



Center for Clinical Standards and Quality/Survey & Certification Group

Admin Info: 17-03-CLIA

DATE: December 16, 2016

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Changes to the Clinical Laboratory Improvement Amendments of 1988 (CLIA)
Certificate of Waiver (CW) Project

Memorandum Summary

- The Centers for Medicare & Medicaid Services (CMS) performed on-site, educational visits to laboratories enrolled in CLIA with a CW from 2002 through 2016.
- There will be no CW Project surveys for FY 2017.
- FY 2017 will be used for planning the transition from CW educational visits to surveys of Provider Performed Microscopy (PPM) laboratories.

Background

In 2002, the CMS initiated on-site visits to facilities enrolled in the CLIA program that have a CW. These visits were designed to:

- Educate the laboratories on sound laboratory practice;
- Facilitate information-gathering for CMS;
- Ensure that laboratory personnel conduct quality testing in a manner which protects patient safety;
- Determine each laboratory's regulatory compliance; and,
- Make certain that each laboratory is only conducting the simple tests that are appropriate for a CW facility.

Discussion

For 14 years, surveyors have visited approximately two percent of CW laboratories per state per year. These surveys were an opportunity for a State Agency surveyor and the CW laboratory to engage in conversations to help educate the laboratory on laboratory compliance and good laboratory practices. The information that surveyors collected during CW surveys was important in identifying key issues and concerns and was used in the creation of educational materials like the READY, SET, TEST (RST) booklet and on-line training offered by the Centers for Disease

Control and Prevention (CDC). Educational materials and on-line training allowed CMS to reach more CW laboratories and has been valuable in improving the quality of laboratory testing that healthcare providers perform during their day-to day interactions with patients.

There will not be any CW project surveys performed for FY2017. CMS has decided to transition from surveying CW laboratories to surveying PPM laboratories as PPM laboratories are another group that does not have routine oversight. These educational survey visits will begin in FY 2018.

FY2017 will be used for development of the survey processes for PPM laboratories. Central Office will work with the CDC to make updates to the State Survey Information System (SSIS), develop the educational survey protocol, train surveyors, and inform stakeholders of our intention to survey.

Budget

It was also previously announced that CW funds would be available during FY 2017 to be used for other CLIA surveys, however we have recently learned that those funds will not be available. FY 2017 will be utilized to wrap up the prior year CW Project and to transition to surveying PPM laboratories in FY 2018. This time will also allow State Agency surveyors to prepare for the implementation of the PPM laboratory survey project.

Contact: Any questions about this policy should be directed to LabExcellence@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
David R. Wright

cc: Survey and Certification Regional Office Management