



Pharmacy Quality Assurance Commission Policy & Procedure

Title:	Inspection Process – WAC 246-869-190 – Implemented March 1, 2018	Number:	58
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Contact:	Steve Saxe, Executive Director		
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Approved:	Chairperson, Pharmacy Quality Assurance Commission		

The process outline below will be followed by the Commission and the Department of Health for purposes of inspecting pharmacies located in the state of Washington.

Step 1	Pharmacy is due for inspection.	
Step 2	Commission sends a letter to the pharmacy that they should expect an inspection in the next 6 months. <i>Pharmacy may provide blackout dates to Commission Pharmacist Inspector (up to 14 calendar days) with justification for unavailability of inspection on those dates. The pharmacy must provide this information within 10 calendar days of receipt of their inspection letter to the Commission.</i>	
Step 3	An unannounced inspection takes place.	
	NOTE	If imminent or immediate harm exists, see DOH HSQA Procedure 1-2-07.
Step 4	At the end of the inspection, the pharmacist inspector will have an exit meeting with the PIC and/or facility leadership, and discuss the observations and deficiencies noted during the inspection.	

Step 5	Commission inspector prepares a Statement of Deficiency (SOD).	
	A	If determined that no deficiencies existed, a letter will be sent to the pharmacy within 10 calendar dates of the exit meeting stating no deficiencies noted , and no further action required.
	B	If determined that deficiencies DO exist, the pharmacy will be sent a letter with the Statement of Deficiencies. The letter will include instructions to submit a Plan of Correction (POC) within 14 days.
Step 6	Pharmacy receives SOD.	
	A	If pharmacy agrees with ALL deficiencies noted they submit a POC addressing each deficiency within 10 business days of receipt of SOD. Go to step 8.
	B	If pharmacy disagrees with any of the deficiencies noted, the pharmacy may dispute those deficiencies by submitting specific objections to the Commission for review within 10 business days of receipt of SOD. Go to step 7.
	C	If the inspected pharmacy takes no action within 10 business days, the inspection report will be forwarded as a complaint to the Commission for consideration. Go to Step 15.
Step 7	A quorum of the commission reviews disputed deficiencies submitted by the inspected pharmacy within 30 days of receipt of disputed deficiencies, and within 10 business days of review does one of the following:	
	A	Letter sent to pharmacy stating quorum agrees with deficiencies noted in the SOD. Go to step 8.
	B	Letter sent to pharmacy stating quorum disagrees with some deficiencies noted in the SOD. Go to step 8.

	C	Letter sent to pharmacy stating panel disagrees with all deficiencies in the SOD, no further action required.
Step 8	Pharmacy submits 1 st POC addressing each deficiency within 10 business days to Commission inspector.	
Step 9	Commission inspector reviews POC.	
	A	If POC is sufficient, pharmacy receives letter of approval of POC within 10 business days. The pharmacy must implement the POC. Letter may indicate any desired follow-up, i.e. re-inspection or progress reports. Process complete until next inspection.
	B	If POC is not sufficient, pharmacy receives letter detailing why POC was insufficient within 10 business days. Go to step 10.
Step 10	Pharmacy receives letter of insufficiency of POC.	
	A	Pharmacy accepts that 1 st POC was not sufficient, and agrees to submit a 2 nd POC within 10 business days. Go to step 12.
	B	If pharmacy disagrees with insufficiency of 1 st POC, pharmacy may dispute the determination of insufficiency within 10 business days, with specific objections to the Commission for review. Go to step 11.
Step 11	A quorum of the Commission reviews dispute of insufficiency of 1 st POC within 30 days of receipt of dispute, and within 10 business days does one of the following:	
	A	Letter sent to pharmacy stating quorum agrees that 1 st POC was insufficient. Go to Step 12.
	B	Letter sent to pharmacy stating that quorum agrees 1 st POC is not fully sufficient, requires pharmacy to submit a 2 nd POC addressing areas 1 st POC was not accepted. Go to Step 12.

	C	Letter sent to pharmacy stating panel agrees 1 st POC is sufficient. Go to Step 9A.
Step 12	Pharmacy submits 2 nd POC within 10 business days of receipt of determination that 1 st POC was not sufficient.	
Step 13	Commission inspector reviews 2 nd POC.	
	A	If 2 nd POC is sufficient, pharmacy receives letter of approval of 2 nd POC within 10 business days, and pharmacy must implement approved 2 nd POC. Letter may indicate any desired follow-up, i.e. re-inspection or progress reports. Process complete until next inspection.
	B	If 2 nd POC is not sufficient, pharmacy receives letter stating 2 nd POC was insufficient. 2 nd POC, and supporting documents, will be forwarded as a complaint to the Commission for consideration of next steps. Go to Step 14.
Step 14	Commission quorum reviews 2 nd POC submitted by pharmacy within 30 days of receiving it as a complaint, and within 10 calendar days does one of the following:	
	A	Quorum agrees that 2 nd POC was not sufficient. Go to Step 15.
	B	Letter sent to pharmacy stating panel finds 2 nd POC is sufficient. Go to Step 9A.
Step 15	Enforcement process may be initiated.	