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

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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.

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 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.

Laboratories have three acceptable QC options during the IQCP Education and Transition Period:
1. Follow the CLIA QC regulatory requirements as written.
2. Continue to follow the Equivalent Quality Control (EQC) procedures as described in the current Interpretive Guidelines, www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories.html.
3. Implement IQCP.

During the Education and Transition period, survey teams have been instructed not to cite QC deficiencies except in cases of: immediate jeopardy, if a laboratory has failed to implement any form of QC, or serious quality problems are identified. At the end of this period, laboratories will receive deficiency citations if they are not in compliance with one of the two options outlined in the previous paragraph.

As of January 1, 2016, EQC will no longer be an acceptable option to meet CLIA QC requirements and will be removed from Appendix C of the 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 Attachment 1 – IQCP document 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:

http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.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 can be found on 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