Part Three Facility Licensing

WAC 246-950-300 General Information, Change of Location, Ownership, or New Construction

(1) As the terms are used in this Part:

   (a) “License” is equivalent to “license”, “licensing”, “licensure”, “certificate”, “certification”, and “registration.”

   (b) “Facility” refers to pharmacies, nonresident pharmacies, health care entities, hospital pharmacy associated clinics, wholesalers, and manufacturers.

(2) Before receiving an initial license, all credentialed facilities will:

   (a) Submit a completed application for the license applied for, on forms provided by the Commission,

   (b) Pay a fee in accordance with WAC 246-950-990. This fee will not be prorated under any circumstances,

   (c) Undergo an inspection by the Commission if the facility is located in Washington pursuant to WAC 246-869-190 that results in either no deficiencies or an approved plan of correction, and

   (d) Obtain a controlled substances registration from the Commission and be registered with the DEA if the facility intends to possess controlled substances.

(3) Once an initial license is issued, all credentialed facilities will:

   (a) Notify the commission and pay a facility inspection fee in lieu of paying an original license fee for modifications or remodels. A modification or remodel of a pharmacy location includes changes to a previously approved area, room or pharmacy building. Remodels include any physical or functional changes, additions, or modifications to an existing pharmacy or a portion of an existing pharmacy.

   (b) Submit a new application on forms provided by the Commission and pay the original license fee in accordance with WAC 246-950-990 if the facility changes location to a different address. If located in Washington, a facility may not relocate prior to the inspection of the new premises.

   (c) Notify the Commission and pay the original license fee in accordance with WAC 246-950-990 whenever there is a change of ownership. Change in ownership
includes changes in business or organizational structure such as a change from sole proprietorship to a corporation, or a change of more than fifty percent ownership in a corporation.

(1) Upon receipt of a change of ownership application and fees, the purchaser may begin operations prior to the issuance of a new pharmacy license only when the purchaser and seller have a written power of attorney agreement. This agreement shall delineate that violations during the pending application process shall be the sole responsibility of the seller.

(2) This agreement shall be provided to the commission upon request.

(d) Notify the Commission within thirty (30) days of any changes to the information provided on their application.

(e) Notify the Commission of any changes in their responsible pharmacy manager, if a responsible pharmacy manager is required for initial licensure.

(f) Renew their license in accordance with WAC 246-950-990.

WAC 246-950-310 Pharmacy Licensing

(1) A pharmacy license may be issued when the applicant has:

..... (a) Complied with the requirements to obtain an initial license in WAC 246-950-300,

..... (b) Designated a responsible pharmacy manager, and

..... (c) Produces evidence of being built or remodeled in accordance with all building, health and fire codes required for the particular area.

WAC 246-950-350 Hospital Pharmacy Associated Clinics (HPACs).

(1) A parent hospital pharmacy may add or delete HPACs to a hospital pharmacy license at any time in compliance with WAC 246-950-300.

(2) The HPAC must designate a responsible pharmacist manager and notify the commission of changes.

(3) HPAC locations are identified as follows:

(a) Category 1 HPAC: Receives drugs transferred from the parent hospital pharmacy to the HPAC, and does not perform sterile or nonsterile compounding of drugs.
(b) Category 2 HPAC: Receives drugs transferred from the parent hospital pharmacy to the HPAC and performs sterile or nonsterile compounding of drugs.

WAC 246-950-400 Non-resident Pharmacy License
(1) A non-resident pharmacy license may be issued when the applicant has:
..... (a) Complied with the requirements to obtain an initial license in WAC 246-950-300,
..... (b) Designated a responsible pharmacy manager, and
..... (c) Provided proof that its resident license is in good standing.

WAC 246-950-500 Health Care Entity Licensure.
A health care entity license may be issued when the applicant has:
..... (1) Complied with the requirements to obtain an initial license in WAC 246-950-300, and
..... (2) Designated a responsible pharmacy manager.

WAC 246-950-510 Wholesaler
(1) Every wholesale distributor who engages in wholesale distribution into, out of, or within Washington state must be licensed by the commission before engaging in wholesale distribution of drugs. Entities required to be licensed as a wholesaler includes:
   (a) In-state and out-of-state pharmaceutical wholesalers;
   (b) Out-of-state manufacturer that distribute or sell drugs into Washington;
   (c) Virtual wholesalers;
   (d) Out-of-state virtual manufacturers that distribute or sell drugs into Washington;
   (e) Outsourcing facilities in compliance with the federal drug enforcement administration; and
   (f) Reverse distributors.
(2) A wholesaler license may be issued when the applicant has compiled with the requirements in WAC 246-950-300.
(3) In addition to the requirements in WAC 246-950-510(2), if the applicant is located outside of Washington, the applicant must provide:

Commented [GC(5)]: Are these 503B? Shouldn't that be FDA?
(a) A copy of a site inspection conducted by the regulatory authority in the resident state or third-party inspection program recognized by the commission within the last two years and every two years with the distributor’s renewal,

..... (b) A copy of the resident state license, and

..... (c) A list of licenses, registrations, permits or certificates held in other states.

(5) Minimum qualifications. The commission shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in wholesale distribution of prescription drugs within the state:

(a) Any convictions of the applicant under any federal, state, or local laws relating to drug samples, wholesale, or retail drug distribution, or distribution of controlled substances;

(b) Any felony convictions of the applicant under federal, state, or local laws;

(c) The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

(d) Any false or fraudulent material furnished by the applicant on any application made in connection with drug manufacturing or distribution;

(e) Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

(f) Compliance with licensing requirements under any previously granted licenses;

(g) Compliance with requirements to maintain and/or make available to the commission, federal, state, or local enforcement officials those records required to be maintained by wholesale drug distributors; and

(h) Any other factors or qualifications the commission considers relevant to and consistent with public health and safety.

(7) When operations are conducted at more than one location by a single wholesale distributor, each location shall be licensed by the commission.

WAC 246-950-520 Pharmaceutical Manufacturer License
(1) An entity located in this state that manufactures drugs must be licensed by the commission in accordance with the laws and regulations of this state before engaging in manufacturing.

(2) A manufacturer license may be issued when the applicant has complied with the requirements in WAC 246-950-300 and WAC 246-950-510(2).

(3) When operations are conducted at more than one location by a single manufacturer, each location shall be licensed by the commission.

Part 4 Commission Registrations

WAC 246-950 540 Researcher, and Other Controlled Substance Registration

(1) Initial registration and renewal applications for researcher or other controlled substance registrations must be submitted with fees relevant to the registration type.

   (a) Researcher
       (i) Non-controlled legend drugs; or
       (ii) Researchers requiring to purchase, possess, administer or dispense controlled substances must apply for a controlled substance authority on its license with the commission and register with the DEA.

   (b) Other Controlled Substance registrations;
       (i) Opioid treatment programs;
       (ii) Analytical laboratories;
       (iii) Dog handler;
       (iv) Other agencies who have demonstrated a legitimate need to use precursor chemicals.

(2) The application shall:

   (a) List all legend drugs and controlled substances to be used and the purpose for its use;

   (b) Name the primary registrant;

   (c) List the names of the persons authorized to access the controlled substances.

(3) Applicants must undergo an initial inspection and periodically as deemed appropriate by the commission.
**WAC 246-950 580 Shopkeeper Registration**

(1) A shopkeeper registration is issued to a business license authorizing the holder to purchase, possess, and sell over-the-counter medications, as defined in RCW 18.64.044, and chapter 69.43 RCW if applicable.

(2) A business entity with a licensed pharmacy with different operating hours shall hold a shopkeeper registration to acquire, possess, and sell over-the-counter medications when the pharmacy is closed.

**WAC 246-950-600 Animal Control and Humane Society Registration**

(1) Humane societies and animal control agencies registered with the commission under RCW 69.50.310 may purchase, possess, and administer sodium pentobarbital and approved legend drugs as provided in RCW 69.41.080.

(2) To apply for registration, a humane society or animal control agency shall submit to the commission a completed application for registration on forms provided by the commission.

(3) Designate the person responsible for maintaining all records and submitting all reports required by applicable federal or state law or rule.

(4) Provide a list of staff trained and authorized to administer approved drugs.

**WAC 246-950-610 Chemical Capture – Department of Fish and Wildlife Registration**

(1) The department of fish and wildlife may apply to the commission for a limited registration under chapter 69.50 RCW to purchase, possess, and administer controlled substances for use in chemical capture programs.

(2) Each department of fish and wildlife field office that stores controlled substances must register with the commission. The department of fish and wildlife must notify the commission of the names of individuals who are authorized to possess and administer controlled substances.

(3) The department of fish and wildlife shall designate one individual at each field office who shall be responsible for the ordering, possession, safe storage, and utilization of...
controlled substances. The department of fish and wildlife shall notify the commission of the name of the designated individual.

Part 5
Credentialing Fees

WAC 246-950-990 Pharmaceutical licensing fees and renewal cycle.
(1) Pharmacist, pharmacy intern, pharmacy technician, and pharmacy assistant credentials must be renewed every two years on the credential holder's birthday as provided in chapter 246-950 WAC, Part 2.
(2) Pharmacy location credentials, researcher registration, drug dog handler K9 registration, and other controlled substances act registrations will expire on June 1st of each year.
(3) All other credentials, including health care entity, will expire on October 1st of each year, except the shopkeeper endorsement, which expires annually associated with a business license issued by the department of revenue.
(4) The following nonrefundable fees will be charged for pharmacy professionals:

   (a) All pharmacy professionals:

   *Fees do not reflect two-year renewal cycles for individual credentials

<table>
<thead>
<tr>
<th>Fee</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Verification of credential</td>
<td>$25.00</td>
</tr>
<tr>
<td>Duplicate credential</td>
<td>10.00</td>
</tr>
</tbody>
</table>

   (b) Pharmacist:

<table>
<thead>
<tr>
<th>Fee</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Original credential</td>
<td>$200.00</td>
</tr>
<tr>
<td>Renewal</td>
<td>265.00</td>
</tr>
<tr>
<td>Late renewal penalty</td>
<td>135.00</td>
</tr>
<tr>
<td>Expired credential reissuance</td>
<td>265.00</td>
</tr>
<tr>
<td>Inactive credential renewal</td>
<td>265.00</td>
</tr>
</tbody>
</table>
Temporary permit: 100.00
Reciprocity: 465.00

(c) Pharmacy technician:

- Original credential: $70.00
- Renewal: 70.00
- Late renewal penalty: 50.00
- Expired credential reissuance: 70.00

(d) Pharmacy intern:

- Original credential: $45.00
- Renewal: 45.00
- Late renewal penalty: 45.00
- Verification of internship hours: 25.00
- Expired credential reissuance: 45.00

(e) Pharmacy assistant:

- Original credential: $35.00
- Renewal: 35.00
- Late renewal penalty: 35.00
- Expired credential reissuance: 35.00

(5) The following nonrefundable fees will be charged for pharmaceutical firms:

(a) All pharmaceutical firms:

- Verification of credential: $25.00
- Duplicate credential: 10.00
- Facility inspection: 400.00

(b) Pharmacy (includes hospital pharmacies):
Pharmacy credential (for hospital pharmacy associated clinics, see WAC 246-950-1000)

<table>
<thead>
<tr>
<th>Type</th>
<th>Original</th>
<th>Renewal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy credential</td>
<td>$540.00</td>
<td>540.00</td>
</tr>
<tr>
<td>Late renewal penalty</td>
<td></td>
<td>270.00</td>
</tr>
</tbody>
</table>

Pharmacy technician utilization

<table>
<thead>
<tr>
<th>Type</th>
<th>Original</th>
<th>Renewal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Original utilization</td>
<td>100.00</td>
<td>100.00</td>
</tr>
</tbody>
</table>

Controlled substances authority

<table>
<thead>
<tr>
<th>Type</th>
<th>Original</th>
<th>Renewal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Original credential</td>
<td>150.00</td>
<td>150.00</td>
</tr>
<tr>
<td>With differential hours</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Original credential</td>
<td>55.00</td>
<td>55.00</td>
</tr>
</tbody>
</table>

(c) Nonresident pharmacy:

Pharmacy credential

<table>
<thead>
<tr>
<th>Type</th>
<th>Original</th>
<th>Renewal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Original credential</td>
<td>$540.00</td>
<td>540.00</td>
</tr>
<tr>
<td>Late renewal penalty</td>
<td></td>
<td>270.00</td>
</tr>
</tbody>
</table>

Controlled substances authority

<table>
<thead>
<tr>
<th>Type</th>
<th>Original</th>
<th>Renewal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Original credential</td>
<td>150.00</td>
<td>150.00</td>
</tr>
</tbody>
</table>

(d) Drug researcher:

<table>
<thead>
<tr>
<th>Type</th>
<th>Original</th>
<th>Renewal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Original credential</td>
<td>$160.00</td>
<td>160.00</td>
</tr>
</tbody>
</table>

Controlled substance authority

<table>
<thead>
<tr>
<th>Type</th>
<th>Original</th>
<th>Renewal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Original credential</td>
<td>$240.00</td>
<td>240.00</td>
</tr>
</tbody>
</table>
(e) Other controlled substances act registrations (i.e., analytical laboratories, school laboratories):

Original credential $360.00
Renewal 360.00

(f) Drug dog handler K9 registration:

Original credential $55.00
Renewal 55.00

(g) Health care entity:

Health care entity credential
Original credential $540.00
Renewal 540.00
Late renewal penalty 270.00

Controlled substances authority
Original credential 150.00
Renewal 150.00

(h) Drug manufacturer:

Manufacturer credential
Original credential $825.00
Renewal 825.00
Late renewal penalty 300.00

Controlled substances authority
Original credential 150.00
Renewal 150.00

(i) Drug wholesaler – Full line:

Wholesaler credential
<table>
<thead>
<tr>
<th>Category</th>
<th>Original credential</th>
<th>Renewal</th>
<th>Late renewal penalty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controlled substances authority</td>
<td>$825.00</td>
<td>825.00</td>
<td>300.00</td>
</tr>
<tr>
<td>Drug wholesaler – Export</td>
<td>$825.00</td>
<td>825.00</td>
<td>300.00</td>
</tr>
<tr>
<td>Drug wholesaler – OTC only</td>
<td>$465.00</td>
<td>465.00</td>
<td>235.00</td>
</tr>
<tr>
<td>Drug wholesaler – Export nonprofit humanitarian organization</td>
<td>$25.00</td>
<td>25.00</td>
<td>25.00</td>
</tr>
<tr>
<td>Legend drug sample distributor</td>
<td>$540.00</td>
<td>540.00</td>
<td>270.00</td>
</tr>
<tr>
<td>(n) Poison manufacturer/seller:</td>
<td>Original credential</td>
<td>150.00</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Renewal</td>
<td>150.00</td>
<td></td>
</tr>
</tbody>
</table>

| (o) Precursor chemicals: | Original credential | $55.00 |
| | Renewal | 55.00 |
| | Late renewal penalty | 50.00 |

| (p) Itinerant vendor: | Original credential | $55.00 |
| | Renewal | 55.00 |
| | Late renewal penalty | 50.00 |

| (q) Sodium pentobarbital for animal euthanization: | Original credential | $55.00 |
| | Renewal | 55.00 |
| | Late renewal penalty | 50.00 |

| (r) Shopkeeper: | Original credential | $55.00 |
| | Renewal | 55.00 |

WAC 246-950-1000 Hospital pharmacy associated clinic fees and renewal cycle.
(1) Parent hospital pharmacy licenses with one or more hospital pharmacy associated clinics (HPAC) expire on June 1st of each year.

(2) A parent hospital pharmacy must submit fees for HPACs in addition to fees set in WAC 246-950-990(4). HPAC fees are due annually, except as provided under subsection (3)(d) of this section.

(3) A parent hospital pharmacy must submit the following nonrefundable fees based on category and number of HPACs as defined in WAC 246-945-010 (General Provisions) added to the parent hospital pharmacy license.

(a) **Category 1 HPAC.** A parent hospital pharmacy must submit the Category 1 HPAC fee according to the number of Category 1 HPACs under the parent hospital pharmacy license.

<table>
<thead>
<tr>
<th>HPAC tier</th>
<th>Number of Category 1 HPACs under parent hospital pharmacy license</th>
<th>Total annual fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1-10</td>
<td>$895.00</td>
</tr>
<tr>
<td>B</td>
<td>11-50</td>
<td>$2,240.00</td>
</tr>
<tr>
<td>C</td>
<td>51-100</td>
<td>$3,125.00</td>
</tr>
<tr>
<td>D</td>
<td>Over 100</td>
<td>$4,025.00</td>
</tr>
</tbody>
</table>

(b) **Category 2 HPAC.** A parent hospital pharmacy must submit the Category 2 HPAC fee for each Category 2 HPAC under the parent hospital pharmacy license.

| Category 2 HPAC fee | $55.00 |

(c) The department charges a processing fee of fifty-five dollars for an amended license to change the number of HPACs.

(d) If at any time a parent hospital pharmacy submits an addendum increasing the number of HPACs on the parent hospital pharmacy license, which changes the applicable HPAC tier to a higher fee amount, the parent hospital pharmacy shall
submit the difference in fees with the addendum.

(e) The department will not refund fees when a tier reduction occurs between renewal periods.