

## CHAPTER 12

### INSTITUTIONAL PHARMACY PRACTICE REGULATIONS

#### Section 1. Authority.

These regulations are promulgated as authorized by the Act.

#### Section 2. Purpose.

The purpose of this Chapter is to provide standards for the conduct, practice activities, and operation of a pharmacy located in a hospital or other inpatient facility that is licensed under the Wyoming Department of Health. The intent of these standards is to establish a minimum acceptable level of pharmaceutical care to the patient so that the patient's health is protected while contributing to positive patient outcomes.

#### Section 3. Scope of Chapter.

This Chapter applies to any person, partnership, corporation, limited liability company, or other entity engaging in the practice of pharmacy in an Institutional Facility, as defined below, within this state.

#### Section 4. Definitions.

(a) "Automated Dispensing Device" means a mechanical system that performs operations or activities, other than Compounding or Administration, relative to the storage, packaging, Dispensing, or Distribution of medications, and which collects, controls and maintains all transaction information.

(b) "Beyond-Use Date" means a date placed on a prescription label at the time of Dispensing that is intended to indicate to the patient or caregiver a time beyond which the contents of the prescription are not recommended to be used.

(c) "Clean Room" means a room with a minimum of an ISO Class 7 environment as defined in Chapter 17:

~~(i) — in which the concentration of airborne particles is controlled~~

~~(ii) — that is constructed and used in a manner to minimize the introduction, generation, and retention of particles inside the room;~~

~~(iii) — in which other relevant variables (e.g., temperature, humidity, and pressure) are controlled as necessary; and~~

~~(iv) — in which microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear is not exceeded for a specific cleanliness class.~~

(d) “Drug Room” means a secure and lockable location within an inpatient care facility that does not have an Institutional Pharmacy.

(e) “Emergency Drug Cart (“crash cart)” means a cart containing those drugs that may be required to meet the immediate therapeutic needs of ~~inpatients or emergency room patients and are not available from any other authorized source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining such drugs from such other source.~~

(f) “Floor Stock” means prescription drugs not labeled for a specific patient and maintained at a nursing station or other Institutional Facility department (excluding the Institutional Pharmacy) for the purpose of administration to a patient of the Institutional Facility.

(g) “Formulary” means a continually revised compilation of pharmaceuticals that reflects the current clinical judgment of the pharmacy staff and medical staff of the Institutional Facility.

(h) “Institutional Facility” means a hospital, convalescent home, nursing home, extended care facility, correctional or penal facility, or any other organization, public or private, which provides a physical environment for patients to obtain medical, surgical, and/or nursing services, except those places where physicians, dentists, veterinarians, or other practitioners of the healing arts engage in private office practice.

(i) “Institutional Pharmacy” means a pharmacy where medications are dispensed to other health care professionals for administration to institutionalized patients served by an Institutional Facility, and which is:

(i) Located within the Institutional Facility, or

(ii) Located outside the Institutional Facility but only provides pharmaceutical pharmacy services to institutionalized patients.

(j) “Investigational Drug” means:

(i) a substance in a clinical stage of evaluation not released by the Food and Drug Administration (FDA) for general use or for sale in interstate commerce; or

(j) Commercial drugs that are proposed for a new use, contain a new component, have a new dosage or mode of administration, or are in a new combination or combined in new proportions.

(k) “Medication Order” means a written, electronic, or verbal order from a practitioner (or his/her agent) authorized by law to prescribe medications for administration to a patient.

(l) "Remote Order Processing for Institutional Pharmacies" includes any of the following activities performed for an Institutional Pharmacy from a remote location:

- (i) Receiving, interpreting, or clarifying medication orders;
- (ii) Entering or transferring medication order data;
- (iii) Performing prospective drug use review;
- (iv) Obtaining substitution authorizations;
- (v) Interpreting and acting on clinical data;
- (vi) Performing therapeutic interventions;
- (vii) Providing drug information;
- (viii) Authorizing the release of a medication for administration.

#### Section 5. Licensing.

(a) All institutional pharmacies shall register annually with the Board of Pharmacy on a form provided by the Board. Institutional Pharmacies that also provide outpatient pharmacy services shall also register as a retail pharmacy.

(b) All Institutional Pharmacy licenses shall expire on June 30. Renewal notices will be sent by the Board's office at least sixty days prior to June 30.

(c) The fee established in ~~Wyoming Pharmacy Act, Rules and Regulations~~ Chapter 2, ~~Section 25(a)(xi)~~, will be charged for issuance of a new license and renewal. The late fee established in ~~Wyoming Pharmacy Act, Rules and Regulations~~, Chapter 2, ~~Section 25 (b)(vi)~~, will be charged, in addition to the renewal fee, for any license renewal application that is postmarked after June 30 or is hand-delivered to the Board office after June 30.

#### Section 6. Change of Ownership.

(a) If an Institutional Pharmacy changes ownership, it must obtain a new and separate registration from the Board. In the case of a corporation, limited liability company, or partnership holding an Institutional Pharmacy license, the Board shall be notified and a new license applied for any time the majority of stock in the corporation is sold or a majority of the partners of the partnership or members of the limited liability company change.

#### Section 7. Personnel.

(a) A ~~pharmacist, hereinafter referred to as the~~ Pharmacist-in-Charge (PIC), who is licensed to engage in the practice of pharmacy in Wyoming, shall direct each Institutional Pharmacy.

(b) The storage, compounding, repackaging, dispensing, and distribution of drugs by an Institutional Pharmacy shall be under the direction, supervision, and responsibility of the PIC. Depending upon the size and needs of the Institutional Facility, pharmacy service may be provided on a full or part-time basis.

(i) In hospital Institutional Facilities with fifty (50) or more acute care beds, a pharmacist shall be in the hospital Institutional Facility during the time the Institutional Pharmacy is open for pharmacy services, except in case of emergencies. Pharmacy services shall be provided for a minimum of forty (40) hours per week, unless an exception is made upon written request by the hospital Institutional Facility and with express permission of the Board.

(ii) In hospital Institutional Facilities with less than fifty (50) acute care beds, a pharmacist shall be in the hospital Institutional Facility during the time the Institutional Pharmacy is open for pharmacy services. Upon written request by the hospital Institutional Facility, and with the express permission of the Board, the services of a pharmacist may be on a part-time basis, according to the needs of the hospital Institutional Facility. The services of a pharmacist shall be required as follows:

(A) In hospital Institutional Facilities with one to twenty-five (1-25) acute care beds, a pharmacist shall be ~~available-on-site~~ a minimum of five (5) hours per week.

(B) In hospital Institutional Facilities with twenty-six to forty-nine (26-49) acute care beds, a pharmacist shall be ~~available-on-site~~ a minimum of twenty (20) hours per week.

(iii) In a non-hospital Institutional Facility, a pharmacist shall be available commensurate with the needs of the Institutional Facility. The hours shall be identified on the initial application and provided with each license renewal.

(c) Policies and procedures defining the ~~pharmaceutical-pharmacy~~ services to be provided and the responsibilities of the Institutional Pharmacy shall be established. Such policies and procedures shall be made available to the Board ~~and/or its authorized representative~~ upon request.

(d) The responsibilities of the PIC shall include, at a minimum, the following:

(i) Providing the appropriate level of pharmaceutical care services to patients of the Institutional Facility;

(ii) Ensuring that drugs and/or devices are dispensed and distributed safely and accurately ~~as prescribed~~;

(iii) Developing a system for ~~the compounding, sterility assurance, quality assurance, and quality control of sterile pharmaceuticals compounded within the Institutional Pharmacy~~; sterile compounding as required in Chapter 17

~~(iv) Developing a system to assure that all Institutional Pharmacy personnel responsible for compounding and/or supervising the compounding of sterile pharmaceuticals within the Institutional Pharmacy receive appropriate education, training, and competency evaluation;~~

(iv) Providing guidelines and approval of the procedure to assure that all pharmaceutical requirements are met when any part of preparing, sterilizing, and labeling of sterile pharmaceuticals is not performed under direct Institutional Pharmacy supervision;

(vi) Participating in the development of a Formulary for the Institutional Facility which is approved by the appropriate committee, including the medical staff of the Institutional Facility;

(vii) Developing a system to assure that drugs to be administered to inpatients are distributed pursuant to ~~an original or direct copy~~ of the practitioner's Medication Order;

(viii) Maintaining records of all transactions of the Institutional Pharmacy as may be required by applicable state and federal law, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials, ~~including pharmaceuticals and components used in the compounding of pharmaceuticals~~;

~~(ixviii)~~ Participating in those aspects of the Institutional Facility's patient care evaluation program that relate to pharmaceutical utilization and effectiveness as required in Chapter 9 for prospective and retrospective drug use review;

(ix) Assuring that a reasonable effort is made to obtain, record, and maintain patient medication records;

(xi) Assuring the legal operation of the Institutional Pharmacy, including meeting all inspection and other requirements of state and federal laws or rules governing the practice of pharmacy; and

(xii) Collaborating with the nursing staff and the medical staff to develop a list of standardized concentrations of medications that will be used in the Institutional Facility (e.g., therapeutic heparin intravenous infusions). Pediatric formulations will be considered as a separate listing from adult formations.

(e) The PIC shall be assisted by a sufficient number of additional licensed pharmacists as may be required to operate the Institutional Pharmacy competently, safely, and adequately to meet the needs of the patients ~~of the Institutional Facility~~. All pharmacists shall assist the PIC in meeting the responsibilities as outlined in ~~Subsection (c) of this Section and in ordering, accounting for, and other administrative duties regarding pharmaceutical products this Chapter~~

(f) Pharmacy technicians may assist the PIC, and pharmacists provided the ratio of pharmacy technicians, pharmacy technician specialists and pharmacy technicians-in-training to licensed pharmacists does not exceed ~~three to one (3:1)~~. ~~The duties of the pharmacy technicians or pharmacy technicians-in-training shall be established by the PIC and may not exceed the responsibilities as outlined in Wyoming Pharmacy Act, Rules and Regulations, Chapter 10~~the requirement of Chapter 10.

(g) The PIC may be assisted by secretarial and clerical assistance ~~as required to assist with record-keeping, report submission, and other administrative duties~~for non-pharmacy functions as defined in Chapter 10

#### Section 8. Environment.

(a) The Institutional Pharmacy shall be enclosed and lockable.

(b) The Institutional Pharmacy shall have adequate space necessary for the storage, compounding, labeling, dispensing, and sterile preparation of drugs prepared in the Institutional Pharmacy, depending on the size and scope of pharmaceutical services provided.

(c) A sink with hot and cold running water, exclusive of restroom facilities, shall be ~~available to all Institutional Pharmacy personnel and shall be maintained in a sanitary condition at all times~~in the Institutional Pharmacy.

(d) The Institutional Pharmacy shall be arranged in an orderly fashion and shall be kept clean. All required equipment shall be clean and in good operating condition.

(e) The Institutional Pharmacy shall be properly lighted and ventilated.

(f) The temperature of the Institutional Pharmacy shall be maintained within a range of 59 to 86 degrees Fahrenheit (15 to 30 degrees Centigrade). The temperature of the refrigerator shall be maintained within a range of 36 to 46 degrees Fahrenheit (2 to 8 degrees Centigrade) and the freezer shall be maintained within a range of -13 to +14 degrees Fahrenheit (-25 to -10 degrees Centigrade).

(g) The Institutional Pharmacy shall store ~~antiseptics, other~~ drugs for external use, ~~and disinfectants~~ separately from internal and injectable medications.

(h) If the Institutional Pharmacy compounds sterile pharmaceuticals, they shall be prepared in accordance ~~with Wyoming Pharmacy Act, Rules and Regulations,~~ Chapter 17.

#### Section 9. References.

Each Institutional Pharmacy shall maintain in its library at least one current reference (text or electronic format, including online access or PDA) from each category

listed below. ~~The Board reserves the right to accept new references in lieu of the following:~~

(a) Drug Monograph Reference:

~~(i) American Hospital Formulary Service<sup>®</sup>;~~

~~(ii) Drug Facts and Comparisons<sup>®</sup>;~~

~~(iii) Thomson's Micromedex<sup>®</sup>;~~

~~(iv) USPDI<sup>®</sup> Volume I, Drug Information for the Health Care Professional; or~~

~~(v) Drug Information Handbook (Lexi-Comp)~~

(b) Stability and Incompatibility Reference:

~~(i) Handbook on Injectable Drugs, Lawrence A. Trissel;~~

~~(ii) King Guide to Parenteral Admixtures; or~~

~~(iii) Thomson's Micromedex<sup>®</sup>~~

(c) Reference on Drug Availability and Identification:

~~(i) American Hospital Formulary Service<sup>®</sup>~~

~~(ii) Drug Facts and Comparisons<sup>®</sup>;~~

~~(iii) American Drug Index or~~

~~(iv) Drug Information Handbook (Lexi-Comp)~~

(d) Drug Interactions:

~~(i) American Hospital Formulary Service<sup>®</sup>;~~

~~(ii) Thomson's Micromedex<sup>®</sup>;~~

~~(iii) Drug Interactions Facts;~~

~~(iv) USPDI<sup>®</sup> Volume I, Drug Information for the Health Care Professional;~~

~~(v) Drug Information Handbook (Lexi-Comp); or~~

~~(vi) Drug Interactions Analysis and Management (DIAM)~~

(e) Reference on Pharmacology and Therapeutics:

~~(i) Conn's Current Therapy (Rakel and Bope);~~

~~(ii) Drug Information Handbook (Lexi-Comp);~~

~~(iii) Applied Therapeutics: The Clinical Use of Drugs (Koda-Kimble);~~

~~(iv) Pharmacotherapy (DiPiro); or~~

~~(v) Textbook of Therapeutics (Herfindal and Gourley).~~

(f) Current copies of the Wyoming Pharmacy Act and Rules and Regulations, and Wyoming Controlled Substances Act and Rules and Regulations, text or electronic format, and including internet access to the Board website.

(g) Wyoming State Board of Pharmacy Quarterly Newsletter, ~~maintained in a binder from the Board website.~~

#### Section 10. Equipment.

(a) Institutional pharmacies distributing Medication Orders shall have the following equipment:

(i) Refrigerator, including a system or device to monitor the temperature daily to ensure that proper storage requirements are met;

(ii) Computer and software appropriate for the Institutional Facility;  
~~and,~~

~~(iii) Facsimile capability located in the Institutional Pharmacy.~~

(b) If the Institutional Pharmacy compounds Medication Orders, that require the use of a balance, a Class A prescription balance or electronic scale with 10 mg sensitivity shall be available. Such balance or electronic scale shall be properly maintained by the PIC and may be inspected ~~at least every three (3) years~~ by the Board of Pharmacy.

(c) ~~If the An~~ Institutional Pharmacy that compounds sterile pharmaceuticals, ~~the Institutional Pharmacy~~ shall have equipment and supplies listed in ~~Wyoming Pharmacy Act, Rules and Regulations~~ Chapter 17.

#### Section 11. Security.

(a) No one shall be permitted in the Institutional Pharmacy unless the pharmacist is on duty, except as provided in this Chapter, ~~Section 12~~. If the pharmacist must leave the Institutional Pharmacy for an emergency or patient care duties, pharmacy technicians may remain to perform duties as authorized by the ~~Pharmacist-in-Charge (PIC)~~, provided that the pharmacist remains in the Institutional Facility.

(b) All Institutional Pharmacy areas shall be capable of being locked ~~by key or programmable lock, so as to prevent access by unauthorized personnel.~~ The ~~Director~~ PIC shall designate in writing, by title and specific area, those persons who shall have access to specific Institutional Pharmacy areas.

(c) Each pharmacist on duty shall be responsible for the security of the Institutional Pharmacy, ~~including provisions for adequate safeguards against theft or diversion of drugs including controlled substances and the records thereof.~~

(d) Pharmacists, technicians, clerical staff, and interns working in the Institutional Pharmacy shall wear identification badges, including name and position, whenever on duty.

(e) The PIC shall be responsible for policies and procedures for the safe distribution and control of prescription blanks ~~bearing identification of the Institutional Facility and tamper resistant paper.~~

#### Section 12. Absence of Pharmacist.

(a) General. During such times as Institutional Pharmacy services are not available on-site, arrangements shall be made in advance by the ~~Pharmacist-in-Charge (PIC)~~ for provision of drugs ~~to the medical staff and other authorized personnel of the Institutional Facility~~ by use of Floor Stock ADD, and/or access to the Institutional Pharmacy ~~under the standing order of the PIC.~~

(b) If Floor Stock is used, the following shall prevail:

(i) In the absence of a registered pharmacist, medication for inpatients shall be obtained from a locked cabinet(s) or other enclosure(s) located outside the Institutional Pharmacy to which only authorized nurses, ~~specifically authorized in writing by the PIC,~~ may obtain ~~access by key or combination, and which is sufficiently secure to deny access to unauthorized persons.~~

(ii) The PIC shall, ~~in conjunction with the appropriate committee, if any, of the Institutional facility,~~ develop inventory listings of those drugs to be included in such Floor Stock, and shall ensure that:

(A) Such drugs are available ~~therein~~, properly labeled;

(B) Such drugs are prepackaged in appropriately small amounts, unless commercially prepared packages, e.g. ophthalmics, otics, topicals, etc.

(C) All drugs ~~therein~~ shall be checked and replenished as needed;

(D) A record shall be ~~made on a copy of the physician's order or in a separate file or logbook located where the Floor Stock is~~ maintained, and shall include:

- (I) The date and time of removal of a drug;
- (II) The patient's name and location;
- (III) The name, strength, dosage form, and quantity of drug removed; and
- (IV) The printed name and signature of the nurse removing the drug.

~~(E) The nurse removing the drug shall leave a direct copy of the new physician's order for the medication with the above record or, if the copy of the physician's order is utilized in place of the log book, then this copy must be left in a designated area where Floor Stock is maintained; and~~

~~(F) Written policies and procedures are established to implement the requirements of this Paragraph.~~

(c) Access to the Institutional Pharmacy. Whenever any drug is not available from Floor Stock, ~~and such drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such drug may be obtained from the Institutional Pharmacy, in accordance with the requirements of this Paragraph. Only~~only supervisory or charge nurses may have access to the Institutional Pharmacy and may remove drugs ~~therefrom. Such nurses shall be designated in writing by the PIC.~~

(i) Removal of any drug from the Institutional Pharmacy by an authorized nurse must be recorded ~~on a suitable form at the Institutional Pharmacy~~ showing:

- (A) The date and time of the removal of the drug;
- (B) The patient's name and location;
- (C) The name, strength, dosage form, and quantity of drug removed; and
- (D) The printed name and signature of the nurse.

(ii) The nurse removing the drug shall leave a copy of the physician's order for the new drug with the above record.

(iii) The quantity of drug removed shall not exceed the amount of medication needed until the Institutional Pharmacy reopens. Drugs, that are usually dispensed as a unit of use package, such as ~~MDI~~inhalers, otics, topicals, insulin, and ophthalmics, are excluded.

(iv) A procedure shall be established to allow verification by the pharmacist of the drug removed (such as by leaving the identifying container or unit-dose sample of the drug with the records).

(d) If off-site pharmaceutical care is provided whenever an Institutional Pharmacy is closed, then the following requirements must be met:

(i) The Institutional Pharmacy shall have a pharmacist on duty at the Institutional Facility the minimum number of hours required in this Chapter, Section 7.

(ii) Any pharmacist providing off-site pharmaceutical care under this Section shall be licensed to practice pharmacy in Wyoming.

(iii) The Board shall be notified in writing by the Institutional Pharmacy of any arrangement whereby pharmaceutical care is provided off-site. This notification shall include the following:

(A) The name, address, and Wyoming license number of each pharmacist who will be providing this service.

(B) The name, address, and Wyoming license number of each pharmacy exchanging information with the Institutional Facility.

(C) Description of the ~~audio, video, and data~~communication link that will be utilized to exchange information between the Institutional Facility and the off-site pharmacist.

(D) Description of the scope of work of any pharmacist who provides off-site pharmaceutical care ~~under this Section~~.

(E) Description of patient information that is to be shared between the Institutional Facility and the off-site pharmacist. At minimum, the off-site pharmacist shall have access to the patient's medical record.

(iv) A pharmacist providing off-site pharmaceutical care may perform Remote Order Processing, if the pharmacist has access to appropriate patient information, including laboratory results.

(v) A pharmacist providing off-site pharmaceutical care shall provide the following services as a minimum:

(A) Review of any new Medication Order or change in existing Medication Order prior to administration by the nursing staff at the Institutional Facility.

~~(B) Review of all sterile compounding performed by nursing staff. Medications compounded during cardiopulmonary resuscitation or similar medical emergency or procedure shall be exempt from an off-site pharmacist review prior to administration. In all other circumstances, all sterile compounding is subject to review by the off-site pharmacist.~~

(CB) The off-site pharmacist shall communicate with the Institutional Pharmacy staff on a daily basis or, ~~if the Institutional Pharmacy is not~~

~~opened on a daily basis, then communication shall occur~~ whenever the Institutional Pharmacy is open for business.

Section 13. Emergency Outpatient Medication.

(a) Institutional Facilities, which provide for the administration and distribution of emergency pharmaceuticals to outpatients and/or inpatients being discharged during hours when normal community or outpatient Institutional pharmacy services are not available, may:

(i) Allow a designated nurse on the original written or electronic order of a practitioner to administer and distribute medications pursuant to the following requirements:

(A) A written or electronic order of a practitioner authorized to prescribe a drug is presented.

(B) The medication is prepackaged by a pharmacist or a technician under a pharmacist's supervision or is administered and distributed utilizing an automated drug dispensing device;

(C) The quantity of medication administered and distributed is limited to a seventy-two hour (72-hour) supply. Exceptions to the 72-hour supply include: oral pediatric antibiotic preparations ~~(PO)~~, otics, ophthalmics, topicals, ~~or metered dose~~ inhalers, nitroglycerin tablets, nasal sprays, manufacture packaged courses of therapy such as Z-paks or dosepaks; and

(D) The labeling of the administered and distributed medication includes:

Institutional Facility;

(I) Name, address, and telephone number of the

(II) Name of patient;

(III) Name of drug, strength, and quantity;

(IV) Directions for use;

(V) Date;

patient safety;

(VI) Accessory cautionary information, as required for

(VII) Name of practitioner; and

the medication.

(VIII) Initials of the nurse administering and distributing

(b) The order may be in the form of a separate written or electronic prescription or a prescription entered in the patient's medical record. A practitioner must sign the order. A copy of the prescription order must be readily available for review by the pharmacist.

(c) A record shall be maintained for ~~recording~~ all medications administered and distributed from the ~~Institutional Facility's~~ emergency room. The record shall include the following information:

- (i) Name of patient;
- (ii) Date of issuance;
- (iii) Name of drug;
- (iv) Patient's Institutional Facility record number; and
- (v) Initials of the nurse who administered and distributed the drug.

(d) The emergency room log for drugs administered and distributed after hours shall be ~~reviewed~~ available for review by the pharmacist ~~at least weekly~~. Inventory levels will be compared to drugs administered and distributed. Discrepancies will be reviewed with the emergency room nursing supervisor.

(e) Security of all drugs prepackaged must be maintained in a locked cabinet, ADD or storeroom location in the emergency room area to which only specifically authorized personnel shall have ~~a key or combination~~ access.

#### Section 14. Emergency Drug Carts (crash carts).

Emergency Drug Carts may be used by Institutional Facilities if:

(a) All drug kits are supplied, and kept up-to-date, under the supervision of a licensed pharmacist;

(b) A committee composed of the ~~Pharmacist-in-Charge~~ PIC, nursing staff, and medical staff of the Institutional Facility develops a standard drug inventory, including kind and quantity of each drug;

(c) All drug kits are equipped with a breakable seal, and are secure from access by unauthorized persons;

(d) A listing of all drugs, their respective strength, quantity, and location, shall be placed on the cart in a conspicuous location. If the pharmacy which services this Emergency Drug Cart is not located within the Institutional Facility, the name, address, and telephone number of the pharmacy shall be displayed in a conspicuous location;

(e) All drugs are properly labeled;

(f) The drugs are distributed, pursuant to a valid order, by authorized personnel, and the pharmacist is notified of entry into the Emergency Drug Cart; and

(g) The ~~pharmacist~~PIC, nursing staff, and medical staff develop and implement written policies and procedures for using Emergency Drug Carts.

#### Section 15. Automated Dispensing Devices.

(a) No drug shall be distributed or issued by the use of any automated dispensing device unless the device and method of operation ~~have been found by the Board to~~ ensure the purity, potency, and integrity of the drug, ~~and to~~ protect the drug from diversion, and provided that:

(i) The device shall be stocked with drugs only by or under the supervision of a pharmacist;

(ii) The device shall be used only for the furnishing of drugs for administration to patients of that Institutional Facility; and

(iii) At the time of removal of any drug from the device, it shall automatically make a written or electronic record to be retained by the pharmacist for at least one (1) year, indicating:

(A) The date of removal of the drug;

(B) The name, strength, dosage form, and quantity of drug removed;

(C) The name of the patient for whom the drug was ordered; and

(D) The name or identification code of the nurse removing the drug from the device.

#### Section 16. Parenteral Medications.

(a) The ~~Pharmacist-in-Charge (PIC)~~ shall be responsible for the preparation, sterilization, labeling, and dispensing of parenteral medications prepared within the Institutional Facility and shall participate in the education and training, including the provision of appropriate incompatibility information, of all personnel involved in the preparation of parenteral medications.

(b) If intravenous admixtures are prepared within the Institutional Facility, the Institutional Pharmacy shall have adequate equipment, personnel, and space for such preparation. The compounding and labeling of intravenous admixtures, including all total parenteral nutrition, shall be performed by, or under, the direct supervision of a pharmacist; however, if twenty-four hour (24-hour) pharmacy service is not provided at the Institutional Facility, the PIC shall establish written policies and procedures to be

followed in the preparation of intravenous admixtures when the Institutional Pharmacy is closed or in emergency situations.

(c) All admixtures shall be labeled with a distinctive supplementary label, indicating the name and amount of drug added, date and time of addition, ~~expiration~~ beyond use date, and rate of administration, and the name or identification code of the person adding the drug.

(d) The PIC shall be responsible for removing concentrated electrolytes (including, but not limited to, potassium chloride, potassium phosphate, sodium chloride greater than 0.9%) from patient care areas and limiting their access to pharmacists, ~~if at all possible~~. If twenty-four hour (24-hour) on-call status for pharmacists is not available, the Institutional Facility must utilize the most trained professional available to process concentrated electrolytes. Training in the safe use of concentrated electrolytes should be conducted by the Institutional Pharmacy for non-pharmacist staff with access to concentrated electrolytes. Evidence of training will be documented and retrievable, and the Institutional Facility will have policies and procedures that detail this process. Premixed large volume intravenous solutions containing electrolytes and premixed potassium bolus doses will be used whenever possible.

#### Section 17. Practitioner's Orders.

(a) All orders for drugs shall be transmitted to the Institutional Pharmacy by electronic order entry, or by means of an order format, that is capable of producing a direct copy or an electronically reproduced facsimile. A pharmacist shall review the practitioner's order before the initial dose of medication is dispensed provided that, in emergencies or when pharmacy services are not available, the Medication Order shall be reviewed by the pharmacist as soon ~~thereafter~~ as possible. Verification of the accuracy of the medication dispensed and of any transcriptions made of that order shall be documented by the initials of the pharmacist so certifying.

(b) Orders for drugs for use by inpatients shall, at a minimum, contain the patient name and location, drug name, strength, directions for use, date, and practitioner's written or electronic signature or written or electronic signature of the practitioner's agent, ~~either written or electronic signatures~~.

(c) Orders for outpatient dispensing shall meet the requirements ~~of Wyoming Pharmacy Act Rules and Regulations, Chapter 2, Section 19.~~

#### Section 18. Dispensing.

(a) If unit-dose packaging is used, medication for each patient, when not supplied by an automated dispensing device, shall be distributed and stored in separate trays, drawers, compartments, or containers assigned to that patient and bearing the patient's name and location.

#### Section 19. Investigational Drugs and Protocols.

(a) All Investigational Drugs shall be stored in the Institutional Pharmacy and distributed only from the Institutional Pharmacy. Basic information concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions, and symptoms of toxicity of such drugs shall be available in the Institutional Pharmacy. Investigational Drugs shall be properly labeled and shall be administered only under the personal and direct supervision of the principal physician-investigator or his or her authorized clinician(s) with prior approval of the appropriate committee(s) of the Institutional Facility and with verifications that the patient (or his or her legal designee) has signed the informed consent form.

(b) A copy of all Investigational Drug protocols shall be on file in the Institutional Pharmacy.

#### Section 20. Inspections.

The ~~Pharmacist-in-Charge~~PIC or his/her designee shall document on at least a quarterly basis an inspection of all drug storage areas in the Institutional Facility. Records of such inspections shall be dated, signed, and maintained so as to be readily retrievable at the Institutional Pharmacy for at least two (2) years. These inspections must ascertain that:

(a) Test reagents, germicides, and disinfectants are stored separately from medications;

(b) External medications are stored separately from internal medications;

(c) ~~Thermolabile~~dDrugs are stored at the proper temperature;

(d) There are no outdated or deteriorated drugs;

(e) All drugs are properly labeled;

(f) Emergency Drug Carts (crash carts) are adequate and in proper supply;

(g) Medication storage areas are locked when not in use, and only authorized individuals have access to these areas;

(h) Distribution and administration of controlled substances are properly and adequately documented;

(i) Telephone numbers of the regional poison control center and other emergency assistance organizations are posted;

(j) Metric-apothecaries' weight and measure conversion tables and charts are available; and

(k) Adequate pharmaceutical references ~~texts~~s are available at these areas.

#### Section 21. Medications brought into the institution by patients.

Whenever patients bring drugs into an Institutional Facility, such drugs shall not be administered unless they can be precisely identified; administration shall be pursuant to a practitioner's order. If such drugs are not to be administered, they shall be delivered to the Institutional Pharmacy, packaged, sealed, and returned to an adult (18 years or older) member of the patient's immediate family (spouse, unless legally separated; adult child; parent; grandparent; adult brother or sister; adult grandchild), the patient's legal guardian or conservator, or the patient's designated agent, or they shall be stored and returned to the patient upon discharge, only after advice is provided regarding continuing the returned medication.

## Section 22. Controlled Drugs.

(a) All controlled substances issued by the Institutional Pharmacy to any Institutional Facility department, excluding those controlled substances for which the dispensing and record-keeping are maintained utilizing an automated drug dispensing device, shall be labeled and accompanied with control sheets (proof of use forms) that provide space for recording:

(i) The drug name, strength, and dosage form;

(ii) The date and time of administration;

(iii) The quantity administered;

(iv) Name of patient;

(v) The signature of the nurse who administered the medication, when issued to nursing units; and

(vi) The signature of the practitioner who administered the medication and a witness, when issued to surgery or other specialized areas such as endoscopy labs.

(b) Such drugs shall be limited both in kind and quantity commensurate with the needs of the area to which they are distributed; the Institutional Pharmacy shall maintain a record of such distribution. The ~~Pharmacist-in-Charge (PIC)~~, in consultation with the Director of Nursing or other appropriate hospital staff, shall establish written requirements for the frequency of controlled substance inventories in drug storage areas outside of the Institutional Pharmacy.

(c) All control sheets must be returned to the Institutional Pharmacy upon completion. The pharmacist shall verify the returned sheets for accountability and control prior to drug reissuance. These control sheets, as well as any records generated, must be maintained so as to be readily retrievable at the Institutional Pharmacy for two (2) years. Records of controlled substance, which are dispensed utilizing an automated ~~drug~~ dispensing device, shall be maintained at the Institutional Pharmacy for two (2) years.

(d) All controlled substances that must be wasted shall be destroyed by a method approved by the PIC. Documentation of all destruction must occur on the control sheet, in the patient's medical record, or utilizing the format available with an automated drug dispensing device, and be signed (written or electronically) by the nurse/physician destroying and one witness who observed the destruction.

(e) Transdermal patches containing controlled substances shall be handled in the following manner:

(i) The PIC, in coordination with the Director of Nursing, will implement a policy requiring all nursing personnel applying a transdermal patch containing a controlled substance to write the date on the patch when it is first applied to a patient.

(ii) All used transdermal patches containing a controlled substance shall be destroyed in front of a witness, and documented ~~in a manner similar to Section 22(d). The destruction will be done in a manner that does not subject the health care worker to exposure to the controlled substance and that makes the patch irretrievable (e.g., using gloves to cut the patch, placing it in a sharps container, cleaning the scissors with alcohol, etc.)~~ currently recommended by the FDA.