



Center for Clinical Standards and Quality/Survey & Certification Group

Admin Info: 16-19-CLIA

DATE: March 18, 2016

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Quality Improvement Plan (QIP) for Clinical Laboratory Improvement
Amendments (CLIA) State Agency Performance Review (SAPR)

Memorandum Summary

- **Quality Improvement Plan (QIP):** Regional Office (RO) personnel will have a mechanism available to direct the State Agencies (SA) to implement a QIP in order to improve the SA's performance of their survey and certification responsibilities.
- **Quality Improvement Plan (QIP) Requirements and Response:** The RO will direct the SA to take specific steps within specific time frames to improve their performance; the SA will submit a response in the form of a written plan to accomplish the QIP.

Background

The CLIA SAPR is a mandated annual evaluation of each SA performance of its survey and certification responsibilities under the CLIA program. The evaluation is performed by the CMS Regional Office (RO) CLIA program personnel. The current SAPR review includes seven criteria. Each of the individual seven criteria include quantitative thresholds for performance that the SA must meet. The Performance Threshold is neither a score nor a pass/fail rating. It serves as a demarcation point for the CMS RO to request a written corrective action plan.

The Performance Threshold also serves to ensure nationwide consistency among the CMS ROs for requesting that the SA submit a Corrective Action Plan (CAP). The average number of SAs needing a CAP from 2011 through 2014 was 34.5 percent. A comparison of performance results from 2009 through 2014 revealed that there were 36 instances when the quantitative performance results did not meet the threshold for one or more criteria for at least two consecutive fiscal years (FY).

Objectives and Goal

The objective is to provide the RO the ability, via a written QIP, to help those SAs whose SAPR performance for one or more criteria does not meet the threshold for a minimum of two

consecutive FYs, and whose CAP has not provided sustainable corrective action, to support and facilitate improvement of the SA performance. The goal is optimal SA performance in fulfilling their survey and certification responsibilities under their 1864 Agreement.

Quality Improvement Plan (QIP)

For those SAs who do not meet the Performance Threshold for a specific criterion, do not meet the Performance Threshold for the same criterion in the following year (i.e., two consecutive years), and have submitted CAPs which have not corrected the identified issues, the RO will have the ability to develop a QIP which will outline what the SA will need to do to improve the performance of their survey and certification responsibilities. The RO, via the QIP, will direct the SA to take specific action(s) to improve the SA performance and will describe specific time frames as well as the action(s) the SA needs to take to improve performance.

The QIP response should be received by the RO no later than 30 days from the date of receipt of the QIP by the SA, and should contain the following information:

- Name of the State
- Name and number of the Criterion needing action and the action that will be taken
- What measure(s) or systemic change has(s) have been put into place?
- Describe the SA monitor(s) verifying that the required action(s) outlined in the QIP are successful and the failure to meet the threshold do not recur?
- Name of the individual responsible for completion of the implementation of the QIP and expected dates of completion (prior to, or within, the timeline directed by the RO).
- Documentation of new policies and procedures.

If the QIP process is not effective, an evaluation of further action will be determined by the RO on a case by case basis.

Contact: If you have any questions regarding this memorandum, please contact Sarah Bennett at 410.786.3354 or at sarah.bennett1@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/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management