**Chapter 246-950 WAC – General Licensing**

Part One –Pharmacy Interns and Pharmacists

**WAC 246-950-005 Pharmacy Interns - Registration Requirements**

(1) Each person shall register as a pharmacy intern before beginning pharmacy practice experiences in this state. A registration to practice pharmacy as a pharmacy intern shall be granted only to those individuals who are:

(a) Currently enrolled in an accredited professional degree program of a school or college of pharmacy that has been approved by the commission and making satisfactory progress towards meeting the requirements for licensure as a pharmacist;

(b) Graduates of an approved professional degree program of a school or college of pharmacy;

(c) Graduates of a school or college of pharmacy located outside the United States who have established educational equivalency by obtaining certification by the foreign pharmacist graduate equivalency committee.

(d) Required by the commission, if the commission determines an individual needs to complete additional practical experience before a pharmacist license is issued or reissued.

(2) A pharmacy intern shall practice under the direct supervision of a licensed pharmacist excluding pharmacy practice experience associated with a professional degree program of a school or college of pharmacy which is accredited by the commission.

(3) A pharmacy intern registration will expire in accordance with WAC 246-950-990 on the credential holder’s birthday if not renewed.

(4) A pharmacy intern registration may not be renewed more than three times without prior authorization by the commission.

(5) The commission may consider a pharmacy intern registration inoperable or superseded if one of the following occurs:

(a) A registered pharmacy intern, who has not graduated from a school or college of pharmacy and is no longer enrolled or in good standing with, an accredited school or college of pharmacy.

(b) A registered pharmacy intern is issued a license to practice as a pharmacist in this state or another U.S. jurisdiction.

**WAC 246-950-010 Pharmacy Intern - Temporary practice permit**.

(1) A person that holds a pharmacy intern credential in another state that meets substantially equivalent standards as in WAC 246-950-005 (1) (a) or (b) may request to receive a temporary practice permit to earn pharmacy practice internship hours, practice under the supervision of a licensed pharmacist, or participate in an accredited residency program if:

(a) The applicant is not subject to denial of a license or issuance of a conditional or restricted license;

(b) Does not have a criminal record in Washington state; and

(c) The applicant’s fingerprint-based national background check results are pending.

(2) A temporary practice permit expires when any one of the following occurs:

(a) The pharmacy intern registration is issued;

(b) A notice to deny or restrict the registration is mailed to the applicant, unless the notice specifically extends the duration of the temporary practice permit; or

(c) Ninety days (90) after the temporary practice permit is issued.

(3) To request a temporary practice permit, the pharmacy intern applicant shall submit the fingerprint card, a written request for a temporary practice permit, and any applicable fees.

**WAC 246-950-100 Pharmacist License required.**

(1) Practice in Washington. All pharmacists located in the state of Washington shall be duly licensed under chapter 18.64 RCW to engage in the practice of pharmacy.

(2) Practice into Washington. Nonresident pharmacists who are employed by, or affiliated with, and practicing for a Washington state licensed nonresident pharmacy are exempt from license and registration requirements for practice into Washington.

**WAC 246-950-120 Pharmacist license qualifications.**

(1) Qualifying applicants for a pharmacist license shall hold a baccalaureate degree in pharmacy or a doctor of pharmacy degree granted by a school or college of pharmacy accredited by the Accreditation Council for Pharmacy Education. Documentation must include:

(a) Official transcripts that shows a baccalaureate of pharmacy or doctorate of pharmacy degree is awarded or conferred; and

(b) Certification of a minimum of seventeen hundred and forty (1740) pharmacy internship hours.

(c)Take and pass approved licensure examinations.

(2)Qualifying applicants for a pharmacist license whose academic training in pharmacy is from institutions in foreign countries must:

(a)Achieve certification by the Foreign Pharmacy Graduate Examination Committee(FPGEC) including:

(i) Passing the Foreign Pharmacy Graduate Equivalency Examination (FPGEE);

(ii) Passing required test of English as a Foreign Language;

(b) Provide official transcripts or diploma that shows a baccalaureate of pharmacy or doctorate of pharmacy degree is awarded or conferred;

1. Certification of a minimum of seventeen hundred and forty (1740) pharmacy internship hours; and
2. Take and pass approved licensure examinations.

(3) For licensure requirements, interns seeking certification of pharmacy practice hours not certified by an accredited school or college of pharmacy approved by the commission or required under subsection (2) of this section:

(a) Hours shall be reported thirty (30) days after the completion of any site internship experience.

(b) For certification the documentation must include the supervising pharmacist’s evaluation and certification of internship hours, and intern site evaluation for each site.

(c) If the report indicates that the intern has not adequately performed the practice of pharmacy, the commission may reject all or part of the hours reported.

**WAC 246-950-125 Pharmacist Licensure Examinations**

(1) Upon authorization by the commission or its designee, a person applying for a pharmacist license shall take and pass a pharmacy licensure examination and jurisprudence examination approved by the commission.

(2) A score of 75 or higher is required to pass each examinations.

1. A person failing to pass the jurisprudence examination three times shall not be authorized for further examination until he or she has satisfactorily completed a pharmacy law course provided by a college or school of pharmacy or commission directed study or tutorial program approved by the commission.
2. A person taking an approved licensure examination in another state for the purpose of score transfer to Washington shall meet the requirements in WAC 246-950-120. The official score transfer application is valid for one year from the date the department receives notification. The applicant shall complete the license process before the score transfer expires. Once expired, the applicant shall apply using the license reciprocity or license transfer process (see WAC 246-950-130).

**246-950-130 Pharmacist Licensure by Reciprocity or License Transfer – Temporary Practice Permits**

1. A person who holds an active pharmacist license issued by another state or U.S. jurisdiction whose license is in good standing may apply for licensure by reciprocity or license transfer. In addition to the state application, the applicant must:
	1. File for license transfer using the NABP eLTP process; and

(b) Take and pass the commission approved pharmacy jurisprudence examination.

(2) A temporary practice permit to practice pharmacy may be issued to a pharmacist applicant for license by reciprocity or license transfer if the applicant meets all of the requirements and qualifications in subsection 1, and if the following criteria are met:

1. The applicant is not subject to denial of a license or issuance of a conditional or restricted license, and
2. Does not have a criminal record in Washington state; and
3. The applicant’s fingerprint-based national background check results are pending.
4. A temporary practice permit expires when any one of the following occurs:
5. The pharmacist license is issued;
6. A notice to deny or restrict the registration is mailed to the applicant, unless the notice specifically extends the duration of the temporary practice permit; or
7. One hundred eighty days (180) after the temporary practice permit is issued. The applicant may request a one-time extension of one hundred eighty days (180) on approval of the commission.
8. To request a temporary practice permit, the applicant shall submit the fingerprint card, a written request for a temporary practice permit, and applicable fees.
9. A temporary practice permit grants the individual the full scope of practice of pharmacy, except the ability to qualify as a responsible pharmacist manager.

**246-950-135 Pharmacist Expired Credential**

1. A Pharmacist license will expire in accordance with WAC 246-950-990 on the credential holder’s birthday if not renewed.
2. If the pharmacist credential has expired for less than three years the practitioner shall meet the requirements of chapter 246-950 WAC, Part 2, 246-950-145, and WAC 246-950-990.
3. If the credential has expired for over three years, and the pharmacist has been in active practice in another state or U.S. jurisdiction, the pharmacist must:
	1. Meet the requirements in chapter 246-12 WAC, Part 2; and
	2. Take and pass the approved jurisprudence examination.
4. If the credential has expired between three and five years, and the pharmacist has not been in active practice in another state or U.S. jurisdiction, the pharmacist must:
	1. Meet the requirements in chapter 246-12 WAC, Part 2;

(b) Serve an internship of 300 hours; and

(c) Take and pass the approved jurisprudence examination.

(5) If a pharmacist license has been expired for over five years, and the practitioner has not been in active practice in another state or U.S. jurisdiction, the practitioner shall:

* 1. Meet the requirements of WAC 246-12, Part 2;
	2. Serve an internship of 300 hours; and
	3. Take and pass the approved jurisprudence and licensure examinations.

**WAC 246-950-140 Pharmacist Inactive Credential**

1. A pharmacist may obtain an inactive license by meeting the requirements of WAC 246-12-090 and RCW 18.64.140.
2. An inactive license shall be renewed accordance with WAC 246-950-990 on the licensee’s birthday.
3. If a license is inactive for three years or less, to return to active status a pharmacist shall meet the requirements of WAC 246-12, Part 4.
4. If a license is inactive for more than three years, and the pharmacist has been in active practice in another state or U.S. jurisdiction, to return to active practice, the pharmacist must:
	1. Provide certification of an active pharmacist license. The certification shall include:
5. Name and license number;
6. Issue and expiration date; and
7. Verification if the license has been the subject of final or pending disciplinary action.
	1. Provide verification of active practice from another state or U.S. jurisdiction within the last three years;
	2. Meet the requirements of WAC 246-12, Part 4; and
	3. Take and pass an approved jurisprudence examination.
8. If a pharmacist license has been inactive for more than three years, and the pharmacist has not been in active practice in another state or U.S. jurisdiction, to return to active practice, the pharmacist shall comply with the requirements under WAC 246-950-135, subsection (3) or (4).

**WAC 246-950-145 Pharmacist Continuing Education**

1. Each pharmacist shall complete the equivalent of 3.0 of continuing pharmacy education unit (equal to thirty contact hours) administered by an ACPE accredited provider each license renewal cycle.
2. Pharmacists shall register with a program designated by the commission for tracking completed CPE hours
3. Licensed pharmacists shall complete a one-time training in suicide screening and

referral by the end of the first full renewal cycle after initial licensure. The training

Shall meet the following requirements:

1. The training is at least three hours long;
2. The training shall be from the department of health's model list of approved suicide-prevention training programs, and include content related to imminent harm via lethal means.
3. Notwithstanding subsection (1), the hours spent completing the training in this section may count toward meeting continuing pharmacy education requirements.
4. Pharmacist may not carry over CPE hours completed during one renewal cycle to the next renewal cycle.

**WAC 246-950-150 Nuclear Pharmacist Endorsement**

In order for a pharmacist to qualify under these regulations as a nuclear pharmacist,

he or she must:

1. Be a pharmacist licensed to practice in Washington.
2. Meet minimal standards of training and experience in the handling of radioactive materials in accordance with the requirements of the state radiation control agency.
	1. Is certified by a specialty board recognized by the U.S. Nuclear Regulatory Commission National or commission whose certification process requires candidates for certification to:
3. Hold a current, active license to practice pharmacy; and
4. Provide evidence of having acquired at least four thousand hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than two thousand hours of the required training and experience; and

(iii) Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, which assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

(3) Has completed two hundred hours in a structured educational program consisting of both:

1. Didactic training in the following areas:
2. Radiation physics and instrumentation;
3. Radiation protection;
4. Mathematics pertaining to the use and measurement of radioactivity;
5. Chemistry of radioactive material for medical use; and
6. Radiation biology; and

(b) Supervised practical experience in a nuclear pharmacy involving:

* + 1. Shipping, receiving, and performing related radiation surveys;
		2. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha-or beta-emitting radionuclides;
		3. Calculating, assaying, and safely preparing dosages for patients or human research subjects;
		4. Using administrative controls to avoid medical events in the administration of radioactive material; and
		5. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and
1. Has obtained written attestation, signed by an authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in subsections (2) or (3) of this section and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

**PART Two**

**Pharmacy Assistants and Technicians**

**WAC 246-950-200 Pharmacy Assistant**

1. An initial application or renewal for registration as a pharmacy assistant shall meet the requirements of chapter [246-12](http://apps.leg.wa.gov/WAC/default.aspx?cite=246-12) WAC, Part 2 and Part 8.

 (2) No formal training or educational program is required and there is no age or educational restrictions. The supervising pharmacist, or designee, shall instruct the pharmacy assistant regarding their scope of practice.

(3) A pharmacy assistant will expire in accordance with WAC 246-950-990 on the credential holder’s birthday if not renewed.

(4) Refer to WAC 246-950-210 for requirements for an assistant registration with a technician in training registration.

(5) Registration will expire/be superseded upon receipt of a technician certificate.

**WAC 246-950-210 Pharmacy Technician-in-Training Authority for Experiential Training**

1. An individual who is enrolled in an approved pharmacy-technician training program shall obtain a pharmacy technician in-training endorsement for experiential training in a pharmacy for
	1. Initial certification, or
	2. As required by the commission to complete additional practice experience before a pharmacy technician certification is issued, renewed, or reactivated.
2. File an application for pharmacy assistant including the verification of enrollment in a commission approved pharmacy technician education and training program form.

(3) The commission may consider the pharmacy technician-in-training authority inoperable or superseded if one of the following occurs:

(a)A pharmacy technician certification is issued; or

(b) A pharmacy technician-in-training is no longer enrolled or in good standing with a commission approved training program.

**WAC 246-950-220 Pharmacy Technician Certification**

1. An applicant for certification as a pharmacy technician shall meet the qualifications in RCW 18.64A.020 and satisfy the following:

(a) Provide proof of completion of eight (8) hours of guided study of Washington state and federal pharmacy law. The law study shall be done in coordination and oversight of a Washington licensed pharmacist.

(b) Proof of successful completion of a pharmacy-technician training program approved by the commission. Acceptable documentation includes::

(i) On-the-job training program. Successful completion of didactic and practice experience signed by the program director on a form provided by the commission;

(ii) Formal academic or college programs. Official transcripts of completion of a one-year diploma or certification program at a pharmacy technician school or a two-year associate degree program, which shall include evidence of practice training hours or the hours shall be reported on a commission approved form signed by the program director; or

 (iii) Certificate of Release or Discharge from Active Duty, DD214 documenting evidence of your pharmacy technician training provided by a branch of the federal armed services.

1. Pass a national certification examination or hold an active pharmacy technician national certification administered or issued by an organization approved by the commission. For initial certification, the applicant’s national pharmacy technician certification shall be active or the applicant passed the national certification examination within two years prior to applying.
2. Individuals who are graduates of a foreign school or college of pharmacy or medicine, whose professional degree program is approved by the commission shall complete the following:

(a) If English is not the primary language, the applicant shall take and pass a test of English as a Foreign Language; and

### (b) Complete 520 hours of supervised experience under the supervision of a license pharmacist with training hours reported using forms provided by the commission and passing an approved examination under subsection(2).

### **WAC 246-950-225 Pharmacy Technician - Temporary practice permit—Military spouse eligibility and issuance.**

A military spouse or state registered domestic partner of a military person may receive a temporary practice permit while completing any specific additional requirements that are not related to training or practice standards for a pharmacy technician certification. The commission adopts the procedural rules as adopted by the department of health in WAC [246-12-051](http://app.leg.wa.gov/wac/default.aspx?cite=246-12-051).

**WAC 246-950-230 Pharmacy Technician education and training programs.**

1. Pharmacy technician applicants that completes a pharmacy technician-training program that meets one of the following criteria shall be considered approved upon review of the qualification by the commission or its designee. Approved pharmacy technician training programs include those accredited, approved, or administered by:
2. The American Society of Health-System Pharmacists (ASHP);
3. The Accreditation Council for Pharmacy Education;
4. The United States Armed Forces; or
5. Any U.S. state licensing board or commission when the training program meets the minimum requirements as listed in subsection (2);
6. Approved pharmacy technician education and training programs shall meet the following minimum requirements:

(a) Prepare students for entry-level practice in a variety of settings including but not limited to community, hospital, and long-term care to include the following basic areas of training but not limited to:

1. Orientation to Pharmacy Practice—Health care delivery systems, broad definitions of pharmacy practice and practice settings, communication techniques, confidentiality of information and safety considerations;
2. Basic Pharmaceutics—Medical and pharmaceutical terminology and abbreviations, components of a prescription and patient medication record, drug dosage forms, routes of administration and drug product packaging, weighing and measuring, labeling, drug nomenclature, aseptic techniques, drug storage and handling, and drug standard and information sources;
3. A minimum of eight (8) hours in principles of applicable state and federal pharmacy laws, rules, and regulations, guidelines and interpretive statements; and
4. Pharmaceutical Calculations. Basic mathematics (fractions, decimals, percentages, proportions), and weights and measures.
5. Commission approved programs must include a multicultural health curriculum as required by RCW 43.70.614.
6. The program director shall be a pharmacist and is accountable for the overall quality of the program.

(d) Minimum hours of education and training shall extend over a period of fifteen weeks but under twenty-four months; and shall include at a minimum:

(i) Vocational or Technical training shall be eight hundred (800) hours and includes 160 hours supervised practice experience

(ii) Formal or Academic Training programs shall be two academic quarters with thirty (30) credit hours each and includes one-hundred and sixty (160) supervised practice experience.

(iii) On-the-Job Training must be at least five-hundred and twenty (520) hours with twelve (12) hours of instructive education

1. Programs seeking official recognition as a commission approved program must provide the following:
	1. Submit an application on a form provided by the commission;
	2. Designate a licensed pharmacist as program director;
	3. Provide list or copies of training manuals and reference;
	4. Content of instruction;
	5. Methods for evaluating trainees; and
	6. Verification of eight hours of pharmacy law study.
2. Commission approved programs must renewal every five (5) years. Any changes substantive changes to the program or change in program director must be reported to the commission office.

### **WAC 246-950-235 Technician expired status**

1. A technician’s certification will expire in accordance with WAC 246-950-990 on the credential holder’s birthday if not renewed.
2. The holder of an expired technician certification shall not be authorized to practice.
3. If a technician certification has expired for five years or less, the practitioner shall meet the requirements of chapter 246-950 WAC, Part 2.
4. If the technician certification has expired for over five years and they have not practiced in another state, the technician shall:

(a) Complete the requirements for certification under WAC 246-950-220; and

(b) Meet the requirements of chapter [246-950](http://apps.leg.wa.gov/WAC/default.aspx?cite=246-12) WAC, Part 2.

(5) If the practitioner has been in an active practice in another United States jurisdiction with duties that are substantially equivalent to a pharmacy technician in Washington state, the practitioner shall:

(a) Submit verification of active practice from any other United States jurisdiction;

(b) Meet the requirements of chapter 246-950 WAC, Part 2.

### **WAC 246-950-240 Pharmacy technician—Continuing education requirements.**

Each pharmacy technician applicant for certification renewal shall complete twenty (20) CPE hours administered by an ACPE accredited program.

Pharmacy technicians shall register with a program designated by the commission for tracking completed CPE hours.

CPE completed during the current licensing period may not be carried over to the next licensing period.

**Part Three Pharmaceutical Firms**

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

1. In-state pharmacies must notify the commission and pay a facility inspection fee in lieu of the paying an original license fee for modifications or remodels. A modification or alteration of a pharmacy location includes changes to a previously approved area, room or pharmacy building. Alterations include any physical or functional changes, additions, or modifications to an existing pharmacy or a portion of an existing pharmacy.
2. All in-state pharmaceutical facilities credentialed under this chapter will be inspected before a credential is issued and periodically as deemed appropriate by the commission. Refer to WAC 246-945-030 (General Provisions) for pharmacy inspection process.
3. All credentialed facilities that change location to a different address shall require a new application and payment of the original license fee. In-state facilities may not relocate prior to the inspection of the new premises.

(4) An original credential fee will be paid whenever there is any change in ownership, including change 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.

(a) 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.

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

(5) Changes in any information provided on the application must be submitted to the commission within thirty days after such change.

(6) All fees and credential renewal cycles are in accordance with WAC 246-950-990

and will not be prorated.

**WAC 246-950-310 Pharmacy Licensing**

(1) The commission will issue or renew a pharmacy license upon application and determination that the applicant has satisfied the requirements of the Washington Pharmacy Practice Act, and any applicable state, local, and federal laws, rules and regulations.

(a) Initial licensure and renewal applications shall be submitted on forms provided by the commission.

(b) A pharmacy license is issued to a location and is not transferable.

(c) The applicant must designate a responsible pharmacy manager at the time of application and notify the commission of changes as required under chapter 246-960-170.

(2) Pharmacies that purchase, possess, administer or dispense controlled substances shall apply for controlled substance authority on its pharmacy license with the commission and register with the DEA.

**WAC 246-950-350 Hospital Pharmacy Associated Clinics (HPAC’s**).

(1) A parent hospital pharmacy may add or delete HPACs to a hospital pharmacy license at any time by filing a hospital pharmacy license addendum with the commission along with applicable fees set forth in WAC 246-950-990. Added HPACs are subject to inspection in accordance with this WAC 246-945-030.

(2) 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. This does not infer that pharmaceutical services are proved at this location.

(b) Category 2 HPAC: Receives drugs transferred from the parent hospital pharmacy to the HPAC and performs sterile or nonsterile compounding of drugs.

(3) A HPAC licensed under the parent hospital pharmacy license must obtain a Drug Enforcement Administration (DEA) registration for purposes of possessing controlled substances.

**WAC 246-950-400 Non-resident Pharmacy License**

(1) The commission will issue or renew a non-resident pharmacy license upon application and determination that the applicant has satisfied the requirements in chapter 18.64 RCW and its resident license is in good standing.

(2) A pharmacy license is issued to a location and is not transferable.

(3) The non-resident pharmacy must designate a responsible pharmacist manager with the commission as part of the application process and notify the commission of changes.

(4) Any non-resident pharmacy that distributes or dispenses controlled substances shall apply for a controlled substance authority on its license with the commission and hold a DEA registration.

**WAC 246-950-500 Health Care Entity Licensure.**

(1) The commission will issue or renew a health care entity license upon application and determination that the applicant has satisfied the requirements of the all applicable state and federal laws, rules, and regulations.

(2) Initial licensure and renewal applications will be submitted on forms provided by the commission.

(3) Facility must designate a responsible pharmacy manager.

(4) A health care entity license is issued to a location and is nontransferable. Each 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.

 (5) In case of a change of ownership or location of a health care entity, the original license becomes void and must be returned with a new application and original license fees.

(6) Health care entities that 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.

**WAC 246-950-510 Wholesaler**

(1) Every wholesale distributor, wherever located, who engages in wholesale distribution into, out of, or within this state must be licensed by the commission before engaging in wholesale distribution of prescription 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 distributes or sells drugs;

(c) Virtual wholesalers;

(d) Out of state virtual manufacturers;

(e) Outsourcing facilities in compliance with the federal drug enforcement administration; and

(f) Reverse distributors.

(2) Minimum required information for licensure. The commission requires the following from each wholesale drug distributor as part of the initial licensing procedure and as part of any renewal of such license.

1. The name, full business address, and telephone number of the licensee;
2. All trade or business names used by the licensee;
3. Addresses, telephone numbers, and the names of contact persons for the facility used by the licensee for the storage, handling, and distribution of prescription drugs;
4. The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and
5. The name(s) of the owner and/or operator of the licensee, including:
6. If a person, the name of the person;
7. If a partnership, the name of each partner, and the name of the partnership;
8. If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation, and the name of the parent company, if any;
9. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

(vi) Each location shall be licensed by the commission when operations are conducted at more than one location by a single wholesaler.

 (3) 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:

1. 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;
2. Any felony convictions of the applicant under federal, state, or local laws;
3. The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;
4. Any false or fraudulent material furnished by the applicant in any application made in connection with drug manufacturing or distribution;
5. 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;
6. Compliance with licensing requirements under previously granted licenses, if any;
7. 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
8. Any other factors or qualifications the commission considers relevant to and consistent with public health and safety.
9. Export Wholesaler. Application for wholesaler license for the primary business of exporting drugs to foreign countries.
	1. The license authorizes the holder to export non-controlled drugs to persons in a foreign jurisdiction that have legitimate reasons to possess such drugs.
	2. The application must include letters from consulate of the country to which drugs are exported and should verify consignee receiving such drugs is legally entitled in that country to receive them, if applicable. These letters shall be made available to the commission upon its request.
	3. The issuance of an export wholesaler license does not authorize delivery of drugs in the United States.

(5) Out of state applicants must include:

(a) A copy of a site inspection conducted by the regulatory authority in the resident state within the last two years and every two years with the distributor’s renewal; or third-party inspection program recognized by the commission;

(b) A copy of the resident state license; and

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

(6) Wholesaler that distribute or sell controlled substances shall register with the commission and with the federal Drug Enforcement Administration (DEA), and must be licensed as a full-line wholesaler.

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

(8) Changes in any information provided in this section or on the application must be submitted to the commission within thirty days after such change.

**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 pharmaceutical manufacturing as defined in RCW 18.64.011.

(2) Initial licensure and renewal applications must be submitted on forms provided by the Commission.

 (3) Comply with the requirement and qualifications under WAC 246-950-510 subsection (2) and (3).

 (4) Manufacturers that manufacture controlled substances shall apply for a controlled substance authority with the commission and register with the DEA.

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

**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 on forms provided by the commission with fees relevant to the registration type.
	1. Researcher
		1. Non-controlled legend drugs; or
		2. 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.
	2. Other Controlled Substance registrations;
		1. Opioid treatment programs;
		2. Analytical laboratories;
		3. Dog handler;
		4. Other agencies who have demonstrated a legitimate need to use precursor chemicals.
2. The application shall:
	1. List all legend drugs and controlled substances to be used and the purpose for its use;
	2. Name the primary registrant;
	3. List the names of the persons authorized to access the controlled substances
3. Applicants must undergo an initial 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 purchase, 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](http://app.leg.wa.gov/RCW/default.aspx?cite=69.50.310) may purchase, possess, and administer sodium pentobarbital and approved legend drugs as provided in RCW [69.41.080](http://app.leg.wa.gov/RCW/default.aspx?cite=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](http://app.leg.wa.gov/RCW/default.aspx?cite=69.50) RCW (Uniform Controlled Substances Act) 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 in writing 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 in writing of the name of the designated individual.

**Part Six**

**Credentialing Fees**

**WAC 246-950-990 Pharmaceutical licensing fees and renewal cycle.**

(1) Pharmacist, pharmacy technician, pharmacy intern, and pharmacy assistant credentials must be renewed every two years on the practitioner'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

|  |  |
| --- | --- |
|  | **Fee** |
| Verification of credential | $25.00 |
| Duplicate credential | 10.00 |

1. Pharmacist:

|  |  |
| --- | --- |
| Original credential | $200.00 |
| Renewal | 265.00 |
| Late renewal penalty | 135.00 |
| Expired credential reissuance | 265.00 |
| Inactive credential renewal | 265.00 |
| Temporary permit | 100.00 |
| Reciprocity | 465.00 |

1. Pharmacy technician:

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

1. 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 |

1. 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:

1. All pharmaceutical firms:

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

1. Pharmacy (includes hospital pharmacies):

|  |
| --- |
| **Pharmacy credential** (for hospital pharmacy associated clinics, see WAC 246-950-1000) |
| Original credential | $540.00 |
| Renewal | 540.00 |
| Late renewal penalty | 270.00 |
| **Pharmacy technician utilization** |  |
| Original utilization | 100.00 |
| Renewal | 100.00 |
| **Controlled substances authority** |  |
| Original credential | 150.00 |
| Renewal | 150.00 |
| **With differential hours** |  |
| Original credential | 55.00 |
| Renewal | 55.00 |

1. Nonresident pharmacy:

|  |  |
| --- | --- |
| **Pharmacy credential** |  |
| Original credential | $540.00 |
| Renewal | 540.00 |
| Late renewal penalty | 270.00 |
| **Controlled substances authority** |  |
| Original credential | 150.00 |
| Renewal | 150.00 |

1. Drug researcher:

|  |  |
| --- | --- |
| Original credential | $160.00 |
| Renewal | 160.00 |
| **Controlled substance authority** |  |
| Original credential | $240.00 |
| Renewal | $240.00 |

1. Other controlled substances act registrations (i.e., analytical laboratories, school laboratories):

|  |  |
| --- | --- |
| Original credential | $360.00 |
| Renewal | 360.00 |

1. Drug dog handler K9 registration:

|  |  |
| --- | --- |
| Original credential | $55.00 |
| Renewal | 55.00 |

1. 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 |

1. 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 |

1. Drug wholesaler – Full line:

|  |  |
| --- | --- |
| **Wholesaler credential** |  |
| Original credential | $825.00 |
| Renewal | 825.00 |
| Late renewal penalty | 300.00 |
| **Controlled substances authority** |  |
| Original credential | 150.00 |
| Renewal | 150.00 |

1. Drug wholesaler – Export:

**Wholesaler credential**

|  |  |
| --- | --- |
| Original credential | $825.00 |
| Renewal | 825.00 |
| Late renewal penalty | 300.00 |

1. Drug wholesaler – OTC only:

|  |  |
| --- | --- |
| Original credential | $465.00 |
| Renewal | 465.00 |
| Late renewal penalty | 235.00 |

1. Drug wholesaler – Export nonprofit humanitarian organization:

|  |  |
| --- | --- |
| **Wholesaler credential** |  |
| Original credential | $25.00 |
| Renewal | 25.00 |
| Late renewal penalty | 25.00 |

1. Legend drug sample distributor:

|  |  |
| --- | --- |
| **Distributor credential** |  |
| Original credential | $540.00 |
| Renewal | 540.00 |
| Late renewal penalty | 270.00 |
| **Controlled substances authority** |  |
| Original credential | 150.00 |
| Renewal | 150.00 |

1. Poison manufacturer/seller:

|  |  |
| --- | --- |
| Original credential | $55.00 |
| Renewal | 55.00 |
| Late renewal penalty | 50.00 |

1. Precursor chemicals:

|  |  |
| --- | --- |
| Original credential | $55.00 |
| Renewal | 55.00 |
| Late renewal penalty | 50.00 |

1. Itinerant vendor:

|  |  |
| --- | --- |
| Original credential | $55.00 |
| Renewal | 55.00 |
| Late renewal penalty | 50.00 |

1. Sodium pentobarbital for animal euthanization:

|  |  |
| --- | --- |
| Original credential | $55.00 |
| Renewal | 55.00 |
| Late renewal penalty | 50.00 |

1. 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.
	1. **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.

|  |  |  |
| --- | --- | --- |
| **HPAC tier** | **Number of Category 1 HPACs under parent hospital pharmacy license** | **Total annual fee** |
| A | 1-10 | $895.00 |
| B | 11-50 | $2,240.00 |
| C | 51-100 | $3,125.00 |
| D | Over 100 | $4,025.00 |

* 1. **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 | $755.00 |

* 1. The department charges a processing fee of fifty-five dollars for an amended license to change the number of HPACs.
	2. 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.
	3. The department will not refund fees when a tier reduction occurs between renewal periods.