



STATE OF MARYLAND
DHMH

Maryland Department of Health and Mental Hygiene
55 Wade Avenue • Catonsville, Maryland 21228

Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein, M.D., Secretary

Alcohol and Drug Abuse Administration

Kathleen Rebbert-Franklin, LCSW-C
Acting Director

MEMORANDUM

To: All Behavioral Health Treatment Programs

From: Renee Webster, Assistant Director, OHCQ
Kathleen Rebbert-Franklin, Acting Director, ADAA *Kathleen Rebbert-Franklin*

Date: April 4, 2013

Re: Point of Care Toxicology Testing

This memo serves as notification to behavioral health treatment programs that, in order to conduct point of care (POC) drug testing (also known as “dipstick tests”), the treatment program must comply with regulations overseen by the Office of Health Care Quality, Laboratory Licensing Program. Recent changes were made to COMAR 10.10.06.02 that allow for a behavioral health treatment program to apply for a Letter of Exception, which would authorize clinical treatment staff to order and administer the test. The tests are designed to determine patient compliance with the plan of care. Clinical staff as identified in COMAR 10.47.01.06D are allowed to order and administer the test.

COMAR 10.10.03.01 states that POC testing can only be done by the holder of a laboratory permit or a Letter of Exception. A recent regulatory change allows for substance abuse treatment programs to apply for a Letter of Exception (COMAR 10.10.03.02) in order to conduct point of care toxicology tests. Below are the steps to be taken in order to be in compliance with these regulations.

1. The program must complete two applications: a State Compliance Application requesting a Letter of Exception and an application for a required CLIA (Clinical Laboratory Improvement Amendments) certificate of waiver for the Centers for Medicare and Medicaid Services (CMS). The applications can be obtained at www.dhmv.maryland.gov/ohcq/.

2. The State Compliance Application and CLIA application request the name of a Laboratory Director. The staff person in your organization selected to fulfill this role must ensure compliance with the 10.10.06.12 Quality Control regulations.
3. The program must send the completed applications to the Office of Health Care Quality. The program will be invoiced a \$100.00 fee after a completed application has been received. The Letter of Exception is good for two years. CLIA will invoice the program separately after the State enters their information into the CLIA database. The CLIA fee is \$150.00.

For those treatment programs currently performing this point of care testing, the program should immediately file the required applications for a Letter of Exception as these regulations became effective May 2012. OHCQ will accept applications on an ongoing basis for programs that are considering future testing.

If you have questions or need additional information, programs may contact Paul Celli, Coordinator of Laboratory Licensing Programs at the Office of Health Care Quality, at paul.celli@maryland.gov or 410-402-8023.