Writing an Acceptable Plan of Correction (PoC) or Credible Allegation of Compliance (AoC) - West Virginia CLIA

(updated 9/12/2024)

A laboratory must develop a Plan of Correction (standard-level deficiencies) or Allegation of Compliance (condition-level deficiencies) when found to be out of compliance with the CLIA regulations during inspection. The plan or allegation, hereinafter simply referred to as "plan," must be approved by the WV CLIA office before the laboratory is deemed back into compliance.

The ***required*** elements of the plan are as follows:

1. **Patient Impact Statement**
    a. The patient impact statement is a **detailed** description of how the lab determined whether patient results were impacted by the deficiency and must be relevant to the deficiency.
        i. If patient results were impacted:
            1. Description and documentation of the immediate corrective actions taken or planned for patients determined to have been affected.
            2. Description of how the lab determined if other patients may have been affected and documentation of the corrective actions taken or planned, when applicable.
2. **Systemic Change/Corrective Action Statement**
    a. The systemic change/corrective action statement is a **detailed** description of what steps the lab has taken/planned to correct the deficiency and prevent reoccurrence.
        i. The change must be relevant to the regulatory deficiency identified.
        ii. The lab must provide documentation demonstrating the corrective action.
3. **Monitoring Statement**
    a. The monitoring statement is a **detailed** description of how the systemic changes/corrective actions will be monitored to ensure the deficiency does not recur.
        i. Must name the individual(s) (by position) who will be responsible for the plan.
        ii. Must describe the monitoring process.
        iii. Must describe at what frequency or interval the monitoring will occur.
        iv. The lab should provide documentation of the monitoring plan, if possible.
4. **Date of Completion**
    a. Each deficiency must have a date of completion.
        i. Laboratories with ***condition-level deficiencies*** must have corrected the deficient practice(s) prior to submitting the plan.
        ii. Laboratories with ***standard-level deficiencies*** may make plans for future corrections not to exceed 12 months from the date of survey. Use your best estimate for future dates.
5. **Laboratory Director Signature**

Tips for writing your plan:

1. Each deficiency must be addressed individually, even if the plan is the same for all.
2. **You are not required to type or write your plan directly on Form 2567**; a separate document is fine. However, the laboratory director must sign the first page of the 2567 and return it with the document.
3. If handwritten, the plan must be legible.
4. Be incredibly specific!
5. Submit all documentation at one time whenever possible.
6. Please contact us if you have questions. That is why we are here!
    a. Phone: 304-205-8913
    b. Email: DHOLSCLIA@wv.gov