Sec. 13. RCW 18.64.005 is amended to read as follows:

The commission shall:

(1) Regulate the practice of pharmacy and enforce all laws placed under its jurisdiction;

(2) Prepare or determine the nature of, and supervise the grading of, examinations for applicants for pharmacists' licenses;

(3) Establish the qualifications for licensure of pharmacists or pharmacy interns;

(4) Conduct hearings for the revocation or suspension of licenses, permits, registrations, certificates, or any other authority to practice granted by the commission, which hearings may also be conducted by an administrative law judge appointed under chapter 34.12 RCW or a presiding officer designated by the commission. The commission may authorize the secretary, or their designee, to serve as the presiding officer for any disciplinary proceedings of the commission ~~authorized under this chapter~~. The presiding officer shall not vote on or make any final decision in cases pertaining to standards of practice or where clinical expertise is necessary. All functions performed by the presiding officer shall be subject to chapter 34.05 RCW;

(5) Issue subpoenas and administer oaths in connection with any hearing, or disciplinary proceeding held under this chapter or any other chapter assigned to the commission;

(6) Assist the regularly constituted enforcement agencies of this state in enforcing all laws pertaining to drugs, controlled substances, and the practice of pharmacy, or any other laws or rules under its jurisdiction;

(7) Promulgate rules for the dispensing, distribution, wholesaling, and manufacturing of drugs and devices and the practice of pharmacy for the protection and promotion of the public health, safety, and welfare. Violation of any such rules shall constitute grounds for refusal, suspension, or revocation of licenses or any other authority to practice issued by the commission;

(8) Adopt rules establishing and governing continuing education requirements for pharmacists and other licensees applying for renewal of licenses under this chapter;

(9) Be immune, collectively and individually, from suit in any action, civil or criminal, based upon any disciplinary proceedings or other official acts performed as members of the commission. Such immunity shall apply to employees of the department when acting in the course of disciplinary proceedings;

(10) Suggest strategies for preventing, reducing, and eliminating drug misuse, diversion, and abuse, including professional and public education, and treatment of persons misusing and abusing drugs;

(11) Conduct or encourage educational programs to be conducted to prevent the misuse, diversion, and abuse of drugs for health care practitioners and licensed or certified health care facilities;

(12) Monitor trends of drug misuse, diversion, and abuse and make periodic reports to disciplinary boards of licensed health care practitioners and education, treatment, and appropriate law enforcement agencies regarding these trends;

(13) Enter into written agreements with all other state and federal agencies with any responsibility for controlling drug misuse, diversion, or abuse and with health maintenance organizations, health care service contractors, and health care providers to assist and promote coordination of agencies responsible for ensuring compliance with controlled substances laws and to monitor observance of these laws and cooperation between these agencies. The department of social and health services, the department of labor and industries, and any other

state agency including licensure disciplinary boards, shall refer all apparent instances of over-prescribing by practitioners and all apparent instances of legend drug overuse to the department. The department shall also encourage such referral by health maintenance organizations, health service contractors, and health care providers.

Sec. 14. RCW 18.64.011 is amended to read as follows:

The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(1) "Administer" means the direct application of a drug or device, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject.

(2) "Business licensing system" means the mechanism established by chapter 19.02 RCW by which business licenses, endorsed for individual state-issued licenses, are issued and renewed utilizing a business license application and a business license expiration date common to each renewable license endorsement.

(3) "Chart order" means a lawful order for a drug or device entered on the chart or medical record of an inpatient or resident of an institutional facility by a practitioner or his or her designated agent.

(4) "Closed door long-term care pharmacy" means a pharmacy that provides pharmaceutical care to a defined and exclusive group of patients who have access to the services of the pharmacy because they are treated by or have an affiliation with a long-term care facility or hospice program, and that is not a retailer of goods to the general public.

(5) "Commission" means the pharmacy quality assurance commission.

(6) "Compounding" means the act of combining two or more ingredients in the preparation of a prescription. Reconstitution and mixing of (a) sterile products according to federal food and drug administration-approved labeling does not constitute compounding if prepared pursuant to a prescription and administered immediately or in accordance with package labeling, and (b) nonsterile products according to federal food and drug administration-approved labeling does not constitute compounding if prepared pursuant to a prescription.

(7) "Controlled substance" means a drug or substance, or an immediate precursor of such drug or substance, so designated under or pursuant to the provisions of chapter 69.50 RCW.

(8) "Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a drug or device, whether or not there is an agency relationship.

(9) "Department" means the department of health.

(10) "Device" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (a) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals, or (b) to affect the structure or any function of the body of human beings or other animals.

(11) “Directed plan of correction” means a plan devised by the commission that includes specific corrective actions that must be taken to correct identified unresolved deficiencies with time frames to complete them.

(12~~1~~) "Dispense" means the interpretation of a prescription or order for a drug, biological, or device and, pursuant to that prescription or order, the proper selection, measuring, compounding, labeling, or packaging necessary to prepare that prescription or order for delivery.

(13~~2~~) "Distribute" means the delivery of a drug or device other than by administering or dispensing.

(143) "Drug" and "devices" do not include surgical or dental instruments or laboratory materials, gas and oxygen, therapy equipment, X-ray apparatus or therapeutic equipment, their component parts or accessories, or equipment, instruments, apparatus, or contrivances used to render such articles effective in medical, surgical, or dental treatment, or for use or consumption in or for mechanical, industrial, manufacturing, or scientific applications or purposes. "Drug" also does not include any article or mixture covered by the Washington pesticide control act (chapter **15.58** RCW), as enacted or hereafter amended, nor medicated feed intended for and used exclusively as a feed for animals other than human beings.

(154) "Drugs" means:

(a) Articles recognized in the official United States pharmacopoeia or the official homeopathic pharmacopoeia of the United States;

(b) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals;

(c) Substances (other than food) intended to affect the structure or any function of the body of human beings or other animals; or

(d) Substances intended for use as a component of any substances specified in (a), (b), or (c) of this subsection, but not including devices or their component parts or accessories.

(165) "Health care entity" means an organization that provides health care services in a setting that is not otherwise licensed by the state to acquire or possess legend drugs. Health care entity includes a freestanding outpatient surgery center, a residential treatment facility, and a freestanding cardiac care center. "Health care entity" does not include an individual practitioner's office or a multipractitioner clinic, regardless of ownership, unless the owner elects licensure as a health care entity. "Health care entity" also does not include an individual practitioner's office or multipractitioner clinic identified by a hospital on a pharmacy application or renewal pursuant to RCW **18.64.043**.

(176) "Hospice program" means a hospice program certified or paid by medicare under Title XVIII of the federal social security act, or a hospice program licensed under chapter **70.127** RCW.

(18) "Immediate jeopardy" means a situation in which a licensee's noncompliance with one or more statutory or regulatory requirements has placed the health and safety of individuals or animals at risk for serious injury, serious harm, serious impairment, or death.

(197) "Institutional facility" means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services including, but not limited to, services in a hospital, long-term care facility, hospice program, mental health facility, drug abuse treatment center, residential habilitation center, or a local, state, or federal correction facility.

(208) "Labeling" means the process of preparing and affixing a label to any drug or device container. The label must include all information required by current federal and state law and pharmacy rules.

(219) "Legend drugs" means any drugs which are required by any applicable federal or state law or regulation to be dispensed on prescription only or are restricted to use by practitioners only.

(22) "License," "licensing," and "licensure" shall be deemed equivalent to the terms "approval", "credential", "license," "licensing," "licensure," "certificate," "certification," "permit" and "registration".

(230) "Long-term care facility" means a nursing home licensed under chapter **18.51** RCW, an assisted living facility licensed under chapter **18.20** RCW, or an adult family home licensed under chapter **70.128** RCW.

(24~~1~~) "Manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance or device or the packaging or repackaging of such substance or device, or the labeling or relabeling of the commercial container of such substance or device, but does not include the activities of a practitioner who, as an incident to his or her administration or dispensing such substance or device in the course of his or her professional practice, personally prepares, compounds, packages, or labels such substance or device. "Manufacture" includes the distribution of a licensed pharmacy compounded drug product to other state licensed persons or commercial entities for subsequent resale or distribution, unless a specific product item has approval of the commission. The term does not include:

(a) The activities of a licensed pharmacy that compounds a product on or in anticipation of an order of a licensed practitioner for use in the course of their professional practice to administer to patients, either personally or under their direct supervision;

(b) The practice of a licensed pharmacy when repackaging commercially available medication in small, reasonable quantities for a practitioner legally authorized to prescribe the medication for office use only;

(c) The distribution of a drug product that has been compounded by a licensed pharmacy to other appropriately licensed entities under common ownership or control of the facility in which the compounding takes place; or

(d) The delivery of finished and appropriately labeled compounded products dispensed pursuant to a valid prescription to alternate delivery locations, other than the patient's residence, when requested by the patient, or the prescriber to administer to the patient, or to another licensed pharmacy to dispense to the patient.

(25~~2~~) "Manufacturer" means a person, corporation, or other entity engaged in the manufacture of drugs or devices.

(26~~3~~) "Nonlegend" or "nonprescription" drugs means any drugs which may be lawfully sold without a prescription.

(27~~4~~) "Person" means an individual, corporation, government, governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.

(28~~5~~) "Pharmacist" means a person duly licensed by the commission to engage in the practice of pharmacy.

(29~~26~~) "Pharmacy" means every place properly licensed by the commission where the practice of pharmacy is conducted.

(30) “Plan of correction” means a proposal devised by the applicant or licensee that includes specific corrective actions that must be taken to correct identified unresolved deficiencies with the time frames to complete them.

(~~27~~31) "Poison" does not include any article or mixture covered by the Washington pesticide control act (chapter **15.58** RCW), as enacted or hereafter amended.

(~~28~~32) "Practice of pharmacy" includes the practice of and responsibility for: Interpreting prescription orders; the compounding, dispensing, labeling, administering, and distributing of drugs and devices; the monitoring of drug therapy and use; the initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs; the participating in drug utilization reviews and drug product selection; the proper and safe storing and distributing of drugs and devices and maintenance of proper records thereof; the providing of information on legend drugs which may include, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs and devices.

(3329) "Practitioner" means a physician, dentist, veterinarian, nurse, or other person duly authorized by law or rule in the state of Washington to prescribe drugs.

(340) "Prescription" means an order for drugs or devices issued by a practitioner duly authorized by law or rule in the state of Washington to prescribe drugs or devices in the course of his or her professional practice for a legitimate medical purpose.

(351) "Secretary" means the secretary of health or the secretary's designee.

(362) "Shared pharmacy services" means a system that allows a participating pharmacist or pharmacy pursuant to a request from another participating pharmacist or pharmacy to process or fill a prescription or drug order, which may include but is not necessarily limited to preparing, packaging, labeling, data entry, compounding for specific patients, dispensing, performing drug utilization reviews, conducting claims adjudication, obtaining refill authorizations, reviewing therapeutic interventions, or reviewing chart orders.

(37) “Statement of deficiency” means a written statement of the deficiencies completed by the commission, or its designee, identifying one or more violations of law. The report clearly identifies the specific law or rule that has been violated along with a description of the reasons for noncompliance.

(383) "Wholesaler" means a corporation, individual, or other entity which buys drugs or devices for resale and distribution to corporations, individuals, or entities other than consumers.

NEW SECTION. **Sec. 15**. A new section is added to chapter 18.64 RCW to read as follows:

This section governs the denial of an application for a license or the suspension, revocation, or modification of a license issued by the commission. This section does not govern actions taken under chapter 18.130 RCW.

(1) The commission shall give written notice of the denial of an application for a license to the applicant or their agent. The notice shall state the reasons for the action. The notice shall be served in accordance with the procedural rules adopted by the Commission.

(2) The commission shall give written notice of revocation, suspension, or modification of a license to the licensee or their agent. The notice shall state the reasons for the action. The notice shall be served in accordance with the procedural rules adopted by the Commission.

(3) Except as otherwise provided in this chapter, revocation, suspension, or modification is effective twenty-eight days after the licensee or the agent receives the notice.

(a) The commission may make the date the action is effective later than twenty-eight days after receipt. If the commission does so, it shall state the effective date in the written notice given the licensee or agent.

(b) The commission may make the date the action is effective sooner than twenty-eight days after receipt when necessary to protect the public health, safety, or welfare. When the commission does so, it shall state the effective date and the reasons supporting the effective date in the written notice given to the licensee or agent.

(4) A license applicant or licensee who is aggrieved by a commission denial, revocation, suspension, or modification has the right to an adjudicative proceeding. The proceeding is governed by the Administrative Procedure Act, chapter 34.05 RCW. The application must be in writing, state the basis for contesting the adverse action, include a copy of the adverse notice, be served on and received by the commission within twenty-eight days of the license applicant's or licensee's receiving the adverse notice, and be served in accordance with the procedural rules adopted by the Commission.

(5)(a) If the commission gives a licensee twenty-eight or more days notice of revocation, suspension, or modification and the licensee files an appeal before its effective date, the

commission shall not implement the adverse action until the final order has been entered. The commission may implement part or all of the adverse action while the proceedings are pending if the appellant causes an unreasonable delay in the proceeding, if the circumstances change so that implementation is in the public interest, or for other good cause.

(b) If the commission gives a licensee less than twenty-eight days notice of revocation, suspension, or modification and the licensee timely files a sufficient appeal, the commission may implement the adverse action on the effective date stated in the notice. The commission may stay implementation of part or all of the adverse action while the proceedings are pending if staying implementation is in the public interest or for other good cause.

NEW SECTION. **Sec. 16**. A new section is added to chapter 18.64 RCW to read as follows:

This section governs the assessment of a civil fine against a licensee issued by the commission. This section does not govern actions taken under chapter **18.130** RCW.

(1) The commission shall give written notice to the licensee or their agent against whom it assesses a civil fine. The notice shall state the reasons for the adverse action. The notice shall be served in accordance with the procedural rules adopted by the Commission.

(2) Except as otherwise provided in subsection (4) of this section, the civil fine is due and payable twenty-eight days after receipt by the licensee or their agent. The commission may make the date the fine is due later than twenty-eight days after receipt by licensee or their agent. When the commission does so, it shall state the date the fine is due in the written notice given the licensee against whom it assesses the fine.

(3) The licensee against whom the commission assesses a civil fine has the right to an adjudicative proceeding. The proceeding is governed by the Administrative Procedure Act, chapter **34.05** RCW. The application must be in writing, state the basis for contesting the fine, include a copy of the adverse notice, be served on and received by the commission within twenty-eight days of the licensee receiving the notice of civil fine, and be served in accordance with the procedural rules adopted by the Commission.

(4) If the licensee files a timely and sufficient appeal, the commission shall not implement the action until the final order has been served. The commission may implement part or all of the action while the proceedings are pending if the appellant causes an unreasonable delay in the proceeding, if the circumstances change so that implementation is in the public interest, or for other good cause.

NEW SECTION. **Sec. 17**. A new section is added to chapter 18.64 RCW to read as follows

This section does not govern actions taken under chapter **18.130** RCW.

(1) The commission is authorized to take any of the actions identified in this section against licenses, registrations, permits, or other credentials or approvals issued by the commission under chapters 18.64, 18.64A, 69.38, 69.41, 69.43, 69.45, and 69.50 RCW in any case in which it finds the licensee has failed or refused to comply with any state or federal statute or administrative rule regulating the license in question, including but not limited to title 69 RCW, chapters 18.64 and 18.64A RCW, and administrative rules adopted by the commission.

(a) When the commission determines a licensee has previously been subject to an enforcement action for the same or similar type of violation of the same or similar statute or rule, or has been given any previous statement of deficiency that included the same or similar type of violation of the same or similar statute or rule, or when the licensee failed to correct noncompliance with a statute or rule by a date established or agreed to by the commission, the

commission may impose reasonable conditions on a license. Conditions may include correction within a specified amount of time, a directed plan of correction, training, or hiring a commission-approved consultant if the licensee cannot demonstrate to the commission that it has access to sufficient internal expertise.

(b)(i) In accordance with the commission's authority under Section 16, the commission may assess a civil fine of up to $10,000 dollars per violation, not to exceed a total fine of $1,000,000 dollars, on a licensee when the commission determines the licensee has previously been subject to an enforcement action for the same or similar type of violation of the same or similar statute or rule, or has been given any previous statement of deficiency that included the same or similar type of violation of the same or similar statute or rule, or when licensee failed to correct noncompliance with a statute or rule by a date established or agreed to by the commission.

(ii) Proceeds from these fines may only be used by the commission to provide training or technical assistance to licensees and to offset costs associated with licensing.

(iii) The commission shall adopt in rules under this chapter to establish specific fine amounts in relation to the severity of the noncompliance and at an adequate level to be a deterrent to future noncompliance.

(iv) If a licensee is aggrieved by the commission's action of assessing civil fines, the licensee has the right to appeal under Section 16.

(c) The commission may restrict the ability of a licensee to engage in a specific service related to a violation by imposing a limited stop service. This may only be done if the commission finds that noncompliance results in immediate jeopardy.

(i) Prior to imposing a limited stop service, the commission shall provide a licensee written notification upon identifying deficient practices or conditions that constitute an immediate jeopardy. The licensee shall have 24 hours from notification to develop and implement a commission-approved plan to correct the deficient practices or conditions that constitute an immediate jeopardy. If the deficient practice or conditions that constitute immediate jeopardy are not verified by the commission as having been corrected within the same 24-hour-period, the commission may issue the limited stop service.

(ii) When the commission imposes a limited stop service, the licensee may not provide the services subject to the limited stop service, unless otherwise allowed by the commission, until the limited stop service order is terminated.

(iii) The commission shall conduct a follow-up inspection within five business days or within the time period requested by the licensee if more than five business days is needed to verify the violation necessitating the limited stop service has been corrected.

(iv) The limited stop service shall be terminated when:

(A) The commission verifies the violation necessitating the limited stop service has been corrected or the commission determines that the licensee has taken intermediate action to address the immediate jeopardy; and

(B) The licensee establishes the ability to maintain correction of the violation previously found deficient.

(d) The commission may deny an application, or suspend, revoke, modify, or refuse to renew a license.

(2)(a) Except as otherwise provided, Section 15 and 16 govern notices of actions taken by the commission under subsection (1) of this section and provides the right to an adjudicative proceeding. Adjudicative proceedings and hearings under this section are governed by the administrative procedure act, chapter **34.05** RCW.

(b) When the commission determines a licensee's noncompliance results in immediate jeopardy, the commission may make the imposition of conditions on a licensee, limited stop service, suspension or modification of a license effective immediately upon receipt of the notice by the licensee, pending any adjudicative proceeding.

(i) When the commission makes the suspension of a license or imposition of conditions on a license effective immediately, a licensee is entitled to a show cause hearing before a hearing panel of the commission within fourteen days of making the request. The licensee must request the show cause hearing within twenty-eight days of receipt of the notice of immediate suspension or immediate imposition of conditions. At the show cause hearing the commission has the burden of demonstrating that more probably than not there is an immediate jeopardy.

(ii) At the show cause hearing, the hearing panel of the commission may consider the notice and documents supporting the immediate suspension or immediate imposition of conditions and the licensee's response and must provide the parties with an opportunity to provide documentary evidence and written testimony, and to be represented by counsel. Prior to the show cause hearing, the commission must provide the licensee with all documentation that supports the commission's immediate suspension.

(iii) If the hearing panel of the commission determines there is no immediate jeopardy, the hearing panel of the commission may overturn the immediate suspension or immediate imposition of conditions.

(iv) If the hearing panel of the commission determines there is immediate jeopardy, the immediate suspension or immediate imposition of conditions shall remain in effect pending a full hearing.

(v) If the commission sustains the immediate suspension or immediate imposition of conditions, the licensee may request an expedited full hearing on the merits. A full hearing must be provided within ninety days of the licensee's request, unless otherwise stipulated by the parties.

(3) The Commission may only take action under subsection (1) of this section against a nonresident pharmacy for failure to comply with any requirement of RCW 18.64.350 through RCW 18.64.400, unless the nonresident pharmacy's conduct caused ~~serious bodily or psychological~~ injury to a resident of this state and the commission has referred the matter to the regulatory or licensing agency in the state in which the nonresident pharmacy is located and that regulatory or licensing agency fails to initiate an investigation within forty-five days of the referral under this subsection or fails to make a determination on the referral.

NEW SECTION. **Sec. 18**. A new section is added to chapter 18.64 to read as follows

The Uniform Disciplinary Act, chapter 18.130 RCW, governs unlicensed practice of persons required to obtain a license under this chapter.

Sec. 19. RCW 18.64.047 is amended to read as follows:

(1) Any itinerant vendor or any peddler of any nonprescription drug or preparation for the treatment of disease or injury, shall pay a registration fee determined by the secretary on a date to be determined by the secretary as provided in RCW **43.70.250** and **43.70.280**. The department may issue a registration to such vendor on an approved application made to the department.

(2) Any itinerant vendor or peddler who shall vend or sell, or offer to sell to the public any such nonprescription drug or preparation without having registered to do so as provided in this

section, is guilty of a misdemeanor and each sale or offer to sell shall constitute a separate offense.

(3) In event the registration fee remains unpaid on the date due, no renewal or new registration shall be issued except upon compliance with administrative procedures, administrative requirements, and fees determined as provided in RCW 43.70.250 and 43.70.280. This registration shall not authorize the sale of legend drugs or controlled substances.

(4) An itinerant vendor may purchase products containing any detectable quantity of ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers only from a wholesaler licensed by the department under RCW 18.64.046 or from a manufacturer licensed by the department under RCW 18.64.045. The commission shall issue a warning to an itinerant vendor who violates this subsection, and may suspend or revoke the registration of the vendor for a subsequent violation.

(5) An itinerant vendor who has purchased products containing any detectable quantity of ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, in a suspicious transaction as defined in RCW 69.43.035, is subject to the following requirements:

(a) The itinerant vendor may not sell any quantity of ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, if the total monthly sales of these products exceed ten percent of the vendor's total prior monthly sales of nonprescription drugs in March through October. In November through February, the vendor may not sell any quantity of ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, if the total monthly sales of these products exceed twenty percent of the vendor's total prior monthly sales of nonprescription drugs. For purposes of this section, "monthly sales" means total dollars paid by buyers. ~~The commission may suspend or revoke the registration of an itinerant vendor who violates this subsection.~~

(b) The itinerant vendor shall maintain inventory records of the receipt and disposition of nonprescription drugs, utilizing existing inventory controls if an auditor or investigator can determine compliance with (a) of this subsection, and otherwise in the form and manner required by the commission. The records must be available for inspection by the commission or any law enforcement agency and must be maintained for two years. The commission may suspend or revoke the registration of an itinerant vendor who violates this subsection. For purposes of this subsection, "disposition" means the return of product to the wholesaler or distributor.

Sec. 20. RCW 18.64.165 is amended to read as follows:

In addition to any other grounds, ~~T~~the commission ~~shall have the power to refuse, suspend, or revoke the license of any manufacturer, wholesaler, pharmacy, shopkeeper, itinerant vendor, peddler, poison distributor, health care entity, or precursor chemical distributor~~ may take action against a license under chapters 18.64, 18.64A, 69.38, 69.41, 69.43, 69.45, and 69.50 RCW, except nonresident pharmacies, upon proof that:

(1) The license was procured through fraud, misrepresentation, or deceit;

(2) Except as provided in RCW 9.97.020, the licensee has violated or has permitted any employee to violate any of the laws of this state or the United States relating to drugs, controlled substances, cosmetics, or nonprescription drugs, or has violated any of the rules and regulations of the commission or has been convicted of a felony.

Sec. 21. RCW 18.64A.020 is amended to read as follows

(1)(a) The commission shall adopt, in accordance with chapter **34.05** RCW, rules fixing the classification and qualifications and the educational and training requirements for persons who may be employed as pharmacy technicians or who may be enrolled in any pharmacy technician training program. Such rules shall provide that:

(i) Licensed pharmacists shall supervise the training of pharmacy technicians;

(ii) Training programs shall assure the competence of pharmacy technicians to aid and assist pharmacy operations. Training programs shall consist of instruction and/or practical training; and

(iii) Pharmacy technicians shall complete continuing education requirements established in rule by the commission.

(b) Such rules may include successful completion of examinations for applicants for pharmacy technician certificates. If such examination rules are adopted, the commission shall prepare or determine the nature of, and supervise the grading of the examinations. The commission may approve an examination prepared or administered by a private testing agency or association of licensing authorities.

(2) The commission may disapprove or revoke approval of any training program for failure to conform to commission rules. In the case of the disapproval or revocation of approval of a training program by the commission, a hearing shall be conducted in accordance with Section 15, and appeal may be taken in accordance with the administrative procedure act, chapter **34.05** RCW.

Sec. 22. RCW 18.64A.060 is amended to read as follows

No pharmacy licensed in this state shall utilize the services of pharmacy ancillary personnel without approval of the commission.

Any pharmacy licensed in this state may apply to the commission for permission to use the services of pharmacy ancillary personnel. The application shall be accompanied by a fee and shall comply with administrative procedures and administrative requirements set pursuant to RCW **43.70.250** and **43.70.280**, shall detail the manner and extent to which the pharmacy ancillary personnel would be used and supervised, and shall provide other information in such form as the secretary may require.

The commission may approve or reject such applications. In addition, the commission may modify the proposed utilization of pharmacy ancillary personnel and approve the application as modified. Whenever it appears to the commission that pharmacy ancillary personnel are being utilized in a manner inconsistent with the approval granted, the commission may withdraw such approval. In the event a hearing is requested upon the rejection of an application, or upon the withdrawal of approval, a hearing shall be conducted in accordance with Section 15 ~~chapter **18.64** RCW, as now or hereafter amended,~~ and appeal may be taken in accordance with the administrative procedure act, chapter **34.05** RCW.

NEW SECTION. **Sec. 23**. A new section is added to chapter 69.38 RCW to read as follows

Chapter 18.64 RCW governs the denial of licenses and the discipline of persons licensed under this chapter. The Uniform Disciplinary Act, chapter 18.130 RCW, governs unlicensed practice of persons required to obtain a license under this chapter.

Sec. 24. RCW 69.45.080 is amended to read as follows

(1) The manufacturer is responsible for the actions and conduct of its representatives with regard to drug samples.

(2) Chapter 18.64 RCW governs the denial of licenses and the discipline of persons registered under this chapter.

~~(2) The commission may hold a public hearing to examine a possible violation and may require a designated representative of the manufacturer to attend.~~

~~(3) If a manufacturer fails to comply with this chapter following notification by the commission, the commission may impose a civil penalty of up to five thousand dollars. The commission shall take no action to impose any civil penalty except pursuant to a hearing held in accordance with chapter **34.05** RCW.~~

(34) Specific drug samples which are distributed in this state in violation of this chapter, following notification by the commission, shall be subject to seizure following the procedures set out in RCW **69.41.060**.

NEW SECTION. **Sec. 25**. A new section is added to chapter 69.45 RCW to read as follows

The Uniform Disciplinary Act, chapter 18.130 RCW, governs unlicensed practice of persons required to obtain a registration under this chapter.

Sec. 26. RCW 69.43.100 is amended to read as follows:

In addition to any other grounds, t~~T~~he pharmacy quality assurance commission ~~shall have the power to refuse, suspend, or revoke~~ may take action against a ~~the~~ permit issued under this chapter ~~of any person manufacturer or wholesaler~~ upon proof that:

(1) The permit was procured through fraud, misrepresentation, or deceit;

(2) The permittee has violated or has permitted any employee to violate any of the laws of this state relating to drugs, controlled substances, cosmetics, or nonprescription drugs, or has violated any of the rules and regulations of the ~~pharmacy quality assurance~~ commission.

Sec. 27. RCW 69.43.140 is amended to read as follows:

~~(1) In addition to the other penalties provided for in this chapter or in chapter **18.64** RCW, the pharmacy quality assurance commission may impose a civil penalty, not to exceed ten thousand dollars for each violation, on any licensee or registrant who has failed to comply with this chapter or the rules adopted under this chapter. In the case of a continuing violation, every day the violation continues shall be considered a separate violation.~~

(1) Chapter 18.64 RCW governs the denial of permits and the discipline of permits issued under this chapter. The Uniform Disciplinary Act, chapter 18.130 RCW, governs unlicensed practice of persons required to obtain a permit under this chapter.

(2) The ~~pharmacy quality assurance~~ commission may waive action taken under chapter 18.64 RCW against a ~~the suspension or revocation of a~~ permit ~~license or registration~~ issued under this chapter ~~chapter **18.64** RCW, or waive any civil fine penalty under this chapter~~, if the ~~licensee or registrant~~ permittee establishes that he or she acted in good faith to prevent violations of this chapter, and the violation occurred despite the licensee's or registrant's exercise of due diligence. In making such a determination, the ~~pharmacy quality assurance~~ commission may consider evidence that an employer trained employees on how to sell, transfer, or otherwise furnish substances specified in RCW **69.43.010**(1) in accordance with applicable laws.

Sec. 28. RCW 69.50.302 is amended to read as follows

(a) Every person who manufactures, distributes, or dispenses any controlled substance within this state or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance within this state, shall obtain annually a registration issued by the ~~department~~ commission in accordance with the commission's rules.

(b) A person registered by the ~~department~~ commission under this chapter to manufacture, distribute, dispense, or conduct research with controlled substances may possess, manufacture, distribute, dispense, or conduct research with those substances to the extent authorized by the registration and in conformity with this Article.

(c) The following persons need not register and may lawfully possess controlled substances under this chapter:

(1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance if the agent or employee is acting in the usual course of business or employment. This exemption shall not include any agent or employee distributing sample controlled substances to practitioners without an order;

(2) A common or contract carrier or warehouse operator, or an employee thereof, whose possession of any controlled substance is in the usual course of business or employment;

(3) An ultimate user or a person in possession of any controlled substance pursuant to a lawful order of a practitioner or in lawful possession of a substance included in Schedule V.

(d) The commission may waive by rule the requirement for registration of certain manufacturers, distributors, or dispensers upon finding it consistent with the public health and safety. Personal practitioners licensed or registered in the state of Washington under the respective professional licensing acts shall not be required to be registered under this chapter unless the specific exemption is denied pursuant to RCW **69.50.305** for violation of any provisions of this chapter.

(e) A separate registration is required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances.

(f) The department, at the direction of the commission, may inspect the establishment of a registrant or applicant for registration in accordance with rules adopted by the commission.

Sec. 29. RCW 69.50.303 is amended to read as follows

(a) The commission ~~department~~ shall register an applicant to manufacture, distribute, dispense, or conduct research with ~~or distribute~~ controlled substances included in RCW **69.50.204**, **69.50.206**, **69.50.208**, **69.50.210**, and **69.50.212** unless the commission determines that the issuance of that registration would be inconsistent with the public interest. In determining the public interest, the commission shall consider the following factors:

(1) maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, research, or industrial channels;

(2) compliance with applicable state and local law;

(3) promotion of technical advances in the art of manufacturing controlled substances and the development of new substances;

(4) any convictions of the applicant under any laws of another country or federal or state laws relating to any controlled substance;

(5) past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion of controlled substances into other than legitimate medical, scientific, research, or industrial channels;

(6) furnishing by the applicant of false or fraudulent material in any application filed under this chapter;

(7) suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law; and

(8) any other factors relevant to and consistent with the public health and safety.

(b) Registration under subsection (a) of this section does not entitle a registrant to manufacture or distribute controlled substances included in Schedule I or II other than those specified in the registration.

(c) Practitioners must be registered, or exempted under RCW 69.50.302(d), to dispense any controlled substances or to conduct research with controlled substances included in Schedules II through V if they are authorized to dispense or conduct research under the law of this state. The commission need not require separate registration under this Article for practitioners engaging in research with nonnarcotic substances included in Schedules II through V where the registrant is already registered under this Article in another capacity. Practitioners registered under federal law to conduct research with substances included in Schedule I may conduct research with substances included in Schedule I within this state upon furnishing the commission evidence of that federal registration.

(d) A manufacturer or distributor registered under the federal Controlled Substances Act, 21 U.S.C. Sec. 801 et seq., may submit a copy of the federal application as an application for registration as a manufacturer or distributor under this section. The commission may require a manufacturer or distributor to submit information in addition to the application for registration under the federal act.

Sec. 30. RCW 69.50.304 is amended to read as follows

(a) This chapter and chapter 18.64 RCW govern the denial of registrations and the discipline of registrations issued under RCW 69.50.303. The Uniform Disciplinary Act, chapter 18.130 RCW, governs unlicensed practice of persons required to obtain a registration under this chapter.

(~~a~~b) In addition to any other grounds, the commission may take action against the A registration, or exemption from registration, under RCW 69.50.303 to manufacture, distribute, or dispense, or conduct research with a controlled substance ~~may be suspended or revoked by the commission~~ upon finding that the registrant has:

(1) furnished false or fraudulent material information in any application filed under this chapter;

(2) been convicted of a felony under any state or federal law relating to any controlled substance;

(3) had the registrant's federal registration suspended or revoked and is no longer authorized by federal law to manufacture, distribute, or dispense, or conduct research with controlled substances; or

(4) committed acts that would render registration under RCW 69.50.303 inconsistent with the public interest as determined under that section.

(c~~b~~) The commission may limit revocation or suspension of a registration to the particular controlled substance or schedule of controlled substances, with respect to which grounds for revocation or suspension exist.

(~~c~~d) If the commission suspends or revokes a registration, all controlled substances owned or possessed by the registrant at the time of suspension or the effective date of the revocation order may be placed under seal. No disposition may be made of substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded unless a court, upon application, orders the sale of perishable substances and the deposit of the

proceeds of the sale with the court. Upon a revocation order becoming final, all controlled substances may be forfeited to the state.

(~~d~~e) The ~~department~~ commission may seize or place under seal any controlled substance owned or possessed by a registrant whose registration has expired or who has ceased to practice or do business in the manner contemplated by the registration. The controlled substance must be held for the benefit of the registrant or the registrant's successor in interest. The department shall notify a registrant, or the registrant's successor in interest, who has any controlled substance seized or placed under seal, of the procedures to be followed to secure the return of the controlled substance and the conditions under which it will be returned. The department may not dispose of any controlled substance seized or placed under seal under this subsection until the expiration of one hundred eighty days after the controlled substance was seized or placed under seal. The costs incurred by the department in seizing, placing under seal, maintaining custody, and disposing of any controlled substance under this subsection may be recovered from the registrant, any proceeds obtained from the disposition of the controlled substance, or from both. Any balance remaining after the costs have been recovered from the proceeds of any disposition must be delivered to the registrant or the registrant's successor in interest.

(~~e~~f) The ~~department~~ commission shall promptly notify the drug enforcement administration of all orders restricting, suspending, or revoking registration and all forfeitures of controlled substances.

Sec. 31. RCW 69.50.310 is amended to read as follows

On and after September 21, 1977, a humane society and animal control agency may apply to the ~~department~~ commission for registration pursuant to the applicable provisions of this chapter for the sole purpose of being authorized to purchase, possess, and administer sodium pentobarbital to euthanize injured, sick, homeless, or unwanted domestic pets and animals. Any agency so registered shall not permit a person to administer sodium pentobarbital unless such person has demonstrated adequate knowledge of the potential hazards and proper techniques to be used in administering this drug.

The ~~department~~ commission may issue a limited registration to carry out the provisions of this section. The commission shall promulgate such rules as it deems necessary to insure strict compliance with the provisions of this section. Chapter 18.64 RCW governs the denial of licenses and the discipline of registrations issued under this chapter. The Uniform Disciplinary Act, chapter 18.130 RCW, governs unlicensed practice of persons required to obtain a registration under this chapter. ~~The commission may suspend or revoke registration upon determination that the person administering sodium pentobarbital has not demonstrated adequate knowledge as herein provided. This authority is granted in addition to any other power to suspend or revoke registration as provided by law.~~

Sec. 32. RCW 69.50.320 is amended to read as follows

The department of fish and wildlife may apply to the ~~department of health~~ commission for registration pursuant to the applicable provisions of this chapter to purchase, possess, and administer controlled substances for use in chemical capture programs. The department of fish and wildlife must not permit a person to administer controlled substances unless the person has demonstrated adequate knowledge of the potential hazards and proper techniques to be used in administering controlled substances.

The ~~department of health~~ commission may issue a limited registration to carry out the provisions of this section. The commission may adopt rules to ensure strict compliance with the provisions of this section. The commission, in consultation with the department of fish and wildlife, must by rule add or remove additional controlled substances for use in chemical capture programs. Chapter 18.64 RCW governs the denial of licenses and the discipline of registrations issued under this chapter. The Uniform Disciplinary Act, chapter 18.130 RCW, governs unlicensed practice of persons required to obtain a registration under this chapter. In addition to any other grounds, T~~t~~he commission ~~shall~~ may suspend or revoke a registration issued under this chapter upon determination that the person administering controlled substances has not demonstrated adequate knowledge as required by this section. ~~This authority is granted in addition to any other power to suspend or revoke registration as provided by law.~~

Sec. 33. RCW 69.41.080 is amended to read as follows

Humane societies and animal control agencies registered with the ~~pharmacy quality assurance~~ commission under chapter **69.50** RCW and authorized to euthanize animals may purchase, possess, and administer approved legend drugs for the sole purpose of sedating animals prior to euthanasia, when necessary, and for use in chemical capture programs. For the purposes of this section, "approved legend drugs" means those legend drugs designated by the commission by rule as being approved for use by such societies and agencies for animal sedating or capture and does not include any substance regulated under chapter **69.50** RCW. Any society or agency so registered shall not permit persons to administer any legend drugs unless such person has demonstrated to the satisfaction of the commission adequate knowledge of the potential hazards involved in and the proper techniques to be used in administering the drugs.

The commission shall promulgate rules to regulate the purchase, possession, and administration of legend drugs by such societies and agencies and to insure strict compliance with the provisions of this section. Such rules shall require that the storage, inventory control, administration, and recordkeeping for approved legend drugs conform to the standards adopted by the commission under chapter **69.50** RCW to regulate the use of controlled substances by such societies and agencies. Chapter 18.64 RCW governs the denial of licenses and the discipline of registrations issued under chapter 69.50 RCW. The Uniform Disciplinary Act, chapter 18.130 RCW, governs unlicensed practice of persons required to obtain a registration under this chapter. In addition to any other grounds, T~~t~~he commission may suspend or revoke a registration issued under chapter **69.50** RCW upon a determination by the commission that the person administering legend drugs has not demonstrated adequate knowledge as herein provided. ~~This authority is granted in addition to any other power to suspend or revoke a registration as provided by law.~~

Repeal

RCW 18.64.200 Refusal, suspension, and revocation of other licenses—Appeal procedure.

In any case of the refusal, suspension or revocation of a license by the commission under the provisions of this chapter, appeal may be taken in accordance with the administrative procedure act.

RCW 18.64.390 Nonresident pharmacies—Violations—Penalties.

(1) The commission may deny, revoke, or suspend a nonresident pharmacy license or impose a fine not to exceed one thousand dollars per violation for failure to comply with any requirement of RCW 18.64.350 through 18.64.400.

(2) The commission may deny, revoke, or suspend a nonresident pharmacy license or impose a fine not to exceed one thousand dollars per violation for conduct that causes serious bodily or psychological injury to a resident of this state if the secretary has referred the matter to the regulatory or licensing agency in the state in which the pharmacy is located and that regulatory or licensing agency fails to initiate an investigation within forty-five days of the referral under this subsection or fails to make a determination on the referral.

RCW 69.50.305

Procedure for denial, suspension, or revocation of registration.

(a) Any registration, or exemption from registration, issued pursuant to the provisions of this chapter shall not be denied, suspended, or revoked unless the commission denies, suspends, or revokes such registration, or exemption from registration, by proceedings consistent with the administrative procedure act, chapter 34.05 RCW.

(b) The commission may suspend any registration simultaneously with the institution of proceedings under RCW 69.50.304, or where renewal of registration is refused, if it finds that there is an imminent danger to the public health or safety which warrants this action. The suspension shall continue in effect until the conclusion of the proceedings, including judicial review thereof, unless sooner withdrawn by the commission or dissolved by a court of competent jurisdiction.