Chapter 246-873 WAC
PHARMACY—HOSPITAL STANDARDS

WAC

WAC 246-873-010 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 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-873-010, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(12). WSR 82-12-041 (Order 168), § 360-17-010, filed 5/28/82. Statutory Authority: RCW 18.64.005(11). WSR 81-16-036 (Order 162), § 360-17-010, filed 7/29/81.]

WAC 246-873-020 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 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-873-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(12). WSR 82-12-041 (Order 168), § 360-17-020, filed 5/28/82. Statutory Authority: RCW 18.64.005(11). WSR 81-16-036 (Order 162), § 360-17-020, filed 7/29/81.]

WAC 246-873-030 Licensure. Hospital pharmacists shall be licensed by the board of pharmacy in accordance with chapter 18.64 RCW.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-873-030, filed 8/30/91, effective

9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 81-16-036 (Order 162), § 360-17-030, filed 7/29/81.]

WAC 246-873-040 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 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-873-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 81-16-036 (Order 162), § 360-17-040, filed 7/29/81.]

WAC 246-873-050 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 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-873-050, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 81-16-036 (Order 162), § 360-17-050, filed 7/29/81.]

WAC 246-873-060 Provision of emergency department discharge medications when pharmacy services are unavailable. The responsible manager, as defined in WAC 246-869-070, of a hospital or free standing emergency department may, in collaboration with the appropriate medical staff committee of the hospital, develop policies and procedures in compliance with RCW 70.41.480 which must be implemented to provide discharge medications to patients released from hospital emergency departments during hours when community or outpatient hospital pharmacy services are not available. The delivery of a single dose for immediate administration to the patient is not subject to this regulation. Such policies shall allow the practitioner or registered nurse to distribute medications, pursuant to the policies and procedures, as specified in RCW 70.41.480 and the following:

(1) An order of a practitioner authorized to prescribe a drug is presented. Oral or electronically transmitted orders must be verified by the practitioner in writing within seventy-two hours.

(2) A department credentialed pharmacy technician or a licensed pharmacist shall prepackage the medication. Medication prepackaged by a department credentialed pharmacy technician must be checked by a licensed pharmacist. The prepackaged medication must contain any supplemental material provided and an affixed label that contains:

(a) Name, address, and telephone number of the hospital.

(b) The name of the drug (as required by chapter 246-899 WAC), strength and number of units.

(c) Cautionary information as required for patient safety and information on use is provided.

(d) An expiration date after which the patient should not use the medication.

(e) Directions for use.

(3) No more than a forty-eight hour supply is provided to the patient except when the pharmacist has informed appropriate hospital personnel that normal services will not be available within forty-eight hours. A final quantity of medication supply shall not exceed ninety-six hours.

(4) The practitioner or registered nurse will ensure the container is labeled before presenting to the patient and shows the following:

(a) Name of patient;

(b) Complete directions for use, which should include at a minimum the number of units distributed, frequency, and route of administration;

(c) Date of distribution;

(d) Identifying number (i.e., RX number or similar indicator);

(e) Name of prescribing practitioner;

(f) Initials of the practitioner or registered nurse who distributed the medication.

(5) A registered nurse or practitioner will distribute prepackaged emergency medications to patients only after a practitioner has counseled the patient on the medication.

(6) The original hard copy or electronically transmitted order by the practitioner is retained for verification by the pharmacist after completion by the practitioner or registered nurse and shall contain:

(a) Name and address of patient if not already listed in the medical record;

(b) Date of issuance;

(c) Units issued;

(d) Initials of practitioner or registered nurse.

(7) The medications distributed as discharge medications must be stored in compliance with the laws concerning security and access. They must be stored in or near the emergency department in such a manner as to preclude the necessity for entry into the pharmacy when pharmacy services are not available.

[Statutory Authority: RCW 18.64.005 and 70.41.480. WSR 17-01-108, § 246-873-060, filed 12/19/16, effective 1/19/17. Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), § 246-873-060, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-873-060, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 89-12-011 (Order 225), § 360-17-055, filed 5/26/89; WSR 83-23-109 (Order 179), § 360-17-055, filed 11/23/83.]

WAC 246-873-070 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) 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.

(5) 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 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-873-070, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 85-11-066 (Order 194), § 360-17-060, filed 5/21/85. Statutory Authority: RCW 18.64.005(11). WSR 81-16-036 (Order 162), § 360-17-060, filed 7/29/81.]

WAC 246-873-080 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 246-873-050.

(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 two 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 two 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. WSR 92-12-035 (Order 277B), § 246-873-080, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-873-080, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 81-16-036 (Order 162), § 360-17-070, filed 7/29/81.]

WAC 246-873-090 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 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-873-090, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 81-16-036 (Order 162), § 360-17-080, filed 7/29/81.]

WAC 246-873-100 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 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-873-100, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 81-16-036 (Order 162), § 360-17-090, filed 7/29/81.]

WAC 246-873-110 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 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-873-110, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 81-16-036 (Order 162), § 360-17-100, filed 7/29/81.]