

Statement of Deficiencies

And

Plan of Correction

WAC 246-945-005

Instructions on Submitting a Plan of Correction to the **Pharmacy Quality Assurance Commission**



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Pharmacy Quality Assurance Commission*

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Checklist

Before submitting the POC please use the checklist below to prevent rejections.

- Is there a plan for each deficiency listed?
- Is each plan descriptive as to how the correction will be accomplished?
- Does each plan indicate who or which staff position will implement and monitor the correction of each deficiency?
- Does each plan show a time frame of the completion date(s) of when the deficiency will be corrected?
- Does each plan include a monitoring plan?
- Has the responsible manager or another authorized official signed and dated the Plan of Correction?
- If included, are all attachments appropriately labeled with exhibit numbers to be matched with the corresponding deficiency?

The POC will be rejected if these guidelines are not met. Note: Failure to submit an acceptable POC may result in enforcement action by the Commission.

Disputing Deficiencies or Rejection of the Plan of Correction (POC)

- **Disputing Deficiencies:** A licensee may dispute a deficient finding(s) detailed in the Statement of Deficiencies (SOD). This can be done by submitting the specific objection in writing to the pharmacist inspector within 10 business days of receipt of the SOD. The inspector will submit the objection and inspection related documents to the Commission for review. The Commission will communicate the decision back to the licensee.
- **Disputing a POC Rejection:** Licensees may dispute the finding(s) of a POC rejection for inadequacy. This can be done by submitting specific objections in writing to the pharmacist inspector within 10 business days of receipt of the rejection letter. The pharmacist inspector will forward the objections and all inspection related documents to the Commission for review. The Commission will communicate the decision back to the licensee.

Note: The pharmaceutical firm may request a one-time extension pursuant to WAC 246-945-005(a)(iii).

Questions?

Please review the cited regulation first. If clarification is needed or there are outstanding questions about the cited deficiencies, contact the pharmacist inspector who conducted the onsite inspection or the supervising pharmacist inspector.

Introduction

Following an inspection by the Pharmacy Quality Assurance Commission, pharmacist inspectors will identify compliance related deficiencies. The list of deficiencies found by the inspector will be provided on a Statement of Deficiencies (SOD).

The Commission requires licensees to submit a Plan of Correction (POC) for each deficiency listed on the SOD.

The POC must be submitted to the inspector within **ten business days** of receipt of the SOD.

The Statement of Deficiencies and Plan of Correction are made available for public inspection and copying when required by the Public Records Act (RCW 42.56).

Submitting a Plan of Correction (POC)

Licensees are required to respond to the SOD by submitting a POC. Ensure reference to the deficiency number. If exhibits are included, identify them (e.g., Exhibit A) and refer to them as such in the POC. Completed POC's should be submitted to the pharmacist inspector.

Descriptive Content

The POC must provide a step-by- step description of the methods to correct each deficient practice and the plan to prevent recurrence. It must provide enough information to ensure the cited regulation is met

An acceptable POC must contain the following elements:

- The deficiency/citation number and name.
- The plan to correct each specific deficiency.
- The name and/or title of the person responsible for implementing and monitoring the proposed plan of correction.
- The time frame each specific plan will be enacted or implemented.
- The monitoring procedure to ensure that the plan of correction is effective and that specific deficiency cited remains corrected and/or in compliance with the regulatory requirements. The monitoring plan must be measurable and objective.

Simply stating that a deficiency has been "corrected" is not acceptable. If a deficiency has already been corrected, the plan of correction must include the following:

- The deficiency/citation number and name.
- How the deficiency was corrected.
- The date the correction was completed.
- A monitoring plan to prevent possible recurrence of the deficiency.

Completion Dates

The POC must include a completion date that is realistic and pertinent to correct each deficiency. Direct patient care issues must be corrected immediately and monitored appropriately. Some deficiencies may require a staged plan to accomplish total correction. Deficiencies that require bids, remodeling, replacement of equipment, etc., may need additional time to accomplish correction(s). However, the target completion dates should be within a reasonable and mutually agreeable time frame. **Simply stating the completion date is "ongoing" is not acceptable.** The completion date must be specific.

Continued Monitoring

Each POC must indicate the person responsible, either by name, position or title, who will be responsible for implementing and continued monitoring. Monitoring plans should be tailored to each deficiency. The monitoring plan must be measurable and objective, describing the number of observations and the time table for observations as it relates to each deficiency.

Signature and Date

The responsible pharmacy manager must sign and date the POC. In the case where multiple pages are involved, a signature on the last page is sufficient.

Approval of POC

The submitted POC will be reviewed for adequacy by the pharmacist inspector. If acceptable, the pharmacist inspector will send an approval letter to institute the POC.

If the POC does not adequately address the deficiencies in the SOD, a rejection letter will be sent to the responsible pharmacy manager detailing why the POC was not accepted. The responsible manager may submit a 2nd POC or may dispute the findings of inadequacy within 10 business days of receipt of determination that the first POC was not sufficient.

If the 2nd POC is also inadequate, both POCs and all inspection related documents will be forwarded to the Commission for review. The Commission may choose to take enforcement action.