

Department of Health

Pharmacy Quality Assurance Commission

Guidance Document

<i>Title:</i>	Inspection Requirement for Modifications or Remodels	<i>Number:</i>	G002.1
<i>References:</i>	WAC 246-945-230		
<i>Contact:</i>	Marlee B. O'Neill, Executive Director, Pharmacy Quality Assurance Commission		
<i>Phone:</i>	360-236-4946		
<i>Email:</i>	WSPQAC@doh.wa.gov		
<i>Effective Date:</i>	December 12, 2024		
<i>Supersedes:</i>	G002, Approved March 5, 2021		
<i>Approved By:</i>	Hawkins DeFrance, Pharmacy Quality Assurance Commission Chair		

Currently, 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).

The Commission has initiated rulemaking to consider potential amendments to WAC 246-945-230(3)(a). Specifically, the Commission will be considering what changes to a compounding room or space can be made without notifying the Commission and undergoing a remodel inspection. While the rulemaking is ongoing, the Commission will only require licensees to notify the Commission if structural or functional changes are made to a compounding room or space. Structural changes refer to modifications to a compounding room or space that involves changing, removing, or adding any load bearing elements such as ceilings, walls, and floors. Functional changes include repurposing a previously approved compounding space (e.g., conversion of a non-sterile compounding space to a sterile compounding space). Not all changes to equipment will be considered structural or functional changes.

While rulemaking is ongoing, pharmacies that undergo any modifications or remodels that include 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, or necessitates temporary relocation of pharmacy services need to pay a facility inspection fee and receive an inspection.

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, as described above, 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.¹

Finally, 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.

¹ 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.