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Circular Letter: DHCQ 15-12-649

TO: Clinical Laboratories

FROM: Michael Sinacola
Interim Deputy Director
Bureau of Health Care Safety and Quality

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Clinical Laboratory Program

DATE: December 8, 2015

SUBJECT: Guidance Regarding Implementation of Individualized Quality Control Plans

The purpose of this Circular Letter is to provide guidance to clinical laboratories in anticipation of a CMS change to the options available for clinical laboratories to comply with federal Clinical Laboratory Improvement Amendments (CLIA) quality control (QC) requirements outlined in 42 CFR 493.[1,2]

Effective January 1, 2016, CMS will no longer accept Equivalent Quality Control (EQC) to demonstrate compliance with CLIA QC requirements, but instead will allow CLIA-certified laboratories to meet required QC standards for non-waived testing through one of two options:

(1) Implement an Individualized Quality Control Plan (IQCP), in accordance with CMS guidelines, for CLIA non-waived testing;
(2) Follow all CLIA QC regulations set forth at 42 CFR 493.[3]

In response to this change, the Massachusetts Department of Public Health (DPH) is issuing this circular letter to clarify the manner in which a clinical laboratory operating in Massachusetts that is

[1] Centers for Medicare and Medicaid Services (CMS), Ref: S&C: 13-54-CLIA. https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf
[2] 42 CFR 493.1250, http://www.gpo.gov/fdsys/granule/CFR-2011-title42-vol5/CFR-2011-title42-vol5-part493/content-detail.html

subject to 105 CMR 180 may implement IQCP to comply with state QC regulations, set forth at 105 CMR 180.350 through 105 CMR 180.430.

IQCP is voluntary and provides laboratories with greater flexibility in tailoring QC policies and procedures to the test systems in use and the unique aspects of each laboratory. The laboratory director retains overall responsibility for ensuring that QC programs are established and maintained to assure the quality of laboratory services provided, in accordance with 105 CMR 180.070(C) and federal regulations set forth at 493.1407 and 493.1445.

The Clinical Laboratory Program (CLP) has determined that Massachusetts clinical laboratories subject to 105 CMR 180.000 may implement IQCP as an acceptable QC program to meet the QC requirements of 105 CMR 180.000 for CLIA non-waived testing, and for microbiological media and reagents used for identification and susceptibility testing, as long as the following conditions are met:

- All Massachusetts clinical laboratories implementing an IQCP must follow CMS CLIA IQCP guidelines, including the requirement that an IQCP be approved, signed and dated by the laboratory director. Additionally, accredited laboratories implementing an IQCP must also comply with any additional QC guidelines or requirements of the accrediting organization, as applicable.
- A licensed laboratory shall make its IQCP available to DPH upon request.
- For immunohematology testing, laboratories must follow any applicable AABB (formerly the American Association of Blood Banks) QC standards.

Laboratories may not implement an IQCP as an acceptable QC program to meet the QC requirements of 105 CMR 180.000 for the following:

- CLIA-waived testing;
- For tests in the following specialties and subspecialties, as defined in 105 CMR 180.030: Pathology, Histopathology, Oral Pathology, and Cytology.

Testing that does not meet the CLP conditions for IQCP implementation, as listed above, is subject to QC requirements specified in:

(1) 105 CMR 180.000;
(2) CLIA regulations and guidelines;
(3) and AABB Standards, for all Immunohematology testing.

If you have any questions about this guidance, please contact Pamela Waksmonski, Clinical Laboratory Program Manager at (617) 753-7307 or Pamela.Waksmonski@state.ma.us.