Writing an Acceptable Plan of Correction (PoC) or Credible Allegation of Compliance (AoC)

An acceptable Plan of Correction must be developed by a laboratory found to be out of compliance with any ***standards*** set forth by the Centers for Medicare and Medicaid Services (CMS) in the CLIA regulations, pursuant to Title 353 of the Public Health Service Act. A credible Allegation of Compliance must be developed by a laboratory found to be out of compliance with any ***conditions*** of the aforementioned regulations. The plan or allegation, hereinafter referred to as "plan," must be sent to the appropriate state CLIA program and deemed acceptable before the laboratory is considered compliant.

In general, the plan describes how the issues will be or were addressed and how the situation will be monitored to prevent future problems. It must be concise, stating exactly how each deficient practice will be or was corrected. Plans must be reasonable in both timeframe and content.

The ***required*** elements for the plan are as follow:

1. **The proposed action for correcting each specific deficiency. The plan must also address the processes that led to the deficiency and any corrective action(s) already taken to fix those processes;**
2. **Statement of impact for patients that were affected by the deficient practice;**
    a. **Must include an explanation as to how the laboratory identified patients affected by the deficient practice, if applicable; or**
    b. **How the laboratory determined that no patients were affected, if applicable;**
3. **The procedure for implementing the plan of correction for each specific deficiency cited;**
4. **The monitoring procedure to ensure that the plan of correction is effective and each deficiency remains in compliance with the regulatory requirements;**
5. **The title of the person responsible for implementing the plan of correction; and**
6. **The date(s) each deficiency will be/was corrected.**

Laboratories with condition-level deficiencies must correct the deficient practice(s) prior to submitting the plan for review. Laboratories with standard-level deficiencies may make plans for future corrections, not to exceed 12 months from the date of survey.

It is acceptable to send the plan either directly on form 2567,Statement of Deficiencies, or in a separate document. **If using a separate document, the laboratory director or responsible party must sign and return the first page of form 2567.**

Tips for writing your plan:

1. Be incredibly specific! Failure to meet requirements will result in rejection of your plan.
2. Completion dates: If your corrective action has not yet been instituted, give the best estimate of the anticipated date of completion.
3. If recording the response by hand, please write legibly. Illegible writing is grounds for rejection.
4. Submit all documentation at one time, whenever possible.
5. Please contact us if you have questions. That is why we are here!
    a. Phone: 304-205-8913
    b. Email: DHHROLSCLIA@wv.gov