DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality /Survey & Certification Group

November 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 **will end December 31, 2015.**

The Centers for Medicare & Medicaid Services (CMS) is sending out this follow-up letter as a final reminder to laboratories that the IQCP Education and Transition Period will **end on December 31, 2015**. Two letters were previously sent out (on September 30, 2013 and January 20, 2015) to all our nonwaived testing laboratories announcing the IQCP Education and Transition Period, which began January 01, 2014, and will end December 31, 2015.

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. The education and transition period provided laboratories the opportunity to learn about IQCP and implement their chosen QC policies and procedures. 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.

Laboratories will continue to have the option of achieving compliance by following all CLIA QC regulations as written or use IQCP. The laboratory director retains overall responsibility for ensuring that QC programs are established and maintained to assure the quality of laboratory services provided.

CMS is nearing the end of the IQCP Education and Transition Period. Laboratories should have utilized this education and transition period to learn about IQCP and implement their chosen QC policies and procedures.

As of January 1, 2016, Equivalent Quality Control (EQC) will no longer be an acceptable option to meet CLIA QC requirements and will be removed from Appendix C of the State Operations Manual (SOM). It is important to note that on this date **only two options will remain to meet CLIA QC compliance**.

1. Follow the CLIA QC regulatory requirements as written, or,
2. Implement IQCP, as applicable

The S&C letter 16-02-CLIA provides the procedures for laboratories that wish to use IQCP to meet CLIA QC requirements for equivalent quality testing. This attachment can be found at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-02.pdf.

Laboratories that receive CLIA certification by virtue of accreditation by a CMS-approved accrediting organization (AO), or are subject to regulation by an exempt state (ES), **should contact their AO or ES for updated information.**

IQCP educational materials, such as informational brochures, FAQs, and an IQCP Step-by-Step Workbook, can be found on the CLIA website: www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html.

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
Director
CMS/Division of Laboratory Services