



Center for Clinical Standards and Quality /Survey & Certification Group

January 30, 2015

[Lab physical address & CLIA ID number]

Reminder: Education and Transition Period for Individualized Quality Control Plan (IQCP) for Clinical Laboratory Improvement Amendments (CLIA) Laboratory Nonwaived Testing **ending January 1, 2016.**

The Centers for Medicare & Medicaid Services (CMS) is sending out this second letter as a reminder to laboratories that the IQCP Education and Transition Period will end on January 1, 2016.

The Centers for Medicare & Medicaid Services (CMS) is implementing IQCP as a new quality control option based on risk management for CLIA laboratories performing nonwaived testing. IQCP is voluntary and provides laboratories with flexibility in customizing Quality Control (QC) policies and procedures based on the test systems in use and the unique aspects of each laboratory.

For laboratories using tests categorized/approved by the FDA as waived tests, they must continue to follow manufacturer's instructions for these tests, and this requirement will not change. The new CLIA IQCP quality control option was developed for nonwaived testing.

For laboratories performing Provider-Performed Microscopy (PPM) procedures, they must continue to follow the CLIA regulatory requirements for PPM and moderate complexity testing. While IQCP may not be practical for PPM laboratories due to the nature of PPM testing, IQCP is available for those laboratories that would choose to implement it.

CMS is currently midway through the IQCP Education and Transition Period. Laboratories should be utilizing this time period to learn about IQCP and implement their chosen QC policies and procedures. The IQCP Education and Transition Period began on 01/01/2014, and will conclude on 01/01/2016. Laboratories will continue to have the option of achieving compliance by following all CLIA QC regulations as written. The laboratory director retains overall responsibility for ensuring that QC programs are established and maintained to assure the quality of laboratory services provided.

Laboratories can find IQCP educational materials at the CLIA website: www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html. Look for new educational materials to be added in 2015.

If you have any questions, please contact your state agency or submit them to the **IQCP mailbox** at this web link: IQCP@cms.hhs.gov.

Sincerely,

/s/

Karen Dyer

Acting Director
CMS/Division of Laboratory Services

Enclosed: Individualized Quality Control Plan (IQCP) Flyer