

*Department of Health*

*Pharmacy Quality Assurance Commission*

# Guidance Document

<i>Title:</i>	Inspection Requirement for Modifications or Remodels	<i>Number:</i>	G002
<i>References:</i>	WAC 246-945-230		
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<i>Approved By:</i>	Tim Lynch, PharmD, MS, FABC, FASHP, Pharmacy Quality Assurance Commission Chair		

At the March 5<sup>th</sup> business meeting, the Pharmacy Quality Assurance Commission (commission), provided clarification on WAC 246-945-230(3)(a) and the inspection requirement for modifications or remodels for facilities identified in this guidance.

Pharmacies that undergo any modifications or remodels as described in WAC 246-945-230(3)(a) must notify the commission, pay a facility inspection fee, and receive an inspection. "A modification or remodel of a pharmacy location includes changes to a previously approved area, room or pharmacy building which result in changes to the pharmacy that affects security, square footage, access to drugs, compounding or necessitates temporary relocation of pharmacy services" (WAC 246-945-230(3)(a)).

Additionally, health care entities (HCEs), hospital pharmacy associated clinics (HPACs), wholesalers, and manufacturers that undergo any modifications or remodels of their facility relating to compounding must notify the commission, pay a facility inspection fee, and receive a remodel inspection.

Further, HCEs, HPACs, wholesalers, and manufacturers that undergo any modifications or remodels which negatively impact security as determined by the licensee's professional judgment must notify the commission, pay a facility inspection fee, and receive a remodel inspection<sup>1</sup>.

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<sup>1</sup> The Commission will not prospectively evaluate whether specific changes "negatively impact" drug security but expects licensees to use their professional judgment on whether a change "negatively impacts" drug security based on their workflow.

Finally, the commission clarified that changes to a medication storage room or cabinet location or feature does not require submission of a remodel application provided that the storage room or cabinet maintains an equivalent level of security and accessibility. Changes made will be assessed during the next routine inspection.