The Pharmacy Quality Assurance Commission (commission) is issuing this guidance document to clarify requirements for Health Care Entities licensed by the commission, including the following:

I. License of Location Standards
II. Monthly Inspection Requirements
III. Consultant Pharmacist Requirements
IV. Practitioner Dispensing in an HCE

I. **License of Location Standards**

**RCW 18.64.450** requires an owner of a health care entity, as defined in **RCW 18.64.011(15)**, to obtain a license to “to purchase, administer, dispense, and deliver legend drugs” including controlled substances.

All facility licenses issued by the commission are licenses of location, including a license for a health care entity (HCE). **RCW 18.64.460(1)** states a health care entity owner shall pay a fee set by the secretary and in return will receive a license of location for that health care entity. Generally, the commission has interpreted “license of location” as meaning a single physical address. As a result, a separate health care entity license has not been required for each individual clinic within a single physical address that is under common ownership, unless the health care entity intends to purchase, possess, administer, dispense or deliver controlled substances. In that situation, the commission has interpreted the “license of location” requirement for HCEs to mirror the position of the United States Drug Enforcement Administration (DEA) that requires a separate registration for each clinic that has a different suite number, even if the clinics are located within the same physical address and are under common ownership.
Health care entity ownership has changed since the creation of the license in 1995. The health care entity license is used in large part by health systems and organizations that own, operate, or control multiple clinics. The Commission has been informed over the last five or more years about multiple clinics sharing a single physical address, possibly being located in separate suites or multiple clinics sharing a single suite on different days. In these situations the drugs being used at the clinics are from a single source (e.g. pharmacy) that is also under common ownership, control, or operation. The health system and organization keeps complete records of drugs transferred or supplied to the commonly owned health care entities.

The changing landscape of health care delivery, clinic settings and locations has complicated having an health care entity license be a license of location by clinic when common ownership exists.

Due to this change in practice and the modernization of health care delivery, the Commission has determined, that an health care entity license of location can and does include multiple clinics at one physical street address even if they are in different suites unless any of the following exist:

1. There are external providers practicing at the clinic. External provider means a practitioner as identified in RCW 69.41.010(17), that is not employed by the health care entity or parent company or subsidiary,
2. The clinic will possess controlled substances. If controlled substances will be possessed, administered, dispensed, or delivered the clinic must have a separate license consistent with DEA license of location requirements, or
3. The clinics are not under common ownership, control, or operation.

II. Monthly Inspections Requirements

Chapter 246-904 WAC outlines the physical and safety standards HCEs must comply with as part of their operations and to maintain licensure. A number of sections in chapter 246-904 WAC make reference to sections of chapter 246-873 WAC – Pharmacy – Hospital Standards.

WAC 246-873-080(1)(b) requires pharmaceutical services to include “a monthly inspection of all nursing care units or other areas of the hospital where medications are dispensed, administered or stored. Inspection reports shall be maintained for one year.” It has been interpreted that while the HCEs are not a unit of the hospital per se, WAC 246-904-040’s reference to WAC 246-873-080 similarly requires HCEs to have medications inspected once a month.

The commission has been made aware of confusion about how the hospital standard’s “monthly inspection...” WAC 246-873-080(1)(b) is applicable to HCEs through WAC 246-904-040.
The commission interprets these rules to require a monthly inspection of a health care entity. However, at an HCE, those inspections may be performed by non-pharmacy personnel as long as the monthly reports are transmitted to, and in coordination with, pharmacy personnel, and the health care entity's responsible pharmacy manager retains ultimate authority over the inspections taking place and documentation of the inspections.

III. Consultant Pharmacist Responsibilities

WAC 246-904-030 outlines the responsibilities for the responsible pharmacy manager or pharmacist in charge of an HCE. The application for an HCE license asks for the name of the consulting pharmacist, which is the same as a full-time pharmacist in charge or responsible pharmacist manager.¹

WAC 246-904-030 specifically states that each HCE must have a pharmacist in charge, and then further states that pharmacist can be a full-time pharmacist or a consulting pharmacist. In either situation the pharmacist named on the application and identified at the institution as the pharmacist in charge is responsible for meeting all of the requirements outlined in WAC 246-904-030.

IV. Practitioner Dispensing in an HCE

HCEs are allowed to dispense and deliver medications under RCW 18.64.450, however dispensing is limited to patients of that HCE only.

RCW 18.64.450(3) and (4) state the following:

(3) The receipt, administration, dispensing, and delivery of legend drugs or controlled substances by a health care entity must be performed under the supervision or at the direction of a pharmacist.

(4) A health care entity may only administer, dispense, or deliver legend drugs and controlled substances to patients who receive care within the health care entity and in compliance with rules of the commission. Nothing in this subsection shall prohibit a practitioner, in carrying out his or her licensed responsibilities within a health care entity, from dispensing or delivering to a patient of the health care entity drugs for that patient's personal use in an amount not to exceed seventy-two hours of usage.

Dispensing by a practitioner within a HCE is limited to a 72 hour supply as (4) above states, however patients of a HCE can receive a greater than 72 hour supply if that dispensing takes place under the supervision of or at the direction of a pharmacist. This could mean a pharmacist must either be onsite as part of the dispensing or has performed a drug utilization review and authorizes the dispensing through a shared electronic health record system.

¹ The responsible pharmacy manager is used instead of ‘pharmacist in charge’ to proactively align terminology reflected in the 2020 proposed rules re-write.