available or publishes any public record and in any cases when there is reason to believe that disclosure of such details would be an invasion of personal privacy protected by chapter 42.17 RCW. The public records officer will justify such deletion in writing.

- (3) Denials of requests for public records must be accompanied by a written statement specifying the reason for the denial. A statement of the specific exemption in chapter 42.17 RCW authorizing withholding the record and a brief explanation of how the exemption applies to the record withheld will be included.
- (4) Upon written request, denials of requests for public records will be reviewed by the executive secretary within two working days. [Statutory Authority: Chapter 41.64 RCW. 82–01–053 (Order 81–4), § 358–40–060, filed 12/16/81.]

Title 360 WAC PHARMACY, BOARD OF

Chapters	
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Chapter 360-12 WAC PHARMACISTS

WAC
360-12-140 Pharmacist prescriptive authority—Prior board notification of written guideline or protocol required.

WAC 360-12-140 Pharmacist prescriptive authority—Prior board notification of written guideline or protocol required. (1) A pharmacist planning to exercise prescriptive authority in his or her practice (see RCW 18.64.011(11)) by initiating or modifying 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 must have on file at his/her place of practice a properly prepared written guideline or protocol indicating approval has been granted by a practitioner authorized to prescribe. A copy of the written guideline or protocol must also be on file with the board of pharmacy.

- (2) For purposes of pharmacist prescriptive authority under RCW 18.64.011(11), a written guideline or protocol is defined as an agreement in which any practitioner authorized to prescribe legend drugs delegates to a pharmacist or group of pharmacists authority to conduct specified prescribing functions. Any modification of the written guideline or protocol shall be treated as a new protocol. It shall include:
- (a) A statement identifying the practitioner authorized to prescribe and the pharmacist(s) who are party to the agreement. The practitioner authorized to prescribe must be in active practice, and the authority granted must be within the scope of the practitioners' current practice.
- (b) A time period not to exceed 2 years during which the written guideline or protocol will be in effect.
- (c) A statement of the type of prescriptive authority decisions which the pharmacist(s) is (are) authorized to make, which includes:
- (i) A statement of the types of diseases, drugs, or drug categories involved, and the type of prescriptive authority activity (e.g., modification or initiation of drug therapy) authorized in each case.
- (ii) A general statement of the procedures, decision criteria, or plan the pharmacist(s) is (are) to follow when making therapeutic decisions, particularly when modification or initiation of drug therapy is involved.
- (d) A statement of the activities pharmacist(s) is (are) to follow in the course of exercising prescriptive authority, including documentation of decisions made, and a plan for communication or feedback to the authorizing practitioner concerning specific decisions made. Documentation may occur on the prescription record, patient drug profile, patient medical chart, or in a separate log book. [Statutory Authority: RCW 18.64.005(11). 81–19–086 (Order 163, Resolution 8/81), § 360–12–140, filed 9/17/81. Statutory Authority: RCW 18.64.005(4) and (11). 80–08–035 (Order 155, Resolution 6/80), § 360–12–140, filed 6/26/80, effective 9/30/80.]

Chapter 360-13 WAC EXTENDED CARE FACILITY

WAC	
360-13-010	Promulgation.
360-13-020	Emergency kit.
360-13-030	Supplemental [use] dose kits.
360-13-045	Definitions.
360-13-055	Drug facilities.
360-13-065	Repealed.
360-13-066	Pharmaceutical services.

DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

360-13-065 Pharmaceutical services. [Order 121, § 360-13-065, filed 8/8/74.] Repealed by 82-06-042 (Order 165), filed 3/2/82. Statutory Authority: RCW 18.64.005(11) and 69.41.075.

WAC 360-13-010 Promulgation. In the interests of protecting public health the Washington state board of pharmacy shall hereby allow the use of an emergency

drug kit in any nursing home holding a valid Washington state nursing home license. The emergency drug kit shall be considered to be a physical extension of the pharmacy supplying the emergency drug kit and shall at all times remain under the ownership of the supplying pharmacy. [Statutory Authority: RCW 18.64.005(11). 81–10–027 (Order 159), § 360–13–010, filed 4/28/81; Order 104, § 360–13–010, filed 12/5/69; Order 50 (part), filed 3/28/67.]

WAC 360-13-020 Emergency kit. (1) The contents and quantity of drugs and supplies in the emergency kit shall be determined by the pharmaceutical services committee as defined in WAC 360-13-045(9) which shall consider the number of residents to be served and their potential need for emergency medications.

(2) A copy of the approved list of contents shall be

conspicuously posted on or near the kit.

(3) The emergency kit shall be used only for bonafide emergencies and only when medications cannot be obtained from a pharmacy in a timely manner.

(4) Records documenting the receipt and removal of drugs in the emergency kit shall be maintained by the nursing home and the supplying pharmacy.

- (5) The pharmaceutical services committee shall be responsible for ensuring proper storage, security and accountability of the emergency kit
- (a) The emergency kit shall be stored in a locked area or be locked itself;
- (b) Emergency kit drugs shall be accessible only to licensed nurses as defined in WAC 360-13-045(6).
- (6) The contents of the emergency kit, the approved list of contents, and all related records shall be made freely available and open for inspection to representatives of the board of pharmacy and the department. [Statutory Authority: RCW 18.64.005(11). 81–06–077 (Order 158), § 360–13–020, filed 3/4/81; Order 104, § 360–13–020, filed 12/5/69; Order 50, subsection 1–12, filed 3/28/67.]
- WAC 360-13-030 Supplemental [use] dose kits. (1) In addition to an emergency kit, each institution holding a valid Washington state nursing home license, and which employs a unit dose drug distribution system, may maintain a supplemental dose kit for supplemental non-emergency drug therapy if the necessary drug is not available from the pharmacy in a timely manner.
- (2) The pharmaceutical services committee shall determine the quantities of drugs in the supplemental dose kit in light of the number of residents in the facility and their potential needs for supplemental doses.
- (3) The supplemental dose kit shall remain the property of the supplying pharmacy.
- (4) The supplying pharmacy and the facility's pharmaceutical services committee shall be responsible for proper storage, security and accountability of the kit. [Statutory Authority: RCW 18.64.005(11). 81–06–077 (Order 158), § 360–13–030, filed 3/4/81; Order 114, § 360–13–030, filed 6/28/73.]

Reviser's note: RCW 34.04.058 requires the use of underlining and deletion marks to indicate amendments to existing rules, and deems

ineffectual changes not filed by the agency in this manner. The bracketed material in the above section does not appear to conform to the statutory requirement.

WAC 360-13-045 Definitions. (1) "Board" means the Washington state board of pharmacy.

- (2) "Department" means the state department of social and health services.
- (3) "Dose" means the amount of drug to be administered at one time.
- (4) "Drug facility" means a room or area designed and equipped for drug storage and the preparation of drugs for administration.
- (5) "Legend drug" means a drug bearing the legend, "Caution, federal law prohibits dispensing without a prescription."
- (6) "Licensed nurse" means either a registered nurse or a licensed practical nurse.
- (7) "Licensed practical nurse" means a person duly licensed under the provisions of the licensed practical nurse act of the state of Washington, chapter 18.78 RCW.
- (8) "Nursing home" means any home, place or institution licensed as a nursing home under chapter 18.51 RCW.
- (9) "Pharmaceutical services committee" means a committee which develops and maintains written policies and procedures for safe and effective drug therapy, distribution, control, and use which are current and followed in practice. The pharmaceutical services committee shall consist of a staff or consultant pharmacist, a physician, the director of nursing or his/her designee and the administer or his/her designee.
- (10) "Pharmacist" means a person duly licensed by the Washington state board of pharmacy to engage in the practice of pharmacy under the provisions of chapter 18.64 RCW.
- (11) "Pharmacy" means a place where the practice of pharmacy is conducted, properly licensed under the provisions of chapter 18.64 RCW by the Washington state board of pharmacy.
- (12) "Practitioner" means a physician under chapter 18.71 RCW; and osteopathic physician or an osteopathic physician and surgeon under chapter 18.57 RCW; a dentist under chapter 18.32 RCW; a podiatrist under chapter 18.22 RCW; an osteopathic physician's assistant under chapter 18.57A RCW when authorized by the committee of osteopathic commissioners; a physician's assistant under chapter 18.71A RCW when authorized by the board of medical examiners; a registered nurse when authorized by the board of nursing under chapter 18.88 RCW, or a pharmacist under chapter 18.64 RCW.
- (13) "Registered nurse" means a person duly licensed under the provisions of the law regulating the practice of registered nursing in the state of Washington, chapter 18.88 RCW.
- (14) "Unit-dose" means the ordered amount of a drug in [an individually sealed package and in] a dosage form ready for administration to a particular person by the prescribed route at the prescribed time.

(15) "Unit-dose drug distribution system" means a system of drug dispensing and control that is characterized by the dispensing of the majority of drugs in unit doses, ready to administer form, and for most drugs, not more than a 48-hour supply of doses is available at the residential care unit at any time. [Statutory Authority: RCW 18.64.005(11). 81-06-077 (Order 158), § 360-13-045, filed 3/4/81; Order 121, § 360-13-045, filed 8/8/74.]

Reviser's note: RCW 34.04.058 requires the use of underlining and deletion marks to indicate amendments to existing rules, and deems ineffectual changes not filed by the agency in this manner. The bracketed material in the above section does not appear to conform to the statutory requirement.

- WAC 360-13-055 Drug facilities. (1) There shall be facilities for drug preparation and storage near the nurses' station on each unit.
- (2) The drug facilities shall be well illuminated, ventilated and equipped with a work counter, sink with hot and cold running water and drug storage units.
 - (3) The drug storage units shall provide:
 - (a) Locked storage for all drugs,
- (b) Separately keyed storage for Schedule II and III controlled substances,
 - (c) Segregated storage of different resident's drugs.
- (4) There shall be a refrigerator for storage of thermolabile drugs in the drug facility.
- (5) Locks and keys, for drug facilities shall be different from other locks and keys within the nursing home.
- (6) Poisons and other nonmedicinal chemical agents in containers bearing a warning label shall be stored in separate locked storage apart from drugs used for medicinal purposes. [Statutory Authority: RCW 18.64.005(11). 81–06–077 (Order 158), § 360–13–055, filed 3/4/81; Order 121, § 360–13–055, filed 8/8/74.]

WAC 360-13-065 Repealed. See Disposition Table at beginning of this chapter.

WAC 360-13-066 Pharmaceutical services. (1) Administration of pharmaceutical services.

- (a) There shall be provision for timely delivery of drugs and biologicals from a pharmacy so a practitioner's orders for drug therapy can be implemented without undue delay.
- (b) Unless the nursing home operates a licensed pharmacy and employs a director of pharmaceutical services, the nursing home shall have a written agreement with one or more licensed pharmacists who provide for pharmaceutical consultant services. The staff pharmacist or consultant pharmacist supervises the entire spectrum of pharmaceutical services in the nursing home.
- (c) There shall be a pharmaceutical services committee whose membership includes at least a staff or consultant pharmacist, a physician, the director of nursing or his/her designee, and the administrator or his/her designee. The pharmaceutical services committee develops and maintains written policies and procedures for safe and effective drug therapy, distribution, control, and use which are current and followed in practice.

- (d) Reference material regarding the use of medication, adverse reactions, toxicology, and poison control center information shall be available to facility staff.
- (e) There shall be procedures established for the reporting and recording of medication errors and adverse drug reactions.
- (2) A staff pharmacist of consultant pharmacist shall be responsible for coordinating pharmaceutical services which include:
- (a) Provision of pharmaceutical services evaluations and recommendations to the administrative staff.
- (b) On-site reviews to ensure that drug handling and utilization procedures are carried out in conformance with recognized standards of practice.
- (c) Regularly reviewing each resident's therapy to screen for potential or existing drug therapy problems and documenting recommendations.
- (d) Provision of drug information to the nursing home staff and physicians as needed.
- (e) Planning and participating in the nursing home staff development program.
- (f) Consultation regarding resident care services with other departments.
 - (3) Security and storage of drugs.
- (a) The nursing home shall store drugs under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security as defined by regulation and accepted standards of practice.
- (b) All drugs shall be stored in locked cabinets, rooms, or carts, and shall be accessible only to personnel licensed to administer or dispense drugs.
- (c) Schedule III controlled substances shall be stored apart from other drugs on a separate shelf or in a separate compartment or cabinet, provided, however, Schedule III controlled substances may be stored with Schedule II controlled substances. Schedule III controlled substances can be stored with other drugs when distributed in a unit dose drug distribution system.
- (d) Drugs for external use shall be stored apart from drugs for internal use, on a separate shelf or in a separate compartment or cabinet. Any shelf, compartment, or separate cabinet used for storage of external drugs shall be clearly labeled to indicate it is to be used for external drugs only.
- (e) At all times, all keys to drug boxes, cabinets, and rooms shall be carried by persons legally authorized to administer drugs and on duty on the premises.
- (f) If a supplemental dose kit within a unit dose drug distribution system is provided it must comply with WAC 360-13-030.
- (g) If an emergency kit is provided, it shall comply with Washington state board of pharmacy regulations WAC 360-13-010 and 360-13-020.
 - (4) Labeling of drugs.
- (a) The label for each legend drug which is not dispensed in a unit dose shall have the name and address of the pharmacy from which the drug was dispensed; the prescription number; the physician's name; the resident's full name; the date of issue; the initials of the dispensing pharmacist; the name and strength of the drug; a controlled substances schedule, if any; the amount (e.g.,

number of tablets or cc's) of the drug dispensed, and the expiration date. In the case of a compounded drug which contains Schedule II or III controlled substances, the quantity of each controlled substance per cc or teaspoonful shall be shown on the label.

- (b) In a unit dose drug distribution system, a clear, legible label shall be printed or affixed securely to each unit dose package. Each unit dose drug label shall include: the name, strength and, for each unit dose package, the dosage amount of the drug; the expiration date for any time-dated drug; the lot or control number; and controlled substances schedule number, if any. Each individual drug compartment shall be labeled with the full name of the resident whose drug the compartment contains and the name of the resident's physician.
- (c) Nonlegend drugs shall be clearly labeled with at least the patient's name, date of receipt by the facility, as well as display a manufacturer's original label or a pharmacy label if repackaged by the pharmacist.
- (d) A label on a container of drugs shall not be altered or replaced except by the pharmacist. Drug containers having soiled, damaged, incomplete, or makeshift labels shall be returned to the pharmacy for relabeling or disposal. Drugs in containers having no labels or illegible labels shall be destroyed.
 - (5) Control and accountability.
- (a) The nursing home shall maintain and follow written procedures which provide for the accurate control and accountability of all drugs in the nursing home.
- (b) No drugs may be returned from the nursing home to a pharmacy except as provided in paragraph (4)(d) or if the drug is returned in unopened unit dose packages.
- (c) Drugs shall be released to a resident upon discharge only on specific written authorization of the attending physician. A receipt containing information sufficient to document the drug's destination, the person who received the drug, and the name and quantity of drugs released shall be entered in the resident's health record.
- (d) All of an individual resident's drugs including Schedule III, IV and V controlled substances, that are discontinued by the physician and remain unused, shall be destroyed by a licensed nurse employee of the nursing home in the presence of a witness within 90 days after having been discontinued, and accurate records of destruction maintained except from drugs which are sealed in unit dose packages.
- (e) Outdated, unapproved, contaminated, deteriorated, adulterated, or recalled drugs shall not be available for use in the nursing home.
- (f) Except in the case of Schedule II controlled substances and drugs which are sealed in unit dose packages, drugs which remain in the nursing home after the patient has died or been discharged, and drugs in containers with illegible or missing labels, shall be immediately and irretrievably disposed of by a licensed nurse employee in the presence of a witness and proper records maintained of such disposal. Destruction of Schedule II drugs shall be handled in accordance with (6)(g). Unit dose packages may be returned to the pharmacy.
 - (6) Special requirements for controlled substances.

- (a) All Schedule II controlled substances shall be stored in separately keyed and locked secure storage within a drug facility.
- (b) Schedule III controlled substances shall be stored apart from other drugs and may be stored on a separate shelf, drawer, or compartment with Schedule II controlled substances.
- (c) There shall be a record book for Schedule II and Schedule III controlled substances which shall be a bound book with consecutively numbered pages in which complete records of receipt and withdrawal of Schedule II and III controlled substances are maintained.
- (d) At least once each 24 hours, the amount of all Schedule II controlled substances stored in the facility shall be counted by at least two persons who are legally authorized to administer drugs. A similar count shall be made of all Schedule III controlled substances at least weekly. Records of counts shall be entered in the Schedule II and III controlled substances book(s).
- (e) When a resident is discharged, a record of release for any Schedule II or III controlled substances released shall be entered on the appropriate page for the given drug in the controlled substances record book.
- (f) Any discrepancy in actual count of Schedule II or III controlled substances and the record shall be documented in the Schedule II or III controlled substances books and reported immediately to the responsible supervisor who shall investigate the discrepancy. Any discrepancy which has not been corrected within seven calendar days shall be reported to the consultant pharmacist and the Washington state board of pharmacy.
- (g) Discontinued Schedule II controlled substances and all Schedule II controlled substances which remain after the discharge or death of residents shall:
- (i) Be destroyed at the nursing home within 30 days by a registered pharmacist and the director or nursing or a registered nurse designee with appropriate documentation maintained, or
- (ii) be destroyed at the nursing home by a representative of the Washington state board of pharmacy if so requested by the board or the nursing home.
- (h) A nursing home may establish procedures which vary from those paragraphs (6)(a)(g) if they are using a unit dose drug distribution system and if that system provides for the accurate accounting, by the nursing home and the supplying pharmacy, of the receipt and disposition of all Schedule II and III controlled substances.
 - (7) Drug administration.
- (a) Staff shall follow written procedures which provide for the safe handling and administration of drugs to residents.
- (i) Drugs shall be administered only by persons licensed to administer drugs.
- (ii) the resident shall be identified prior to administration.
- (b) All drugs shall be identified up to the point of administration.
- (c) Drugs shall be prepared immediately prior to administration and administered by the same person who prepares them except under a unit dose system.

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- (d) Drug administration shall be documented as soon as possible after the act of administration, and shall include:
 - (i) Verification of administration
 - (ii) reasons for ordered doses not taken
- (iii) reasons for administration of, and response to drugs given on and as needed basis (PRN).
- (e) Drug orders shall be received only by a licensed nurse and administered only on the written or verbal order of a practitioner. Verbal orders shall be signed by the prescribing practitioner in a timely manner.
- (f) The self-administration of medication program shall provide evidence of:
 - (i) Assessment of the resident's capabilities
 - (ii) instructions for administration
- (iii) monitoring of progress and compliance with orders
- (iv) safe storage of drugs. [Statutory Authority: RCW 18.64.005(11). 81–14–055 (Order 161), § 360–13–066, filed 6/30/81.]

Chapter 360-16 WAC PHARMACIES

WAC

360-16-110 Repealed.

360-16-260 Patient medication record system.

DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

360-16-110 Hospital pharmacy standards. [Regulation 35, effective 10/2/59, filed 3/23/60, subsection (4)(b), as corrected, filed 12/8/60.] Repealed by 82-12-024 (Order 167), filed 5/25/82. Statutory Authority:

RCW 18.64.005(11).

WAC 360-16-110 Repealed. See Disposition Table at beginning of this chapter.

- WAC 360-16-260 Patient medication record system. (1) A patient medication record system shall be maintained in all pharmacies. The record shall be devised so as to contain the information which the pharmacist feels necessary to give the patient the best professional advice and required drug information. The pharmacist shall attempt to determine through examination of the record and other information the patient may contribute, prior to the dispensing of a prescription, the possibility of a harmful drug interaction or other problems caused or influenced by the prescription presented for dispensing.
- (2) Patient medication records shall be considered to be a part of prescription records maintained in accordance with RCW 18.64.245 and shall be maintained for a period of at least five years in the same manner as provided for all prescription records (see WAC 360–16–096).
- (3) The information in the patient medication record shall be deemed confidential and may be released to other than patient or prescriber only on written release of the patient. If in the judgment of the pharmacist, the prescription presented for dispensing is determined to

cause a potentially harmful drug interaction or other problem due to a drug previously prescribed by another practitioner, the pharmacist may communicate this information to the prescribers. [Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17.290. 83-01-083 (Order 171), § 360-16-260, filed 12/17/82; Order 125, § 360-16-260, filed 1/28/75, effective 7/1/75.]

Chapter 360–17 WAC HOSPITAL PHARMACY STANDARDS

360-17-010	Definitions.
360-17-020	Applicability.
360-17-030	Licensure.
360-17-040	Personnel.
360-17-050	Absence of a pharmacist.
360-17-060	Physical requirements.
360-17-070	Drug procurement, distribution and control.
360-17-080	Administration of drugs.
360-17-090	Investigational drugs.
360-17-100	Additional responsibilities of pharmacy service

WAC 360-17-010 Definitions. For the purpose of these rules and regulations, the following definitions apply:

- (1) "Authenticated" or "authentication" means authorization of a written entry in a record by means of a signature which shall include, minimally, first initial, last name, and title.
- (2) "Controlled substance" means those drugs, substances or immediate precursors listed in Schedule I through V, chapter 69.50 RCW, State Uniform Controlled Substance Act, as now or hereafter amended.
- (3) "Drug" means any product referenced in RCW 18.64.011(3) as now or hereafter amended.
- (4) "Drug administration" means an act in which a single dose of a prescribed drug or biological is given to a patient by an authorized person in accordance with all laws and regulations governing such acts. The complete act of administration entails removing an individual dose from a previously dispensed, properly labeled container (including a unit dose container) reviewing it with a verified transcription, a direct copy, or the original medical practitioner's orders, giving the individual dose to the proper patient, and properly recording the time and dose given.
- (5) "Drug dispensing" means an act entailing the interpretation of an order for a drug or biological and, pursuant to that order, proper selection, measuring, labeling, packaging, and issuance of the drug for a patient or for a service unit of the facility.
- (6) "Hospital" means any institution licensed pursuant to chapters 70.41 or 71.12 RCW or designated pursuant to RCW 72.23.020.
- (7) "Hospital pharmacy" means that portion of a hospital which is engaged in the manufacture, production, preparation, dispensing, sale, and/or distribution of drugs, components, biologicals, chemicals, devices and other materials used in the diagnosis and treatment of injury, illness and diseases; and which is licensed by the

state board of pharmacy pursuant to the Washington State Pharmacy Practice Act, chapter 18.64 RCW.

- (8) "Immediate supervision" means visual and/or physical proximity that insure adequate safety and controls.
- (9) "Investigational drug" means any article which has not been approved for use in the United States, but for which an Investigational Drug Application (IND) has been approved by the FDA.
- (10) "Nurse" means a registered nurse or a licensed practical nurse licensed pursuant to chapters 18.88 or 18.78 RCW.
- (11) "Practitioner" means any person duly authorized by law or rule in the state of Washington to prescribe drugs in RCW 18.64.011(9).
- (12) "Pharmacist" means a person duly licensed by the state board of pharmacy to engage in the practice of pharmacy.
- (13) "Pharmacy" means every place properly licensed by the board of pharmacy where the practice of pharmacy is conducted.
- (14) "Pharmacy Assistant Level A and Level B" means persons certified under chapter 18.64A RCW.
- (15) "Physician" means a doctor of medicine or a doctor of osteopathy licensed to practice in the state of Washington.
- (16) "Practice of pharmacy" means the definition given in RCW 18.64.011(11) now or hereafter amended.
 - (17) "Protocol" means a written set of guidelines.
- (18) "Registered nurse" means an individual licensed under the provisions of chapter 18.88 RCW, regulating the practice of registered nursing in the state of Washington.
- (19) "Self-administration of drugs" means that a patient administers or takes his/her own drugs from properly labeled containers: *Provided*, That the facility maintains the responsibility for seeing that the drugs are used correctly and that the patient is responding appropriately.
- (20) "Shall" means that compliance with regulation is mandatory.
- (21) "Should" means that compliance with a regulation or standard is recommended. [Statutory Authority: RCW 18.64.005(12). 82–12–041 (Order 168), § 360–17–010, filed 5/28/82. Statutory Authority: RCW 18.64.005(11). 81–16–036 (Order 162), § 360–17–010, filed 7/29/81.]
- WAC 360-17-020 Applicability. The following rules and regulations are applicable to all facilities licensed pursuant to chapters 70.41 and 71.12 RCW or designated pursuant to RCW 72.23.020. [Statutory Authority: RCW 18.64.005(12). 82-12-041 (Order 168), § 360-17-020, filed 5/28/82. Statutory Authority: RCW 18.64.005(11). 81-16-036 (Order 162), § 360-17-020, filed 7/29/81.]
- WAC 360-17-030 Licensure. Hospital pharmacists shall be licensed by the board of pharmacy in accordance with chapter 18.64 RCW. [Statutory Authority:

RCW 18.64.005(11). 81–16–036 (Order 162), § 360–17–030, filed 7/29/81.]

WAC 360-17-040 Personnel. (1) Director of pharmacy. The pharmacy, organized as a separate department or service, shall be directed by a licensed pharmacist appropriately qualified by education, training, and experience to manage a hospital pharmacy. The patient care and management responsibilities of the director of pharmacy shall be clearly delineated in writing and shall be in accordance with currently accepted principles of management, safety, adequate patient care and treatment. The responsibilities shall include the establishment and maintenance of policies and procedures, ongoing monitoring and evaluation of pharmaceutical service, use and control of drugs, and participation in relevant planning, policy and decision making activities. Hospitals which do not require, or are unable to obtain the services of a fulltime director shall be held responsible for the principles contained herein and shall establish an ongoing arrangement in writing with an appropriately qualified pharmacist to provide the services. Where the director of pharmacy is not employed fulltime, then the hospital shall establish an ongoing arrangement in writing with an appropriately qualified pharmacist to provide the services described herein. The director of pharmacy shall be responsible to the chief executive officer of the hospital or his/her designee.

- (2) Supportive personnel. The director of pharmacy shall be assisted by sufficient numbers of additional pharmacists and/or pharmacy assistants and clerical personnel required to operate safely and efficiently to meet the needs of the patients.
- (3) Supervision. All of the activities and operations of each hospital pharmacy shall be professionally managed by the director or a pharmacist designee. Functions and activities shall be under the immediate supervision of a pharmacist and shall be performed according to written policies and procedures. When the hospital pharmacy is decentralized, each decentralized section(s) or separate organizational element(s) shall be under the immediate supervision of a pharmacist responsible to the director. [Statutory Authority: RCW 18.64.005(11). 81–16–036 (Order 162), § 360–17–040, filed 7/29/81.]
- WAC 360-17-050 Absence of a pharmacist. (1) General. Pharmaceutical services shall be available on a 24-hour basis. If round-the-clock services of a pharmacist are not feasible, arrangements shall be made in advance by the director of pharmacy to provide reasonable assurance of pharmaceutical services.
- (2) Access to the pharmacy. Whenever a drug is required to treat an immediate need and not available from floor stock when the pharmacy is closed, the drug may be obtained from the pharmacy by a designated registered nurse, who shall be accountable for his/her actions. One registered nurse shall be designated in each hospital shift for removing drugs from the pharmacy.
- (a) The director of pharmacy shall establish written policy and recording procedures to assist the registered nurse who may be designated to remove drugs from the

pharmacy, when a pharmacist is not present, in accordance with Washington State Pharmacy Practice Act, RCW 18.64.255(2), which states that the director of pharmacy and the hospital be involved in designating the nurse.

- (b) The stock container of the drug or similar unit dose package of the drug removed shall be left with a copy of the order of the authorized practitioner to be checked by a pharmacist, when the pharmacy reopens, or as soon as is practicable.
- (c) Only a sufficient quantity of drugs shall be removed in order to sustain the patient until the pharmacy opens.
- (d) All drugs removed shall be completely labeled in accordance with written policy and procedures, taking into account state and federal rules and regulations and current standards. [Statutory Authority: RCW 18.64.005(11). 81–16–036 (Order 162), § 360–17–050, filed 7/29/81.]

WAC 360-17-060 Physical requirements. (1) Area. The pharmacy facilities shall include:

- (a) Appropriate transportation and communications systems for the distribution and control of drugs within the hospital.
- (b) Sufficient space and equipment for secure, environmentally controlled storage of drugs and other pharmaceutical supplies.
- (2) In order to meet the medical services' need for drugs throughout the hospital, the pharmacy facilities should include:
- (a) Space for the management and clinical functions of the pharmaceutical service.
- (b) Space and equipment for the preparation of parenteral admixtures, radiopharmaceuticals, and other sterile compounding and packaging.
 - (c) Other equipment necessary.
- (3) Access to unattended areas. All areas occupied by the hospital pharmacy shall be locked by key or combination in order to prevent access by unauthorized personnel. The director of pharmacy shall designate in writing, by title and/or position those individuals who shall be authorized access to particular areas within the pharmacy, including authorization of access to keys and/or combinations.
- (4) Current pharmaceutical reference materials shall be provided in order to furnish the pharmaceutical, medical and nursing staff with adequate information concerning drugs. References related to the following subjects should be available:
 - (a) Drug identification
 - (b) Toxicology
 - (c) Pharmacology
 - (d) Drug interaction
 - (e) Drug compatibility
 - (f) Drug source
 - (g) Pharmacy law
 - (h) Microbiology
 - (i) Sterilization and disinfection
 - (j) Pharmacy technology
 - (k) Patient counseling

- (1) Rational therapy
- (m) Pathology
- (n) Chemistry
- (5) Drug storage areas. Drugs shall be stored under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security.
- (a) It is the joint responsibility of the director of pharmacy and the director of nursing to ensure that drug handling, storage, and preparation are carried out in conformance with established policies, procedures, and accepted standards.
- (b) Locked storage or locked medication carts shall be provided for use on each nursing service area or unit.
- (6) Flammable storage. All flammable material shall be stored and handled in accordance with applicable local and state fire regulations, and there shall be written policy and procedures for the destruction of these flammable materials. [Statutory Authority: RCW 18.64.005(11). 81–16–036 (Order 162), § 360–17–060, filed 7/29/81.]

WAC 360-17-070 Drug procurement, distribution and control. (1) General. Pharmaceutical service shall include:

- (a) Procurement, preparation, storage, distribution and control of all drugs throughout the hospital.
- (b) A monthly inspection of all nursing care units or other areas of the hospital where medications are dispensed, administered or stored. Inspection reports shall be maintained for one year.
 - (c) Monitoring the drug therapy.
- (d) Provisions for drug information to patients, physicians and others.
- (e) Surveillance and reporting of adverse drug reactions and drug product defect(s).
 - (2) Additional pharmaceutical services should include:
- (a) Obtaining and recording comprehensive drug histories and participation in discharge planning in order to affect appropriate drug use.
- (b) Preparation of all sterile products (e.g., IV admixtures, piggybacks, irrigation solutions), except in emergencies.
- (c) Distribution and control of all radiopharmaceuticals.
 - (d) Administration of drugs.
 - (e) Prescribing.
- (3) The director shall be responsible for establishing specifications for procurement, distribution and the maintenance of a system of accountability for drugs, IV solutions, chemicals, and biologicals related to the practice of pharmacy.
- (4) The director shall establish, annually review and update when necessary comprehensive written policies and procedures governing the responsibilities and functions of the pharmaceutical service. Policies affecting patient care and treatment involving drug use shall be established by the director of pharmacy with the cooperation and input of the medical staff, nursing service and the administration.
 - (5) Labeling:

- (a) Inpatient. All drug containers in the hospital shall be labeled clearly, legibly and adequately to show the drug's name (generic and/or trade) and strength when applicable. Accessory or cautionary statements and the expiration date shall be applied to containers as appropriate.
- (b) Outpatients. Labels on medications used for outpatients, emergency room, and discharge drug orders shall meet the requirements of RCW 18.64.246.
- (c) Parenteral and irrigation solutions. When drugs are added to intravenous solutions, a suitable label shall be affixed to the container. As a minimum the label shall indicate name and location of the patient, name and amount of drug(s) added, appropriate dating, initials of the personnel who prepared and checked the solution.
- (6) Medication orders. Drugs are to be dispensed and administered only upon orders of authorized practitioners. A pharmacist shall review the original order or direct copy thereof, prior to dispensing any drug, except for emergency use or as authorized in WAC 360–17–050.
- (7) Controlled substance accountability. The director of pharmacy shall establish effective procedures and maintain adequate records regarding use and accountability of controlled substances, and such other drugs as appropriate, in compliance with state and federal laws and regulations.
- (a) Complete, accurate, and current records shall be kept of receipt of all controlled substances and in addition, a Schedule II perpetual inventory shall be maintained.
- (b) The pharmacy shall maintain records of Schedule II drugs issued from the pharmacy to other hospital units which include:
 - (i) Date
 - (ii) Name of the drug
 - (iii) Amount of drug issued
- (iv) Name and/or initials of the pharmacist who issued the drug
- (v) Name of the patient and/or unit to which the drug was issued.
- (c) Records shall be maintained by any unit of the hospital which utilizes Schedule II drugs indicating:
 - (i) Date
 - (ii) Time of administration
- (iii) Name of the drug (if not already indicated on the records
- (iv) Dosage of the drug which was used which shall include both the amount administered and any amount destroyed.
- (v) Name of the patient to whom the drug was administered
 - (vi) Name of the practitioner who authorized the drug
- (vii) Signature of the licensed individual who administered the drug.
- (d) When it is necessary to destroy small amounts of controlled substances following the administration of a dose by a nurse, the destruction shall be witnessed by a second nurse who shall countersign the records of destruction.

- (e) The director of the pharmacy shall develop written procedures for the proper destruction of controlled substances not covered by (d) above conforming with federal and state statutes. A copy of the procedures shall be forwarded to the Drug Enforcement Administration (DEA) and the state board of pharmacy. As a minimum, procedures shall include the following:
- (i) All destructions shall render the drugs unrecoverable.
- (ii) Destruction shall be accomplished by the pharmacist and one other licensed health professional.
- (iii) Records of all destructions shall be maintained by the pharmacy. Quarterly summary reports shall be mailed to the DEA with copies to the state board of pharmacy.
- (iv) A copy of the destruction record shall be maintained in the pharmacy for five years.
- (f) Periodic monitoring of controlled substances records shall be performed by a nurse or a pharmacist to determine whether the drugs recorded on usage records have also been recorded on the patient's chart.
- (g) Use of multiple dose vials of controlled substances shall be discouraged.
- (h) Controlled substances, Schedule II and III, which are floor stocked, in any hospital patient or nursing service area shall be checked by actual count at the change of each shift by two authorized persons licensed to administer drugs.
- (i) All controlled substance records shall be kept for five years.
- (j) Hospitals wishing to use record systems other than that described above shall make application and receive written approval from the board of pharmacy prior to implementation.
- (k) Significant losses or disappearances of controlled substances and the facts surrounding the discrepancy shall be reported to the board of pharmacy, the drug enforcement agency, the chief executive officer of the hospital and other appropriate authorities.
- (8) Drug recall. The director shall develop and implement a recall procedure to assure that potential harm to patients within the hospital is prevented and that all drugs included on the recall are returned to the pharmacy for proper disposition.
- (9) All medications administered to inpatients shall be recorded in the patient's medical record.
- (10) Adverse drugs reactions. All adverse drug reactions shall be appropriately recorded in the patient's record and reported to the prescribing practitioner and to the pharmacy.
- (11) Drug errors. All drug errors shall upon discovery be recorded in an incident report and reported to the prescribing practitioner and to the pharmacy. [Statutory Authority: RCW 18.64.005(11). 81–16–036 (Order 162), § 360–17–070, filed 7/29/81.]
- WAC 360-17-080 Administration of drugs. (1) General. Drugs shall be administered only upon the order of a practitioner who has been granted clinical privileges to write such orders. Verbal orders for drugs shall only be issued in emergency or unusual circumstances

and shall be accepted only by a licensed nurse, pharmacist, or physician, and shall be immediately recorded and signed by the person receiving the order. Such orders shall be authenticated by the prescribing practitioner within 48 hours.

- (2) Administration. Drugs shall be administered only by appropriately licensed personnel in accordance with state and federal laws and regulations governing such acts and in accordance with medical staff approved hospital policy.
- (3) Patient's drugs. The hospital shall develop written policies and procedures for the administration of drugs brought into the hospital by or for patients.
- (a) Drugs brought into the hospital by or for the patient shall be administered only when there is a written order by a practitioner. Prior to use, such drugs shall be identified and examined by the pharmacist to ensure acceptable quality for use in the hospital.
- (b) Drugs from outside the hospital which are not used during the patient's hospitalization shall be packaged and sealed, if stored in the hospital, and returned to the patient at time of discharge or given to the patient's family.
- (c) Return of drugs may be prohibited due to possible jeopardy of the patient's health.
- (d) Written procedures shall be developed for the disposal of unreturned drugs.
- (4) Self-administration. Self-administration of drugs shall occur only within approved protocols in accordance with a program of self-care or rehabilitation. Policy and specific written procedures, approved by the appropriate medical staff, nursing service and administration shall be established by the director of pharmacy. [Statutory Authority: RCW 18.64.005(11). 81–16–036 (Order 162), § 360–17–080, filed 7/29/81.]
- WAC 360-17-090 Investigational drugs. (1) Distribution. Storage, distribution, and control of approved investigational drugs used in the institution shall be the responsibility of the director of pharmacy or his designee. The pharmacy shall be responsible for maintaining and providing information on approved investigational drugs.
- (2) General. Investigational drugs shall be properly labeled and stored for use only under the explicit direction of the authorized principal investigator or coinvestigator(s). Such drugs shall be approved by an appropriate medical staff committee.
- (3) Administration. On approval of the principal investigator or coinvestigator(s), those authorized to administer drugs may administer these drugs after they have been given basic pharmacological information about the drug. Investigational drugs shall be administered in accordance with approved written protocol that includes any requirements for the patient's appropriate informed consent. [Statutory Authority: RCW 18.64.005(11). 81–16–036 (Order 162), § 360–17–090, filed 7/29/81.]

WAC 360-17-100 Additional responsibilities of pharmacy service. (1) General. The pharmacy service

shall participate in other activities and committees within the hospital affecting pharmaceutical services, drugs and drug use.

- (2) Quality assurance. The pharmaceutical service shall establish a pharmacy quality assurance program.
- (3) Clinical activities. The director of pharmacy should develop clinically oriented programs, including but not limited to obtaining and recording comprehensive drug histories and participation in discharge planning to affect appropriate drug use, a formal drug information service, prescribing, and administration of drugs. [Statutory Authority: RCW 18.64.005(11). 81–16–036 (Order 162), § 360–17–100, filed 7/29/81.]

Chapter 360-18 WAC LICENSING PERIODS AND FEES

WAC

360-18-010 Licensing periods. 360-18-020 License fees.

- WAC 360-18-010 Licensing periods. (1) The following are established by the board of pharmacy as the licensing periods for each license specified:
- (a) Pharmacist licenses will expire on February 1 of each year.
- (b) Pharmacy location, CSA (retail), prophylactic (retail pharmacy), pharmacy assistant utilization, shop-keeper and shopkeeper differential hours licenses will expire on June 1 of each year.
- (c) CSA (sodium pentobarbital), Level A assistant, physician assistant, wholesaler (full line), wholesaler (OTC only), intern, manufacturer, CSA wholesaler, CSA manufacturer, prophylactic (vending machine), and prophylactic wholesaler licenses will expire on October 1 of each year.
- (2) Any license that is not renewed on or before the expiration date established herein shall expire and shall no longer be a valid license to practice or conduct the activity for which it is issued. Any license that has not been renewed within sixty days of the expiration date shall be renewed only upon payment of the renewal fee and penalty fee as specified in WAC 360-18-020. [Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17.290. 83-01-083 (Order 171), § 360-18-010, filed 12/17/82. Statutory Authority: RCW 18.64.005(4) and (11). 80-05-074 (Order 154, Resolution 4/80), § 360-18-010, filed 4/28/80.]

WAC 360-18-020 License fees. (1) Pursuant to chapter 90, Laws of 1979, the board hereby determines, sets and establishes, effective October 1, 1980, the following fees for licenses issued by the board:

(a) PHARMACY LOCATION, CSA & PROPHYLACTIC

Original pharmacy fee	\$100.00
Original CSA fee	30.00
Original prophylactic fee	10.00
Original pharmacy assistant	
utilization fee	25.00

	Renewal pharmacy fee	50.00
	Renewal CSA fee	25.00
	Renewal prophylactic fee	10.00
	Renewal pharmacy assistant	
	utilization fee	25.00
	Penalty pharmacy fee	100.00
(b)	VENDOR	
	Original fee	20.00
	Renewal fee	20.00
	Penalty fee	20.00
(c)	PHARMACIST	
	Exam fee	85.00
	Original license fee	50.00
	Renewal fee	25.00
	Penalty fee	25.00
	Reciprocity fee	150.00
(d)	SHOPKEEPER	
	Original fee	20.00
	Renewal fee	20.00
	Penalty fee	20.00
(i)	SHOPKEEPER – 6 or fewer	
	drugs	5.00
	Original fee	5.00
	Renewal fee	5.00
('')	Penalty fee	5.00
(ii)	SHOPKEEPER – with	
	differential hours	20.00
	Original fee	20.00
	Renewal fee	20.00
(0)	Penalty fee	20.00
(e)	DRUG MANUFACTURER	125.00
	Original fee Renewal fee	125.00
	Penalty fee	125.00
(f)	DRUG WHOLESALER – full	123.00
(1)	line	
	Original fee	125.00
	Renewal fee	125.00
	Penalty fee	125.00
(g)	DRUG WHOLESALER – OTC	
	only	
	Original fee	100.00
	Renewal fee	100.00
	Penalty fee	100.00
(h)	PHARMACY ASSISTANT –	
	Level "A"	10.00
	Original fee	10.00
	Renewal fee	10.00

(2) Effective until October 1, 1980, the board establishes as licensing fees those amounts specified in the various provisions of the Pharmacy Practice Act as they appeared prior to the effective date of chapter 90, Laws of 1979, which prior provisions are incorporated herein by this reference. [Statutory Authority: RCW 18.64.005(12). 82–12–041 (Order 168), § 360–18–020, filed 5/28/82. Statutory Authority: RCW 18.64.005(4) and (11). 80–08–035 (Order 155, Resolution 6/80), § 360–18–020, filed 6/26/80, effective 9/30/80; 80–05–074 (Order 154, Resolution 4/80), § 360–18–020, filed 4/28/80.]

Chapter 360-21 WAC WHOLESALERS

WAC	
360-21-010	Definitions.
360-21-020	Minimum standards for wholesalers.
360-21-030	Inspections.
360-21-040	Records.
360-21-050	Security.
360-21-060	Unauthorized sales.
360-21-070	Application for full line wholesaler license and over— the-counter only wholesaler license.
360-21-080	Application for controlled substance wholesaler license.
360-21-090	Export wholesaler.

WAC 360-21-010 Definitions. (1) "Full line whole-saler" means any wholesaler authorized by the board to possess and sell legend drugs, controlled substances (additional registration required) and nonprescription drugs (over-the-counter - OTC) to a licensed pharmacy or other legally licensed or authorized person.

- (2) "Over-the-counter only wholesaler" means any wholesaler authorized by the board to possess and sell nonprescription (OTC) drugs to any outlets licensed for resale.
- (3) "Controlled substances wholesaler" means a licensed wholesaler authorized by the board to possess and sell controlled substances to a licensed pharmacy or other legally licensed or authorized person.
- (4) "Export wholesaler" means any wholesaler authorized by the board to export legend drugs and nonprescription (OTC) drugs to foreign countries. [Statutory Authority: RCW 18.64.005(11) and 69.41.075. 82–06–042 (Order 165), § 360–21–010, filed 3/2/82.]

WAC 360-21-020 Minimum standards for whole-salers. The following minimum standards shall apply to all wholesale outlets for which licenses have been issued by the board:

- (1) Light and ventilation: All wholesale outlets including all storage areas, shall be well lighted, well ventilated and properly heated.
- (2) Sanitary facilities: All wholesale outlets shall have sanitary facilities constructed in accordance with the laws and ordinances applying thereto. Facilities shall include a restroom for employees which shall be provided with a wash basin supplied with hot and cold running water and toilet.
- (3) All drugs and chemicals shall be stored at appropriate temperatures according to label requirements to maintain stability.
- (4) A residence shall not be considered to be an acceptable location for issuance of a wholesaler's license unless the wholesaler's business is operated in a separate space within the residence which otherwise meets the requirements of this section.
- (5) Adequate space shall be provided consistent with the wholesale drug outlet operation.
- (6) Minimum equipment shall be maintained consistent with the wholesale drug outlet's operation and shall be in proper working order at all times.

- (7) Adequate security shall be provided as specified in WAC 360-21-050.
- (8) Surrounding environmental conditions shall be adequate to prevent contamination of stored products. [Statutory Authority: RCW 18.64.005(11) and 69.41-.075. 82-06-042 (Order 165), § 360-21-020, filed 3/2/82.]
- WAC 360-21-030 Inspections. Inspections shall be performed by representatives of the board of pharmacy to ensure compliance with chapter 360-21 WAC. The following items shall be included in these inspections:
- (a) The walls, ceilings, windows, and floors of the premises shall be clean and maintained in good repair and order.
- (b) The licensee's premises shall be free from obnoxious odors.
- (c) All persons working in premises are required to keep themselves and their apparel in a clean and sanitary condition.
- (d) Other areas of inspection include, but are not limited to housekeeping, sanitation, record keeping, accountability, security, types of outlets sold to and sources of drugs purchased. [Statutory Authority: RCW 18.64.005(11) and 69.41.075. 82-06-042 (Order 165), § 360-21-030, filed 3/2/82.]
- WAC 360-21-040 Records. Invoices shall be maintained for a period of five years, and show the source of supply for all drugs and to whom they were sold or distributed. Lack of such records shall be grounds for suspension or revocation of wholesale license. These records shall be available during regular business hours for inspection by any authorized representative of the board of pharmacy. In those instances in which records are stored in a location other than the wholesaler's premises, the records must be available for inspection within 72 hours. [Statutory Authority: RCW 18.64.005(11) and 69.41-.075. 82-06-042 (Order 165), § 360-21-040, filed 3/2/82.]
- WAC 360-21-050 Security. (1) Every wholesaler shall take security precautions to ensure that access from outside the premises is reduced to a minimum and that internal security equipment (alarm systems) are used to detect entry after hours.
- (2) Legend drug storage areas shall be constructed in such a manner as to prevent illegal entry.
- (3) Adequate lighting shall be provided at the outside perimeter of the premises to reduce the possibility of illegal entry.
- (4) All applicants for a license as a controlled substances wholesaler must comply with the security requirements as found in 21 CFR 1301.02, 1301.71 through 1301.74 and 1301.90 through 1301.92. [Statutory Authority: RCW 18.64.005(11) and 69.41.075. 82–06–042 (Order 165), § 360–21–050, filed 3/2/82.]
- WAC 360-21-060 Unauthorized sales. No whole-saler shall sell or distribute any drugs or devices except to an individual, corporation, or entity who is authorized

by law or regulation to possess such drugs or devices. No wholesaler shall sell any drugs or devices to an ultimate consumer. [Statutory Authority: RCW 18.64.005(11) and 69.41.075. 82–06–042 (Order 165), § 360–21–060, filed 3/2/82.]

- WAC 360-21-070 Application for full line whole-saler license and over-the-counter only wholesaler license. No person shall act as a wholesaler unless he/she has obtained a license from the board.
- (1) All application for licensure of a new or relocated wholesaler shall be accompanied by the required fee as set forth in WAC 360-18-020.
- (2) Applications shall specify the location of the wholesaler premises. When the applicant is not the owner of the business, the application shall indicate the owner and the applicant affiliation with the owner:
- (a) If the owner is a partnership or other multiple owner, the names of the partners or person holding the three largest interests shall be indicated on the application.
- (b) If the owner is a corporation, the name filed shall be the same as filed with the secretary of state. The name of the corporation, and the names of the corporation officers shall be indicated on the application.
- (3) All license renewal applications shall be accompanied by the annual fee and contain the same information required in subsection (2) of this rule.
- (4) A change of ownership or location requires a new license.
- (5) The license is issued to a person or firm and is nontransferable. Additions or deletions of a partner/partners shall be considered as a change of ownership.
- (6) The license fee cannot be prorated. [Statutory Authority: RCW 18.64.005(11) and 69.41.075. 82–06–042 (Order 165), § 360–21–070, filed 3/2/82.]
- WAC 360-21-080 Application for controlled substance wholesaler license. No person shall act as a controlled substance wholesaler unless he/she has obtained a controlled substance wholesaler license from the board.
 - (1) He/she must be licensed as a full line wholesaler.
- (2) He/she must meet all security requirements as set forth in WAC 360-21-050(4).
- (3) He/she must meet additional requirements for registration and fees as set forth in WAC 360-36-010. [Statutory Authority: RCW 18.64.005(11) and 69.41-075. 82-06-042 (Order 165), § 360-21-080, filed 3/2/82.]
- WAC 360-21-090 Export wholesaler. (1) Upon application the board may issue a wholesaler license for the primary business of exporting drugs to foreign countries.
- (2) Such license authorizes the holder to export non-controlled drugs to persons in a foreign jurisdiction that have legitimate reasons to possess such drugs.
- (3) Letters from consulate of the country to which drugs are exported 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 board upon its request.

- (4) Records to be kept by export wholesaler:
- (a) Complete description of drug, including, name, quantity, strength, and dosage unit.
 - (b) Name and address of purchaser.
- (c) Name and address of consignee in the country of destination.
 - (d) Name and address of forwarding agent.
 - (e) Proposed export date.
 - (f) Shippers involved and methods of shipment.
- (5) The issuance of an export wholesaler license does not authorize delivery of drugs in the United States. [Statutory Authority: RCW 18.64.005(11) and 69.41-075. 82-06-042 (Order 165), § 360-21-090, filed 3/2/82.]

Chapter 360-30 WAC HYPODERMIC SYRINGES, NEEDLES AND DEVICES

WAC

360-30-010 through 360-30-030 Repealed.

DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

360–30–010	Hypodermic devices sale registrations. [Order 134, § 360–30–010, filed 9/7/77.] Repealed by 81–19–086 (Order 163, Resolution 8/81), filed 9/17/81. Statutory Authority: RCW 18.64.005(11).
360-30-020	Hypodermic devices destruction. [Order 137, § 360–30–020, filed 11/8/77.] Repealed by 81–19–086 (Order 163, Resolution 8/81), filed 9/17/81. Statutory Authority: RCW 18.64.005(11).
360–30–030	Enforcement. [Order 137, § 360–30–030, filed 11/8/77.] Repealed by 81–19–086 (Order 163, Resolution 8/81), filed 9/17/81. Statutory Authority: RCW 18.64.005(11).

WAC 360-30-010 through 360-30-030 Repealed. See Disposition Table at beginning of this chapter.

Chapter 360-32 WAC SALES REQUIRING PRESCRIPTIONS

WAC

360-32-050 Identification of legend drugs for purposes of chapter 69.41 RCW.

360-32-055 Ephedrine prescription restrictions.

WAC 360-32-050 Identification of legend drugs for purposes of chapter 69.41 RCW. (1) In accordance with chapter 69.41 RCW, the board of pharmacy hereby finds that those drugs which have been determined by the food and drug administration, pursuant to the federal Food, Drug and Cosmetic Act, to require a prescription under federal law should also be classified as legend drugs under state law for the reasons that their toxicity or other potentiality for harmful effect, the methods of their use and the collateral safeguards necessary to their use, indicate that they are not safe for use except under the supervision of a practitioner.

(2) The board of pharmacy hereby specifically identifies as legend drugs, for purposes of chapter 69.41 RCW, those drugs which have been designated as legend drugs under federal law and are listed as such in the 1980-81 edition of the American Druggist Blue Book. Copies of the list of legend drugs as contained in the American Druggist Blue Book shall be available for public inspection at the headquarters office of the State Board of Pharmacy, 319 East 7th Avenue, Olympia, Washington 98504. Copies of this list shall be available from the board of pharmacy at the above address upon request made and upon payment of a fee in the amount of \$11 per copy. [Statutory Authority: RCW 69.41.075. 81-10-025 (Order 160), § 360-32-050, filed 4/28/81. Statutory Authority: 1979 1st ex. s. c 139. 79-09-138 (Order 149, Resolution 9/79), § 360–32–050, filed 9/5/79.]

WAC 360-32-055 Ephedrine prescription restrictions. (1) The board of pharmacy, pursuant to RCW 69.41.075, hereby identifies ephedrine, or any of its salts in a solid or aqueous form normally intended for oral administration, in any quantity, as a legend drug subject to the restrictions of RCW 69.41.030.

(2) The following products containing ephedrine or its salts are exempted from the provisions of this regulation:

 Amordrine tablet (Searle) 	25 mg (as racemic hydrochloride)
2. Bronitin tablet (Whitehall)	24 mg ephedrine
3. Bronkaid tablet (Breon)	24 mg (as sulfate)
4. Bronkotabs tablet (Breon)	24 mg (as sulfate)
5. CALCIDRINE SYRUP (Abbott)	4.2 mg/5cc HCl
6. HISTADYL EC (Lilly)	ephedrine hydrochlo- ride, 30 mg/30 ml
7. Histivite–d (Vitarine)	ephedrine sulfate, 30 mg/30 ml
8. NYQUIL (Vicks)	ephedrine sulfate, 8 mg/30 ml
9. Primatine M tablet (Whitehall)	24 mg (as hydrochlo-ride)
10. QUELIDRINE (Abbott)	ephedrine hydrochlo- ride, 5 mg/5 ml
11. Quiet–Nite (Rexall)	ephedrine sulfate, 10 mg/30 ml

[Statutory Authority: RCW 18.64.005(11) and 69.41-.075. 82-06-042 (Order 165), § 360-32-055, filed 3/2/82. Statutory Authority: RCW 69.41.075. 81-10-

12. VERAQUAD tablet –

suspension (Knoll)

24 mg tablet, 12 mg/5 ml

(as hydrochloride)

025 (Order 160), § 360-32-055, filed 4/28/81. Statutory Authority: 1979 1st ex. s. c 139. 79-09-138 (Order 149, Resolution 9/79), § 360-32-055, filed 9/5/79.]

Chapter 360–36 WAC REGULATIONS IMPLEMENTING THE UNIFORM CONTROLLED SUBSTANCES ACT

WAC

360-36-020 Dispensing Schedule V controlled substances.

WAC 360-36-020 Dispensing Schedule V controlled substances. (1) Those drugs classified in Schedule V of the Uniform Controlled Substances Act (RCW 69.50-.212) which can be dispensed without a prescription can be so distributed only for the medical purpose(s) indicated on the manufacturer's label (e.g., cough syrups may only be dispensed for the treatment of coughs) and shall be dispensed in accordance with the following rules.

- (2) Only a licensed pharmacist or a pharmacy intern may dispense a Schedule V drug. The pharmacist or pharmacy intern making the sale is responsible for the recording of the required information in the Schedule V register book. The pharmacist or pharmacy intern shall not sell a Schedule V drug to a person below the age of 21 and shall require the purchaser to supply identification so that the purchaser's true name, address and age can be verified. The pharmacist must keep the Schedule V drugs in a safe place not accessible to members of the public. The name and address of the pharmacy must be placed on the bottle or vial of each Schedule V drug sold and the pharmacist or pharmacy intern dispensing the product must place the date of sale and his/her initials on the label at the time of sale. The pharmacist or pharmacy intern is required to show every purchaser of a Schedule V product a copy of subsections (3) and (4) of this rule (sections relating to purchaser(s) of Schedule V drugs).
- (3) No person shall obtain a Schedule V drug without a practitioner's prescription unless he/she complies with the following:
- (a) The product must be purchased as a medicine for its indicated medical use only;
- (b) The purchaser must sign the Schedule V register book with his/her true name and address and supply proof of identification.
- (c) The purchaser cannot purchase more than 120 mls (four fluid ounces) of Schedule V cough preparations, nor more than 240 mls (eight fluid ounces) of Schedule V anti-diarrheal preparations.
- (4) In the absence of a practitioner's prescription, no pharmacist or pharmacy shall sell to any person, nor shall any person obtain, within a ninety—six hour period, more than the maximum quantity set forth in subsection (3)(c) of this rule. Further, no pharmacist or pharmacy shall sell to any person, nor shall any person obtain more than twice the maximum quantity set forth in (3)(c) above in any sixty—day period.

- (5) (a) Every pharmacy handling Schedule V drugs must keep a Schedule V register book in which the following statement must appear at the top of each page: "I have not obtained any Schedule V preparations within the last ninety—six hours, nor obtained Schedule V preparations more than twice within the last sixty days. This is my true name and address." All sales of Schedule V preparations without a practitioner's prescription shall be recorded in the Schedule V register book and the following information must be recorded therein:
 - (i) Printed name of purchaser
 - (ii) Signature of purchaser
 - (iii) Address of purchaser
 - (iv) Name of the Schedule V preparation sold
 - (v) Quantity of Schedule V preparation sold
 - (vi) Date of sale
- (vii) Initials or name of pharmacist or pharmacy intern who sold the Schedule V drug
- (viii) Proof of identification: A unique identification number from a driver's license or from other state or federally issued photo identification card.
- (b) All register books used to record the sale of Schedule V preparations shall conform to the following standards:
- (i) The book shall be $8\ 1/2$ inches wide, 11 inches long.
- (ii) The book shall be securely bound, not loose leaf or spiral bound.
- (iii) The book shall have its pages consecutively numbered with a unique number assigned to each book and identified on each page.
- (iv) Each page shall consist of an original and duplicate. If any sales are recorded, the duplicate sheet must be mailed to the board of pharmacy when completed or on the last day of each month, whichever is earlier.
- (3) All pharmacy records relating to Schedule V drugs shall be open to examination by state board of pharmacy investigators during normal business hours. The refusal to permit such examination shall constitute grounds for the suspension or revocation of the pharmacist's license. [Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17.290. 83–01–083 (Order 171), § 360–36–020, filed 12/17/82. Statutory Authority: RCW 18.64.005 and 69.41.075. 82–19–022 (Order 169), § 360–36–020, filed 9/8/82; Order 108, § 360–36–020, filed 10/26/71.]

Chapter 360-40 WAC PROPHYLACTICS

360-40-010	Definitions.
360-40-020	Application for license.
360-40-030	Display of licenses and identification.
360-40-040	Sale of condoms prohibited unless approved.
360-40-050	List of approved condoms.
360-40-060	Submission of condoms for testing.
360-40-070	Condom testing.
360-40-080	Suspension or revocation of prophylactic license

WAC

- WAC 360-40-010 Definitions. (1) The definitions set forth in RCW 18.81.010 and 18.64.011 shall be applicable to these rules. In addition:
- (a) A "condom" is a prophylactic consisting of a very thin sheath designed to be placed over the penis to prevent conception or venereal disease during coitus, and is commonly made of rubber, parchment skins, plastic or similar materials. [Statutory Authority: RCW 18.64-.005, 18.81.080 and 42.17.290. 83-01-083 (Order 171), § 360-40-010, filed 12/17/82; Order 108, § 360-40-010, filed 10/26/71.]
- WAC 360-40-020 Application for license. (1) Any person seeking a wholesale or retail license under chapter 18.81 RCW shall file with the board of pharmacy an application on a form provided by the board along with the appropriate license fee as provided in WAC 360-18-020. Licensed pharmacies shall not be required to submit a separate application form for a prophylactic license. All other applicants must submit the required forms setting forth at least the following information:
- (a) The name of the applicant, including the names of the officers if the applicant is a corporation;
 - (b) The location for which the license is sought;
- (c) A statement as to whether the condoms are to be sold by means of a vending machine;
- (d) If the license sought is for a vending machine operation, the location of each vending machine and the hours during which purchasers will have access to each machine shall be listed. [Statutory Authority: RCW 18-.64.005, 18.81.080 and 42.17.290. 83-01-083 (Order 171), § 360-40-020, filed 12/17/82.]
- WAC 360-40-030 Display of licenses and identification. (1) The holder of any retail or wholesale license for the sale of prophylactics shall display that license so that it is readily available for examination by any board investigator.
- (2) All vending machines must have a current decal, supplied by the board, permanently attached to the front of the machine. The name and address of the owner and the licensee of each vending machine must be readily visible on the machine. [Statutory Authority: RCW 18-.64.005, 18.81.080 and 42.17.290. 83-01-083 (Order 171), § 360-40-030, filed 12/17/82.]
- WAC 360-40-040 Sale of condoms prohibited unless approved. No condoms shall be sold in this state unless the following conditions are met:
- (1) The product must be on the list of condom products which have been approved by the board.
- (2) All condoms shall be individually sealed in plastic, foil or a comparable type seal to protect the product from deterioration due to exposure to air.
- (3) The container in which the condom is sold to the purchaser shall bear the date of manufacture and the condom may not be sold in this state three years after the date of manufacture. [Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17.290. 83-01-083 (Order 171), § 360-40-040, filed 12/17/82.]

WAC 360-40-050 List of approved condoms. The board shall prepare annually a list of condom products which have been tested and approved by the board. This list shall be prepared no later than May 1st of each year. [Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17.290. 83-01-083 (Order 171), § 360-40-050, filed 12/17/82.]

WAC 360-40-060 Submission of condoms for testing. In order to be included on the list of approved condoms issued by the board, three dozen samples of the product must be submitted to the board prior to April 1st. Condoms may be submitted for testing at other times, but in order to be approved at these times the individual submitting the three dozen samples for testing must pay a special testing fee of \$300. The board shall complete these special testings within forty-five days of submission of the product samples and special testing fee. Any product which has been placed on the board's list of approved condoms shall remain on this list and the manufacturer shall be required to submit samples for testing only upon request of the board. [Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17.290. 83-01–083 (Order 171), § 360–40–060, filed 12/17/82.]

WAC 360-40-070 Condom testing. The testing of condoms shall be performed under the supervision of an employee of the Washington state board of pharmacy. The test will be conducted as follows:

- (1) Rubber condoms (elastic material):
- (a) Rubber condoms shall be air tested, and shall be capable of withstanding inflation with one cubic foot of air. They shall be free from holes, imperfect rings and blisters.
- (b) Procedure for air testing rubber condoms shall be mechanically inflated with one cubic foot of air at prevailing atmospheric pressure at room temperature of approximately 70° Farenheit. The apparatus used as an air compressor shall be equipped with a guage indicating the amount of air injected into the condom being tested. The rate of air injection to inflate the condom shall be approximately one cubic foot of air per minute.
 - (2) Nonrubber condoms (nonelastic material):
- (a) Nonrubber condoms shall be of suitable length, not patched, and shall be free from grease or any foreign substances that may be used as a filler for hiding imperfections or discolorations.
- (b) Procedure for water testing nonrubber condoms shall be inflated with water, suspended, and observed for a twelve–hour period. If the water is retained, the condom shall be approved in the failure rate exceeds one percent. [Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17.290. 83–01–083 (Order 171), § 360–40–070, filed 12/17/82.]
- WAC 360-40-080 Suspension or revocation of prophylactic licenses. Any license issued pursuant to chapter 18.81 RCW and these rules and regulations is subject to suspension or revocation if it is determined by the board, after notice and hearing, that the licensee has sold condoms that are not on the board-approved list or that the

licensee has distributed condoms to an unlicensed outlet. [Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17.290. 83–01–083 (Order 171), \S 360–40–080, filed 12/17/82.]

Chapter 360–44 WAC PUBLIC RECORDS ACCESS PURSUANT TO INITIATIVE 276

WAC

360-44-020 Definitions.

360-44-040 Operations and procedures.

WAC 360-44-020 Definitions. (1) "Public record" includes any writing containing information relating to the conduct of government or the performance of any governmental or proprietary function prepared, owned, used or retained by any state or local agency regardless of physical form or characteristics.

- (2) "Writing" means handwriting, typewriting, printing, photostating, photographing and every other means of recording any form of communication or representation, including letters, words, pictures, sounds, or symbols or combination thereof, and all papers, maps, magnetic or paper tapes, photographic films and prints, magnetic or punched cards, discs, drums and other documents.
- (3) The "Washington state board of pharmacy" is the board whose members are appointed by the governor, pursuant to RCW 18.64.001. The Washington state board of pharmacy shall hereinafter be referred to as the "board." Where appropriate, the term "board" also refers to the staff and employees of the Washington state board of pharmacy. [Statutory Authority: RCW 18.64-.005, 18.81.080 and 42.17.290. 83-01-083 (Order 171), § 360-44-020, filed 12/17/82; Order 113, § 360-44-020, filed 4/27/73.]
- WAC 360-44-040 Operations and procedures. (1) The board of pharmacy consists of five members, one of whom is designated as a chairman. The members are appointed by the governor for staggered four year terms.
- (2) The board meets approximately once a month in various places throughout the state. The time and place of the meeting can be learned by writing or calling the administrative office of the board.
- (3) The executive secretary is the board's chief executive. He is responsible for carrying out the board's directions and for directing the board's staff.
- (4) It is the board's duty to administer the law in chapters 18.64, 18.64A, 18.81, 69.04, 69.40, 69.41, 69.50, and 70.54 RCW.
- (a) Chapter 18.64 RCW Pharmacy Act creation of board of pharmacy, definition of terms used in pharmacy act, examination and licensing of pharmacists, interns, wholesalers, shopkeepers and vendors, grounds for license suspension or revocation, unlawful practices, prescription labels and records.
- (b) Chapter 18.64A RCW Pharmacy Assistants Law - creation of pharmacy assistants, definition of

terms, regulation of classifications and services, limitations on practice, grounds for certificate suspension or revocation, applications, fees, employment of pharmacy assistants, and pharmacists liability and responsibility.

- (c) Chapter 18.81 RCW Prophylactic Law regulation and licensing of prophylactics and distributors.
- (d) Chapter 69.04 RCW Food, Drug and Cosmetic Act. Board has joint responsibility with director of department of agriculture. Board regulates only the drug and devices portion of the act. DMSO sales and use provisions are contained in this law.
- (e) Chapter 69.40 RCW Poison Act labeling of drugs incorrectly and selling poisons without labeling.
- (f) Chapter 69.41 RCW Legend Drug Act definition of terms, prohibited acts, regulation of sale, delivery, or possession of legend drugs, requirements for prescriptions and labels, search and seizure procedures. Penalties for violations are created and rules regarding legend drugs are authorized. The procedures and requirements for substitution of legend drugs, manufacturing standards and liability of pharmacists are outlined. Requirements for identification and labeling marking of legend drugs are created.
- (g) Chapter 69.50 RCW Controlled Substances Act places all narcotics, barbiturates, amphetamines, hallucinogenics and marihuana into five schedules. Sets standards and definitions for the five schedules. Regulates the manufacture, distribution and dispensing of controlled substances. Sets forth offenses, penalties and prohibited acts. Enforcement and administrative provisions include administrative and criminal search warrants.
- (h) Chapter 70.54 RCW Laetrilė board given authority to sample and test laetrile and promulgate rules regarding it.
- (5) Information concerning all licenses or registrations issued by the board may be obtained by writing or calling the administrative office of the board. [Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17.290. 83-01-083 (Order 171), § 360-44-040, filed 12/17/82; Order 113, § 360-44-040, filed 4/27/73.]

Chapter 360-48 WAC DIMETHYL SULFOXIDE (DMSO)

WAC 360-48-010 Availability. 360-48-020 License. 360-48-030 License application. 360-48-040 Good manufacturing practices. 360-48-050 Purity. 360-48-060 Contents. 360-48-070 Labeling. 360-48-080 Other forms of DMSO.

WAC 360-48-010 Availability. DMSO for topical use (i.e., for application to the skin) shall be available in intrastate commerce to the citizens of the state of Washington in accordance with all applicable state laws and regulations. [Statutory Authority: RCW 69.41.075 and 1981 c 50 § 1. 81-22-048 (Order 164), § 360-48-010, filed 11/2/81.]

WAC 360-48-020 License. Manufacturers and/or wholesale distributors of DMSO must have a license issued by the state board of pharmacy, as provided in RCW 18.64.045 and/or RCW 18.64.046. [Statutory Authority: RCW 69.41.075 and 1981 c 50 § 1. 81-22-048 (Order 164), § 360-48-020, filed 11/2/81.]

WAC 360-48-030 License application. Applications for the manufacture of DMSO for use pursuant to chapter 69.04 RCW shall be filed with the board of pharmacy. Such applications shall include:

- (1) A full list of the articles used as components of such drug;
 - (2) A full statement of the composition of such drug;
- (3) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing in such drug;
- (4) Such samples of such drug and of the articles used as components thereof as the board may require; and
- (5) Specimen of the labeling proposed to be used for such drug;
- (6) Specific information under the following section headings and in the following order:
 - (a) Description.
 - (b) Clinical pharmacology.
 - (c) Indications and usage.
 - (d) Contraindications.
 - (e) Warnings.
 - (f) Precautions.
 - (g) Adverse reactions.
 - (h) Overdosage.
 - (i) Dosage and administration.
- (j) How supplied. [Statutory Authority: RCW 69.41-.075 and 1981 c 50 § 1. 81–22–048 (Order 164), § 360–48–030, filed 11/2/81.]

WAC 360-48-040 Good manufacturing practices. Manufacturers of DMSO shall conform to the standards for good manufacturing practices of finished pharmaceuticals, as provided in WAC 360-46-010 through 360-46-150. Further, manufacturers shall comply with the state Food, Drug, and Cosmetic Act, chapter 69.04 RCW. [Statutory Authority: RCW 69.41.075 and 1981 c 50 § 1. 81-22-048 (Order 164), § 360-48-040, filed 11/2/81.]

WAC 360-48-050 Purity. (1) Certification of batches of DMSO shall be made as required by the state board of pharmacy, with the costs for required testing, including purity and potency, to be borne by the manufacturer and/or wholesale distributor. The manufacturer and/or wholesale distributor shall be held totally responsible for the quality of the drug product, in accordance with RCW 18.64.270.

Such batch testing shall be required upon commencement of manufacture of DMSO and thereafter as the state board of pharmacy shall require.

(2) DMSO shall be packaged in tightly closed light resistant glass containers. Such containers, including lids, caps, or other closures, shall have been tested by the DMSO manufacturer and shown not to interact with the

contents. Such test results must be submitted to the state board of pharmacy upon request. [Statutory Authority: RCW 69.41.075 and 1981 c 50 § 1. 81–22–048 (Order 164), § 360–48–050, filed 11/2/81.]

WAC 360-48-060 Contents. DMSO made available to the public for topical use, must contain purified dimethyl sulfoxide (meeting or exceeding FDA approved drug grade) and in addition may contain one or more of the following ingredients:

Carboxypolymethylene (pharmaceutical grade)

Sodium Carbonate, USP

Sodium Chloride, USP

Urea, USP

Purified Water, USP

Any batch found to contain any ingredient not on the above list shall result in the product being declared to be adulterated in accordance with RCW 69.04.430. [Statutory Authority: RCW 69.41.075 and 1981 c 50 § 1.81–22–048 (Order 164), § 360–48–060, filed 11/2/81.]

WAC 360-48-070 Labeling. (1) The labeling of topical DMSO shall include the following:

- (a) The name and place of business of the manufacturer, the packer, and the distributor. (Each one must appear and be identified.)
- (b) Adequate directions for use under which a lay person can safely use the drugs, including " Warning -Be sure that the skin is clean before using this product."
- (c) Statements of those conditions, purposes, or uses for which such drug is intended, recommended, or suggested in any oral, written, printed, or graphic advertising, except that no such statement shall refer to conditions, uses, or purposes for which the drug can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner.
- (d) The dosage for each of the uses for which it is intended and usual quantities for persons of different physical conditions.
 - (e) Frequency of application.
 - (f) Duration of application.
 - (g) The proprietary name of the drug.
 - (h) The established name of the drug.
 - (i) An identifying lot or control number.
 - (j) The date of manufacture.
- (k) The strength of the solution expressed as a percentage weight in volume at 68° F. (20° C.).
 - (1) Net contents of container.
- (m) Warnings: The labeling shall describe serious adverse reactions and potential safety hazards, limitations in use, and steps that should be taken if they occur. The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with the drug; a casual relationship need not have been provided. In addition to any warning labeling developed by the manufacturer, all immediate containers of DMSO must prominently show the following warnings:
 - (i) "FOR EXTERNAL USE ONLY"

- (ii) "Warning -Use only as directed. Keep out of reach of children."
- (iii) "Caution –Discontinue use if excessive irritation of the skin develops. Avoid getting into the eyes or on mucous membranes.'
- (iv) "Caution –If symptoms persist for more than 10 days, consult a physician."
- (v) "In conditions affecting children under 6 years of age consult a physician."
- (vi) "In case of accidental ingestion, contact a physician immediately."
- (vii) "There is no evidence that this product may be safely used by pregnant women or nursing mothers.'
- (viii) " Warning -Be sure that skin is clean before using this product, which is a powerful solvent. Grease, chemicals, or any other substance could be absorbed into the skin along with the DMSO."
 - (o) Disclaimer. Each label must state:
- "DMSO has not been approved under federal law for use in interstate commerce in the treatment of any condition or disease state in humans other than interstitial cystitis. Testing for safety and afficacy has not been performed by any agency of the State of Washington. Persons using this product do so at their own risk."
- (p) Label locations. The immediate container label must show items: a, b, e, g, h, i, j, k, l, m, i, ii, and v. All other information specified in this section shall be shown in the patient package insert which must be attached to the container when sold. [Statutory Authority: RCW 69.41.075 and 1981 c 50 § 1. 81-22-048 (Order 164), § 360-48-070, filed 11/2/81.]
- WAC 360-48-080 Other forms of DMSO. The board of pharmacy hereby declares that all forms of DMSO intended for medical use, for other than topical application, are legend drugs as defined in chapter 69.41 RCW.

Such other forms shall meet all of the other requirements of this chapter. [Statutory Authority: RCW 69-.41.075 and 1981 c 50 § 1. 81–22–048 (Order 164), § 360-48-080, filed 11/2/81.]

Title 365 WAC PLANNING AND COMMUNITY AFFAIRS **AGENCY**

Chapters

365-40

Rules and regulations regarding state funding of local head start programs

365 - 42

Regulations regarding financial support to private, nonprofit corporations for capital assistance in providing transportation for the elderly and handicapped.

Chapter 365-40 WAC

RULES AND REGULATIONS REGARDING STATE FUNDING OF LOCAL HEAD START PROGRAMS

WAC

365-40-031 Repealed.

365-40-051 Eligibility criteria.

365-40-061 Allowed and forbidden uses of state head start funds.

365-40-071 Method of payment and reporting requirements.

DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS **CHAPTER**

365-40-031

Establishment of advisory council. [Statutory Authority: RCW 43.06.110 and chapter 43.63A RCW. 79-08-050 (Order 79-02), § 365-40-031, filed 7/20/79.] Repealed by 82-07-066 (Order 82-01), filed 3/22/82. Statutory Authority: RCW 43.06.110 and 43.63A.060.

WAC 365-40-031 Repealed. See Disposition Table at beginning of this chapter.

WAC 365-40-051 Eligibility criteria. In order to receive head start funds, a contractor must provide services to families and individuals eligible according to federal head start guidelines who are in need of skills, knowledge, opportunities and motivation to become economically self-sufficient. Each head start program must be designed to improve the health and general well-being of the children involved, develop their mental processes, and enhance their conceptual and verbal skills. Head start funds may be used only for activities which result in direct and measurable services to head start program children. State head start funds are allocated to programs based on the federal enrollment levels. An additional set-aside of 3% of the pass through funds are allocated for programs with 60 or less children. [Statutory Authority: RCW 43.06.110 and 43.63A.060. 82-07-066 (Order 82-01), § 365-40-051, filed 3/22/82. Statutory Authority: RCW 43.06.110 and chapter 43-.63A RCW. 79-08-050 (Order 79-02), § 365-40-051, filed 7/20/79.]

WAC 365-40-061 Allowed and forbidden uses of state head start funds. (1) Allowable uses of state head start funds include but are not limited to:

- (a) Purchase of supplies to be consumed by head start program children.
- (b) Payment of salaries for nonadministrative personnel such as full or part-time teachers or specialists in speech, hearing, hygiene, reading, etc.
- (c) Purchases under contract of medical or dental services for head start children and their families.
- (2) Forbidden uses of head start funds include but are not limited to:
- (a) Payment of salaries for administrative personnel such as program directors, assistant directors, bookkeepers, secretaries, etc.
- (b) Payment of administrative support expenses such as postage, telephone, travel, utilities, and equipment.
- (c) Purchase of nonexpendable equipment with an original cost of \$100 or more and a useful life of at least one year. [Statutory Authority: RCW 43.06.110 and