

Health Care Entity (HCE) FAQ

This FAQ addresses some frequently asked questions about Health Care Entities (HCEs). If you have additional questions, please reach out to your inspector. For a list of inspectors, please go to [Pharmacy Commission | Washington State Department of Health](#).

Fee and Application

Where can I find information about HCE licensure fees?	Licensure fee information can be found in WAC 246-945-990(5)(g) . As a reminder, “an organization (e.g., a clinic) must obtain a separate license for each of its locations. One organization occupying multiple suites in one facility is deemed to be occupying one location requiring one license. Separate organizations occupying the same location must obtain separate licenses.” WAC 246-945-245(2) .
Is there a fee for adding or removing a clinic from an existing HCE credential?	No. There is no fee for adding or removing clinics to an existing HCE credential and updating the addendum section of the HCE application.
Should every service line (e.g., each separate clinic) operating in the HCE be listed on the HCE application addendum?	Yes. The application has an addendum for organizations occupying multiple suites in one facility sharing the same address to list the names of all clinics including any suite number licensed under the HCE credential. The addendum also asks for the number of medication locations in each suite. See Pharmacy Health Care Entity License Application Packet (wa.gov) .

Posting of the HCE License

If an HCE has more than one clinic listed under its license, does each clinic need to have a copy of the HCE license?	No. An HCE must have a copy of its current license on site, but each clinic is not required to have a copy of the HCE license. “It shall be the duty of the owner to keep the license of location, or the renewal license properly exhibited in the health care entity.” (RCW 18.64.460(3)).
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Inspections

When do inspections of health care entities occur?	Pharmacy inspectors perform the following inspections of HCEs. <ul style="list-style-type: none">• Initial (to include a brand new HCE credential and when adding a clinic to an existing HCE credential)
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	<ul style="list-style-type: none"> • Closing (whether closing an entire HCE credential or just one clinic within the larger HCE credential) • Routine • Consolidation • Modification or Remodel • Change of Location • Change of Ownership
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Self-inspections and Self-inspection Form(s)

If an HCE has more than one clinic listed under its license, how many self-inspection forms need to be completed for that HCE?	One self-inspection worksheet needs to be completed for the entire HCE by the RPM or their designee. An entity can choose to complete one self-inspection worksheet for each clinic, but this is not required. See WAC 246-945-005(4) .
If an HCE adds a clinic during the calendar year, does the HCE need to complete a new self-inspection form?	No. The responsible pharmacy manager, or equivalent manager, for an HCE must complete an annual self-inspection on the self-inspection worksheets provided by the commission within the month of March each year and within 30 days of a change in responsible pharmacy manager. See WAC 246-945-005(4) .
If an HCE has more than one clinic listed under its license, does a copy of the HCE's self-inspection form need to be available at each clinic?	No. The commission does not require that a copy of the HCE's self-inspection form be stored at each clinic. However, the HCE is required to ensure the self-inspection form is in a readily retrievable form and location for at least two years. See WAC 246-945-005(4) , WAC 246-945-001(71) , WAC 246-945-020 .
If an HCE has more than one clinic listed under its license, and one or more of those clinics possess controlled substances, is there guidance available regarding best practices regarding licensure?	No. The commission does not provide comprehensive guidance on best practices in this situation. However, HCEs are encouraged to consult with their own legal counsel and the DEA on compliance with applicable federal law.

Transfer of drugs

Can clinics under one HCE credential transfer drugs between the clinics under the one HCE credential?	Whether an HCE can transfer drugs between clinics listed under its license will depend on a number of factors, such as the type of drug being transferred and the HCE's ownership structure. As a result, the Commission cannot definitively say whether all
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	<p>transfers would be prohibited or not. HCEs are encouraged to consult with their legal counsel on whether a proposed transfer is permissible under state and federal law.</p>
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Change of Service Line

<p>Does a change of service line in an HCE require an updated application?</p>	<p>If there is a change in service line to an existing clinic that is currently licensed under an HCE license, the entity should complete the Pharmacy Health Care Entity License Application, check the “update clinics” box, and complete the addendum (pg. 2 of 4) of the application.</p>
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Storage

<p>Does the addition of a new medication storage area in an HCE require the HCE to submit a remodel application and go through a remodel inspection?</p>	<p>Please refer to WAC 246-945-230(3)(a) and the commission’s guidance document on inspection requirements for modifications or remodels in order to determine whether a remodel application and inspection are needed. Regardless of whether the addition of a new medication storage area is a remodel, the addition of medication storage areas does require the HCE to complete the Pharmacy Health Care Entity License Application, check the “update clinics” box, and complete the addendum (pg. 2 of 4) of the application noting the number of medication locations where changes were made.</p>
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