevent potential adverse effects of pharmacotherapy (e.g., opioid screen prior to starting naltrexone) and ensure safety.
- An accountability component of OUD treatment.
- Means to provide immediate access to outcomes including pregnancy results and/or toxicology panels to support timely clinical decision making.

Clinical Laboratory Improvement Amendments (CLIA) Certification

It can be advantageous when managing multiple patients on medications for opioid use disorder (MOUD) to incorporate on-site lab testing. CLIA-waived point-of-care (POC) urine drug tests can provide immediate insights into the presence or absence of substances, prompting meaningful discussions with patients to determine the most appropriate next steps.

Common POC tests that are particularly beneficial for patients on MOUD include urine drug panels and pregnancy tests.

What is a CLIA Waived Test?

As defined by CLIA, waived tests are categorized as "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result."[1] The FDA determines which tests meet these criteria when reviewing a manufacturer's application for test system waiver.

To determine if your supplier's tests are eligible for use with a waiver, visit the **CLIA - Clinical Laboratory Improvement Amendments - Currently Waived Analytes** page on the FDA website: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm.

Clinical Laboratory Improvement Amendments of 1988 (CLIA)

All practice sites and facilities in the United States that perform laboratory testing on human specimens for health assessment or the diagnosis, prevention, or treatment of disease are regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Waived tests include test systems cleared by the FDA for home use and those tests approved for waiver under the CLIA criteria. Once a waived POCT is selected for use, the office utilizing the POCT must have, or must apply for a Certificate of Waiver (COW).

Obtaining a CLIA Certificate of Waiver

You can enroll your testing site in the CLIA program by completing an application available on the CMS CLIA website: **How to Apply for a CLIA Certificate, Including International Laboratories** at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCertificateofWaiver.pdf.

As of September 2024, turnaround time for obtaining a CLIA waiver is typically 4 to 6 weeks after submission, which is subject to change. There is a fee associated with the application for obtaining a CLIA waiver. The fee varies based on the type of laboratory and the volume of testing it performs. For most practices, the fee for a CLIA waiver is typically $180 every two years. It is important to note that this fee covers the cost of the certificate, and administrative expenses associated with the CLIA program. If the practice is considering conducting more complex testing, additional fees and requirements may apply.

The application for CLIA Certification is **Form CMS-116, CLIA Application for Certification:** https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf.

Completed applications and associated fees are submitted to the identified state agency, and practice sites may be subject to inspection by the state.

1 Centers for Medicare & Medicaid Services. (2023). How to obtain a CLIA certificate of waiver. U.S. Department of Health and Human Services. https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCertificateofWaiver.pdf

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