State of New Jersey
Department of Human Services
Division of Medical Assistance & Health Services

NEWSLETTER

Volume 29 No. 01 **January 2019**

TO: Providers of Behavioral Health Services **– For Action**
Manage Care Organizations **– For Information Only**

SUBJECT: **Urine Qualitative Drug Testing**

EFFECTIVE: January 1, 2019

PURPOSE: To clarify existing policy and announce a new billing procedure for urine qualitative drug testing covered by the NJ FamilyCare (NJFC) Fee-For-Service (FFS) Program.

BACKGROUND: In accordance with the New Jersey Administrative Code (N.J.A.C.) 10:161B-13.1 (Provision of laboratory services), an outpatient substance use disorder (SUD) treatment program shall provide laboratory services directly in the program or shall ensure the availability of services through written affiliation agreements. The program shall only contract with laboratories that are licensed or approved by the New Jersey Department of Health, in accordance with N.J.A.C. 8:44 and 8:45, for the provision of drug screening and other diagnostic and screening tests if required by this chapter or otherwise provided by the program.

The NJFC Program provides FFS coverage and reimbursement for urine qualitative drug testing. Under Clinical Laboratory Improvement Amendments (CLIA), a simple laboratory test, such as a urine qualitative rapid result test, qualifies as a "waived" laboratory test for which a CLIA Certificate of Waiver is needed. (visit https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/HowObtainCertificateofWaiver.pdf for CLIA Certificate of Waiver requirements).

Outpatient SUD treatment programs performing rapid result urine qualitative drug tests require a CLIA Certificate of Waiver. A CLIA Certificate of Waiver is required for each site where rapid result testing is performed. In addition to the facility receiving a Certificate of Waiver, a manufacturer or producer of any test system eligible to be provided under a Certificate of Waiver must be cleared by the Food and Drug Administration (FDA). CLIA Certificate of Waiver requirements mandate that all instructions found in the manufacturer's product insert, from "intended use" to "limitations of the procedure," be followed.

A list of tests requiring a Certificate of Waiver may be found by visiting the FDA website at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm.

ACTION: Options available to an outpatient SUD treatment program for performing a urine qualitative drug test include:

- Collection of a urine sample and performing an on-site urine rapid result drug test;

- Collection of urine, performing a urine rapid result test and confirming the results by sending out to a CLIA-certified laboratory; or

- Collection of a urine sample and sending out the sample to a CLIA-certified laboratory;

Billing Procedures

- CLIA-waivered outpatient SUD treatment programs that perform the collection of urine and an on-site urine rapid result test may continue to bill **HCPCS procedure code H0003 HF**.

- CLIA-waivered outpatient SUD treatment programs that perform the collection of urine, an onsite urine rapid result drug test and send out the urine sample to a CLIA-certified laboratory shall bill **HCPCS procedure code H0003 HF**.

- Outpatient SUD treatment programs that **only** perform the collection of urine, do not perform a rapid result drug test, but send out a urine sample to a CLIA-certified laboratory may bill the **new HCPCS procedure code H0048 HF (collection and handling of a urine sample only). NJFC FFS reimbursement for this new procedure code is $2.50.**

If you have any questions concerning this Newsletter, please contact DXC Technology Provider Services at 1-800-776-6334.

RETAIN THIS NEWSLETTER FOR FUTURE REFERENCE