Manual of Standards for the Licensure of Hospital Facilities

Proposed Draft of Standards for Pharmaceutical Services

New Jersey State Department of Health

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Adopted:
Effective:

10.0 Pharmaceutical Services

10.1 Pharmaceutical services shall be available at all times on the premises. The pharmacy shall be licensed by, and operated in accordance with, the New Jersey State Board of Pharmacy and shall possess a current Drug Enforcement Administration registration and a Controlled Dangerous Substance registration from the Department.

10.2 The facility shall maintain the organization, management, and operation of the pharmaceutical service in accordance with a written organizational plan which shall describe the responsibility, authority, and accountability relationships of personnel, the functional structure of the service, and the relationship of the pharmaceutical service to other services.

10.3 A multidisciplinary Pharmacy and Therapeutics Committee shall be appointed by and accountable to the governing authority. The committee shall meet at least two times a year and shall document its activities, findings, and recommendations, as specified in the New Jersey State Board of Pharmacy Rules, N.J.A.C. 13:39-7.15. The committee shall be responsible for, but not limited to, the following:

10.3.1 With the director of the pharmaceutical service, development of policies and procedures, approved by the governing authority, and documentation of their annual review. These policies and procedures shall govern evaluation, selection, obtaining, dispensing, storage, distribution, administration, use, control, accountability, and safe practices pertaining to all drugs used in the treatment of patients;

10.3.2 Development and annual review and approval of a current formulary of drugs for use in the facility. The formulary shall be available to at least nursing personnel and the medical staff;

10.3.3 Provision of consultation and in-service education to at least the medical staff, nursing personnel, and the director of the pharmaceutical service concerning the choice of drugs used in the facility;

10.3.4 Review of the reports of the director of the pharmaceutical service; and

10.3.5 Submission of a report to the governing authority and the medical staff in accordance with the facility's policies and procedures.

10.4 Policies and procedures shall ensure that the right drug is administered to the right patient in the right amounts and at the right times. Policies and procedures shall include, but not be limited to, the following:

10.4.1 Specification of a unit dose drug distribution system. (Note: All facilities shall have a unit dose drug distribution system within

two years of the adoption of these standards.) Policies and procedures for the unit dose drug distribution system shall include, but not be limited to, the following:

10.4.1.1 Each patient shall have his or her own medications, labeled with his or her name and room number. Each unit dose of medication shall be labeled to include the generic name, trade name (if appropriate), and strength of the drug, dose, manufacturer's name and expiration date, and lot number or reference code. Cautionary instructions shall appear on the patient's medication administration record (MAR);

10.4.1.2 Delivery and exchange of patient medications shall occur as scheduled. Patient medications shall be exchanged at least once a day. No more than a 24-hour supply of doses shall be delivered to or available in the patient care area at any time; and

10.4.1.3 There shall be provisions for noting additional information, such as special times or routes of administration and special precautions;

10.4.2 Methods for procuring drugs on a routine basis, in emergencies, and in the event of disaster;

10.4.3 Policies and procedures, approved by the Pharmacy and Therapeutics Committee in accordance with the standards in this manual, regarding emergency kits and emergency carts, including the following:

10.4.3.1 Approval of their locations and contents;

10.4.3.2 Provision for pediatric doses in areas of the facility where pediatric emergencies may occur, including, but not limited to, the pediatric service, the emergency room, and the operating room;

10.4.3.3 Determination of the frequency of checking contents, including expiration dates;

10.4.3.4 Approval of the assignment of responsibility for checking contents; and

10.4.3.5 Ensuring that emergency kits are secure but are not kept under lock and key;

10.4.4 A policy and procedures, approved by the medical staff of the facility, to ensure that all medications are ordered in writing, that the written order specifies the name of the drug, dose, frequency, and route of administration, that the order is signed and dated by the prescriber, and that all medications are administered by licensed or authorized personnel, in accordance with the laws of the State of New Jersey;

10.4.5 Policies and procedures regarding the clarification of orders, including a definition of "clarification;"

10.4.6 A policy that only a pharmacist, or pharmacy personnel other than a pharmacist and under the direction and supervision of a pharmacist, shall compound, prepare, label, or dispense drugs, make labeling changes, or transfer drugs to different containers. Pharmacy personnel other than the pharmacist while performing these functions shall be within view of the pharmacist, who shall check prior to and upon completion of the person's performance;

10.4.7 A definition and policies and procedures for doses of drugs that may be calculated and administered by licensed practical nurses, according to directions on an auxiliary label supplied by the pharmaceutical service. A licensed practical nurse may:

10.4.7.1 Administer drugs orally, subcutaneously, and intramuscularly, according to the unit dosage labeling;

10.4.7.2 Administer drugs that require uncomplicated calculations; and

10.4.7.3 Administer fractional doses that have been precalculated when the dose to be administered is noted on the vial or container;

10.4.8 Policies and procedures for drug administration, including, but not limited to, the following:

10.4.8.1 Specification of additional information and training required for personnel who administer toxic or dangerous drugs (such as chemotherapeutic agents, investigational drugs, or drugs administered intravenously or by clysis), or who administer approved drugs for unapproved uses, new dosage forms, or any unusual or new drug requiring ancillary precautions; and

10.4.8.2 Establishment of the times for administration of drugs prescribed, for example, q.d., b.i.d., t.i.d., and q.i.d. (one, two, three, and four times a day);

10.4.9 If facility policy permits, policies and procedures regarding self-administration of drugs, including, but not limited to, the following:

10.4.9.1 A requirement that self-administration be permitted only upon a written order of the prescriber;

10.4.9.2 Storage of drugs;

10.4.9.3 Labeling of drugs;

10.4.9.4 Methods for documentation in the patient's medical record of self-administered drugs;

10.4.9.5 Assistance in training and education of patients in self-administration and the safe use of drugs; and

10.4.9.6 Establishment of precautions and policies and procedures so that patients do not share their drugs or take the drugs of another patient;

10.4.10 If facility policy permits, policies and procedures regarding the previously acquired drugs of patients. A written order signed by the prescriber shall be required for the administration of such drugs. The drugs shall be given to the pharmacist for identification of contents and dispensing origin, and for relabeling for use in the facility;

10.4.10.1 Policies and procedures regarding drugs brought into the facility by a patient and not authorized in writing by the prescriber;

10.4.11 If facility policy permits, procedures regarding release of drugs to patients upon discharge. Drugs shall be released only on the written order of the prescriber, and shall be relabeled and repackaged by the pharmacist, in accordance with the New Jersey State Board of Pharmacy Rules. Released drugs shall be documented in the patient's medical record, in accordance with facility policy;

10.4.12 Policies and procedures for documenting and reviewing adverse drug reactions, medication errors, and drug defects, including, but not limited to, the following:

10.4.12.1 Adverse drug reactions and/or allergies shall be documented in the patient's medical record and on its outside front cover; and

10.4.12.2 Medication errors and adverse drug reactions shall be orally reported immediately to the charge nurse and the prescriber. By the end of the shift, the director of the pharmaceutical service, the nursing supervisor, and the director of the nursing service shall be notified, an entry made in the patient's medical record, and an incident report completed. As determined by facility policy, incident reports shall be reviewed by the Pharmacy and Therapeutics Committee or by another specified committee, or its equivalent, with the participation of the director of the pharmaceutical service or his or her designee;

10.4.13 Policies and procedures for unused drugs, including, but not limited to, the following:

10.4.13.1 Drugs in opened containers, in containers with broken seals, or in containers missing drug source and exact identification (e.g., control lot number) shall be returned to the pharmacy to be relabeled, replaced, disposed of, or immediately destroyed in accordance with the New Jersey State Board of Pharmacy Rules;

10.4.13.2 Drugs in unopened containers and in unit dose packages which have seal and exact identification intact may be redispensed; and

10.4.13.3 In all areas of the facility where drugs are dispensed, administered or stored, a record shall be made of any controlled

substances that are wasted, either by accident or intent. This record shall be signed by the person responsible, any witnesses, and by the nursing supervisor if nursing personnel wasted the substance, and returned to the pharmacy with a written explanation;

10.4.14 Policies and procedures concerning drug repackaging;

10.4.15 Policies and procedures for ensuring the immediate delivery of stat. doses. Stat. (statim) shall mean immediately;

10.4.16 Policies and procedures to ensure the provision of pharmaceutical services at all times. Drugs shall be removed from the pharmacy in accordance with the New Jersey State Board of Pharmacy Rules;

10.4.17 If facility policy permits, policies and procedures for the use of floor stock drugs. A list shall be maintained of floor stock drugs and their amounts stored throughout the facility;

10.4.18 Policies and procedures regarding outpatient prescriptions, including, but not limited to, prescription labeling, profiles, and record storage, in accordance with the New Jersey State Board of Pharmacy Rules;

10.4.19 Policies and procedures for stop orders, including, but not limited to, the following:

10.4.19.1 The length of time orders may be in effect;

10.4.19.2 A policy for control of drugs, including intravenous infusion solutions, not specifically limited as to duration of use or number of doses when ordered;

10.4.19.3 Automatic stoppage of a patient's drugs as of the time of day specified by facility policy, on the day the patient undergoes surgery, unless otherwise specified by the prescriber; and

10.4.19.4 Notification of the prescriber by specified personnel and within a specified period of time prior to the expiration of a drug order to ensure that the drug is discontinued if no specific renewal is ordered. The prescriber shall rewrite the specific drug orders for postoperative medication, including name of the drug, dose, frequency, and route of administration;

10.4.20 Policies and procedures to control the administration of toxic and dangerous drugs, including narcotics, sedatives, anticoagulants, antibiotics, oxytocics, corticosteroid products, and intravenous infusion solutions;

10.4.21 Policies and procedures for the use of parenterals, including, but not limited to, the following:

10.4.21.1 Safety measures for the preparation, sterilization, and admixture of intravenous infusion solutions. These shall be prepared only by a pharmacist or by pharmacy personnel under the direction and supervision of a pharmacist, and under a laminar air flow hood except in patient care areas specified by facility policy. Pharmacy personnel other than the pharmacist while performing these functions shall be within view of the pharmacist, who shall check prior to and upon completion of the person's performance;

10.4.21.2 Documented quality control measures for laminar air flow hoods shall include cleaning of the equipment used on each shift, microbiological monitoring as required by the Infection Control Committee, or its equivalent, and checks at least every 12 months for operational efficiency;

10.4.21.3 The facility shall have a centralized intravenous infusion admixture service operated by the pharmaceutical service. If the preparation, sterilization, and labeling of parenteral medications and solutions are performed in the exempt areas within the facility, as specified by facility policy, but not under direct supervision of a pharmacist, the director of the pharmaceutical service shall be responsible for providing written guidelines and for approving the procedures; and

10.4.21.4 Labeling of intravenous infusion solutions, such that a supplementary label is affixed to the container of any intravenous infusion solution to which drugs are added. The label shall include the patient's name and location; the name of the solution; the name and amount of the drug(s) added; the date and time of the addition; the date, time, and rate of administration; the name or initials of the pharmacy personnel who prepared the admixture; the name, initials, or identifying code of the pharmacist who prepared or supervised preparation of the admixture; supplemental instructions, including storage requirements; and the expiration date of the solution;

10.4.22 If facility policy permits, policies and procedures for drug research and the use of investigational drugs, in accordance with Federal and State regulations, including, but not limited to, the following:

10.4.22.1 The use, storage, control, and distribution of investigational drugs. The pharmacy shall be accountable for drug storage, control, and distribution;

10.4.22.2 Authorization of personnel who shall administer investigational drugs;

10.4.22.3 Procedures for notification of personnel who administer investigational drugs, or who have patients receiving them, that the drugs are approved for investigational purposes;

10.4.22.4 Procedures for the provision of information to personnel concerning investigational drugs, including their side effects, actions, uses, and symptoms of toxicity;

10.4.22.5 Establishment of a central location, such as the pharmacy, for the maintenance of information on investigational drugs; and

10.4.22.6 Authorization of personnel who shall have access to information concerning investigational drugs;

10.4.23 If drug dispensing devices are used in the facility, policies and procedures for their limited and restricted use, in accordance with the New Jersey State Board of Pharmacy Rules;

10.4.24 Policies and procedures regarding the purchase, storage, safeguarding, accountability, use, and disposition of drugs and devices, in accordance with the New Jersey State Board of Pharmacy Rules and the Controlled Dangerous Substances Acts and amendments thereto;

10.4.25 Needles and syringes are procured, stored, used, and disposed of in accordance with the New Jersey State Board of Pharmacy Rules and the laws of the State of New Jersey and amendments thereto. A verifiable record system shall be maintained of the purchase, storage, and distribution of needles and syringes. There shall be a system of accountability for the disposal of used needles and syringes which shall not necessitate the counting of individual needles and syringes after they are placed in the container for disposal;

10.4.26 Policies and procedures regarding the control of drugs subject to the Controlled Dangerous Substances Acts and amendments thereto, in compliance with the New Jersey State Board of Pharmacy Rules and all other Federal and State laws and regulations concerning procurement, storage, dispensing, administration, and disposition. Such policies and procedures shall include, but not be limited to, the following:

10.4.26.1 Provision for a verifiable record system for controlled substances;

10.4.26.2 Policies and procedures to be followed in the event that the inventories of controlled substances cannot be verified or drugs are lost, contaminated, wasted, or destroyed. A report of any such incident shall be written and signed by the licensed nurses involved, any witnesses present, and the nursing supervisor, and copies shall be sent for review to the director of the nursing service and the director of the pharmaceutical service;

10.4.26.3 In all areas of the facility where drugs are dispensed, administered, or stored, procedures for disposition of partial doses of controlled substances. A second person shall witness the disposition; and

10.4.26.4 A declining inventory shall be maintained by the anesthesia service of all controlled substances. This inventory shall be checked by actual count by two persons at least once every 24 hours. The following shall be recorded: name of the patient receiving the drug, prescriber's name, name and strength of the

drug, date received from the pharmacy, date of administration, dosage administered, route of administration, signature of the person administering the drug, amount of drug remaining, amount of drug destroyed or wasted (when appropriate), and the signature of the person witnessing the destruction or wasting of the drug (when appropriate). The anesthesia service shall return a record of the inventory to the pharmacy when requesting new supplies;

10.4.26.4.1 The anesthesia service shall maintain a system of accountability for all other (noncontrolled) drugs;

10.4.27 Policies and procedures to ensure that all drugs are kept in locked storage areas, except intravenous infusion solutions which shall be stored according to a system of accountability, as specified in the facility's policies and procedures;

10.4.28 Policies and procedures regarding the provision of current pharmaceutical reference materials and sources of information, approved by the Pharmacy and Therapeutics Committee, to at least pharmacy and nursing personnel and medical staff. These shall include pharmaceutical compendia and periodicals, and current editions of texts and reference books;

10.4.28.1 The Pharmacy and Therapeutics Committee shall approve the minimal reference materials to be retained at the drug distribution stations, those to be kept in the pharmacy and made available to at least nursing personnel and the medical staff, and methods for communicating product information to at least nursing personnel and the medical staff;

10.4.28.2 Information on drugs, their indications, contraindications, actions, reactions, interactions, cautions, precautions, toxicity, and dosage, shall be provided in the pharmacy and at each drug distribution station. Authoritative, current antidote information and the telephone number of the regional poison control center shall also be provided in the pharmacy and at each drug distribution station; and

10.4.28.3 Current Federal and State drug law information shall be available to the pharmaceutical service;

10.4.29 A list of abbreviations, metric apothecary conversion charts, and chemical symbols, approved by the medical staff, to be kept in each drug distribution station; and

10.4.30 Policies and procedures concerning the activities of medical and pharmaceutical sales representatives in the facility. Drug samples shall not be distributed or used in the facility.

10.5 If the facility operates a decentralized pharmaceutical service, a pharmacist shall be assigned to each satellite pharmacy or separate organizational element during its hours of operation.

10.6 A pharmacist shall be appointed as director of the pharmaceutical service. He or she shall be responsible for the direction, provision, and quality of the pharmaceutical services provided. He or she shall be responsible for, but not limited to, the following:

10.6.1 Together with the Pharmacy and Therapeutics Committee, developing and maintaining written objectives, standards of practice, policies, a procedure manual, and an organizational plan for the pharmaceutical service;

10.6.2 Implementing and reviewing annually all pharmaceutical policies and procedures, which shall be kept current;

10.6.3 Participating in planning and budgeting for the pharmaceutical service;

10.6.4 Coordinating and integrating the pharmaceutical service with other patient care services;

10.6.5 Participating or ensuring representation of the pharmaceutical service in committees of the facility, or their equivalents, including, but not limited to, committees on patient care policies, infection control, utilization review, antibiotic and other drug utilization review, and evaluation, at least on a consultative basis;

10.6.6 Maintaining working relationships with administration through conferences, written memoranda, and other methods of exchanging information;

10.6.7 Developing and maintaining lines of authority, work schedules, and written job descriptions for pharmacy personnel and the use of pharmacy resources;

10.6.8 Recommending the number and levels of pharmacy personnel to be employed;

10.6.9 Assisting in selecting for employment, assigning duties to, supervising, and evaluating all pharmacy personnel;

10.6.10 Providing a report at least two times a year to the Pharmacy and Therapeutics Committee of the facility's pharmaceutical service, an analysis of any incident reports relating to drug therapy, and results of the monthly inspection of all areas in the facility where drugs are dispensed, administered, or stored;

10.6.11 Providing for the generic listing of drugs;

10.6.12 Maintaining a means of identifying the signatures of all prescribers authorized to use the pharmaceutical service for prescriptions, as well as a listing of their Drug Enforcement Administration numbers;

10.6.13 Maintaining records of the transactions of the pharmaceutical service, as required by Federal, State, and local laws, to ensure control and accountability of all drugs. This shall include a system of controls and records for the requisitioning and dispensing of pharmaceutical supplies to all services of the facility; and

10.6.14 Assisting in the development of, and participating in, staff orientation and educational programs for the facility and the pharmaceutical service, and documenting these activities. Orientation and education shall include, but not be limited to:

10.6.14.1 Providing pharmaceutical guidance to other personnel providing patient care;

10.6.14.2 Instructing facility personnel in continuing education programs concerning the handling and storage of drugs; and

10.6.14.3 Participating in the education of students of the health care professions, if any.

10.7 The director of the pharmaceutical service shall appoint a pharmacist who shall be designated in writing to act in the absence of the director.

10.8 If the facility appoints an assistant director of the pharmaceutical service, he or she shall be responsible for, but not limited to, the following:

10.8.1 Supervising the daily functions of the pharmaceutical service;

10.8.2 Implementing all policies and procedures;

10.8.3 Assisting the director of the pharmaceutical service;

10.8.4 Representing the director of the pharmaceutical service at meetings of the facility's committees, or their equivalents;

10.8.5 Implementing work schedules for supervising and evaluating pharmacy personnel; and

10.8.6 Assisting the director of the pharmaceutical service in determining staff education needs and in the planning, organization, and teaching of staff orientation and staff education programs.

10.9 If the facility appoints staff pharmacists and/or clinical pharmacists, they shall be responsible for, but not limited to, the following. In the event that the facility does not appoint staff pharmacists and/or clinical pharmacists, the director of the pharmaceutical service shall ensure that these functions are performed.

10.9.1 Supervising drug storage and preparation areas within the pharmacy and throughout the facility. A pharmacist shall inspect at least monthly all areas in the facility where drugs are dispensed,

administered, or stored, including, but not limited to, central supply, operating rooms, labor and delivery rooms, drug distribution stations, medication carts, laboratories, emergency service, intensive care service, coronary care service, anesthesia service, and radiological service, and shall maintain a record of such inspections;

10.9.2 Clarifying and processing new and refill medication orders. This shall include reviewing medication orders and the patient's drug regimen (medication profile) prior to the dispensing of an initial dose of medication. Any potential allergies, interactions, interferences, incompatibilities or other irregularities shall be reported immediately to the prescriber, with notification through the nurse in charge to the nurse responsible for administering the drug;

10.9.3 Conducting and supervising the intravenous additive program;

10.9.4 Compounding drugs;

10.9.5 Supervising pharmacy personnel;

10.9.6 Providing education, training, and consultation to patients and to personnel of the facility;

10.9.7 Participating in antibiotic and other drug utilization review, including consultation on the monitoring of drug therapies, monitoring cultures and sensitivities for appropriate antibiotic utilization, and participation in formulary review;

10.9.8 Participating in committees, or their equivalents, including, but not limited to, those on infection control and pharmacy and therapeutics;

10.9.9 Monitoring patients, drug regimens, use of antibiotics, and patient care, including patients receiving ambulatory care services and patients receiving total parenteral nutrition;

10.9.10 Establishing procedures to ensure that patients are instructed concerning medication to be taken following discharge, if so requested by the prescriber or directed by the medical staff;

10.9.11 Making available to facility personnel current drug information resources, including information on investigational drugs in use in the facility; and

10.9.12 Ensuring that:

10.9.12.1 All medications, except intravenous infusion solutions, are kept in locked storage areas. Medication storage and preparation areas shall be kept locked when not in use;

10.9.12.2 Drugs requiring refrigeration are kept in a separate, locked box in the refrigerator, in a locked refrigerator, or in a refrigerator in

the locked medication room, at or near the drug distribution station. All substances in Schedule II of the Controlled Dangerous Substances Acts and amendments thereto shall be stored in a separate, locked, permanently affixed compartment within the locked medication cabinet, medication room, refrigerator, or mobile medication cart. The key to the separate, locked compartment for Schedule II drugs shall not be the same key that is used to gain access to storage areas for other drugs. The refrigerator shall have a thermometer to indicate temperature in conformance with U.S.P. (United States Pharmacopoeia) requirements; and

10.9.12.3 Drugs for external use are kept separate from drugs for internal use.

10.10 If the facility provides pharmacy personnel, other than pharmacists, who assist the registered pharmacists in preparing, compounding, distributing, and dispensing drugs, their functions shall be specified in written job descriptions.

10.11 Nursing Care Services Related to Pharmaceutical Services. Nursing personnel shall be responsible for, but not limited to, ensuring the following:

10.11.1 All medications administered are prescribed in writing and the order signed and dated by the prescriber. Medications shall be administered in accordance with all Federal and State laws and regulations by the following licensed or authorized nursing personnel:

10.11.1.1 Registered professional nurses;

10.11.1.2 Licensed practical nurses who have undergone formal training in drug administration in programs approved by the New Jersey State Board of Nursing;

10.11.1.3 Nurses with valid "permission to work" letters issued by the New Jersey State Board of Nursing (N.J.A.C. 13:37-3.5; 13:37-4.6; 13:37-10.4; and 13:37-11.5). This excludes foreign exchange visitor nurses;

10.11.1.4 Unlicensed nurses who are graduates of domestically accredited nursing schools, pending the results of the first two consecutive licensing examinations immediately following the completion of their nursing program (N.J.A.C. 13:37-2.7 and 13:37-9.5); and

10.11.1.5 Student nurses in a school of nursing approved by the New Jersey State Board of Nursing under the direct supervision and within immediate view of a registered professional nurse;

10.11.2 Licensed practical nurses may calculate and administer drug doses, as defined by facility policy and in accordance with 10.4.7 - 10.4.7.3;

10.11.3 Verbal and telephone orders are accepted only by personnel designated according to title or category by the medical staff, are written into the patient's medical record by the person accepting them, and are authenticated by the prescriber within 24 hours;

10.11.4 Measurement of vital signs, as defined in the facility's policies and procedures, prior to drug administration;

10.11.5 Drugs are not prepoured. Drugs shall be administered promptly (immediately) after the dose has been prepared, and by the individual who prepared the dose, except when a unit dose drug distribution system is used;

10.11.6 If facility policy permits, policies and procedures are implemented regarding self-administration of drugs;

10.11.7 Drugs for individual patients are kept in the original prescription containers, and there is no transferring of drugs between containers;

10.11.8 The patient is identified prior to drug administration. Drugs prescribed for one patient shall not be administered to another patient;

10.11.9 A record of drugs administered is maintained. After each drug administration, the following shall be documented by the nurse who administers the drug: name and strength of the drug, date and time of administration, dosage administered, method of administration, and signature;

10.11.10 Drug errors and adverse drug reactions are orally reported immediately to the charge nurse and the prescriber. By the end of the shift, the director of the pharmaceutical service, the nursing supervisor, and the director of the nursing service shall be notified, an entry made in the patient's medical record, and an incident report completed. As determined by facility policy, incident reports shall be reviewed by the Pharmacy and Therapeutics Committee or by another specified committee, or its equivalent, with the participation of the director of the pharmaceutical service or his or her designee;

10.11.11 Discontinued, unused, expired (outdated), recalled, visibly deteriorated, or unlabeled drugs and intravenous infusion solutions, and containers with worn, illegible, damaged, incomplete, or missing labels, are returned to the pharmacy. Drug product defects shall be reported in accordance with the ASHP-USP-FDA (American Society of Hospital Pharmacists, United States Pharmacopoeia, Food and Drug Administration) Drug Product Defect Reporting System;

10.11.12 All drugs are kept in locked storage areas, except intravenous infusion solutions which shall be stored according to a system of accountability, as specified in the facility's policies and procedures. Drug storage and preparation areas shall be kept locked

when not in use. Drugs requiring refrigeration are kept in a separate, locked box in the refrigerator, in a locked refrigerator, or in a refrigerator in the locked medication room. The refrigerator shall have a thermometer to indicate temperature in conformance with U.S.P. (United States Pharmacopoeia) requirements;

10.11.13 Drugs for external use are kept separate from drugs for internal use;

10.11.14 Needles and syringes are procured, stored, used, and disposed of in accordance with the New Jersey State Board of Pharmacy Rules and the laws of the State of New Jersey and amendments thereto. There shall be a system of accountability for the disposal of used needles and syringes which shall not necessitate the counting of individual needles and syringes after they are placed in the container for disposal; and

10.11.15 Controlled substances are stored and verified according to the following:

10.11.15.1 Substances in Schedules III and IV of the Controlled Dangerous Substances Acts and amendments thereto shall be stored under lock and key. Substances in Schedule II of the Controlled Dangerous Substances Acts and amendments thereto shall be stored in a separate, locked, permanently affixed compartment within the locked medication cabinet, medication room, refrigerator, or mobile medication cart. The key to the separate, locked compartment for Schedule II drugs shall not be the same key that is used to gain access to storage areas for other drugs (except that substances in Schedule II in a unit dose drug distribution system shall be kept under double lock and key, but may be stored with other controlled substances);

10.11.15.2 The keys for the storage compartments for controlled substances in Schedules II, III, and IV shall be kept on a person who meets the criteria listed in 10.11.1.1 - 10.11.1.5;

10.11.15.3 A declining inventory of all substances in Schedule II of the Controlled Dangerous Substances Acts and amendments thereto retained at each drug distribution station or wherever these drugs are maintained shall be made at the termination of each tour of duty. This record shall be signed by both the outgoing and incoming nurses who shall meet the criteria listed in 10.11.1.1-10.11.1.5. The following shall be recorded: name of the patient receiving the drug, prescriber's name, name and strength of the drug, date received from the pharmacy, date of administration, dosage administered, method of administration, signature of the licensed nurse administering the drug, amount of drug remaining, amount of drug destroyed or wasted (when appropriate), and the signature of the nurse witnessing the destruction or wasting of the drug (when appropriate); and

10.11.15.4 In the event that the inventories cannot be verified or drugs are lost, contaminated, wasted, or destroyed, a report of such

incident shall be written and signed by the licensed nurses involved, any witnesses present, and the nursing supervisor, and copies sent for review to the director of the nursing service and the director of the pharmaceutical service.

10.12 Definitions and/or Qualifications

10.12.1 Calculated Dose shall mean a drug dose that requires mathematical computation because the amount of drug to be given differs from the dose that has been supplied for administration. The amount of drug prescribed may be (1) smaller than that supplied, requiring administration of a fractional part of the drug; (2) larger than that supplied, requiring administration of more than one tablet, milliliter, or other measurement; or (3) ordered in one measurement and available in the units of another measurement (e.g., the number of drops per minute to administer a prescribed amount of solution).

10.12.2 Charge Nurse shall mean a person who is licensed in the State of New Jersey as a registered professional nurse.

10.12.3 Controlled Dangerous Substances shall mean drugs subject to the Controlled Substances Act of 1970 (Title II, Public Law 91-513) and the New Jersey Controlled Dangerous Substances Act of 1971.

10.12.4 Current shall mean up-to-date, extending to the present time.

10.12.5 Drug shall mean a substance as defined in the New Jersey State Board of Pharmacy Rules, N.J.A.C. 13:39-1.1. The word "medication," which also occurs in these standards, has an equivalent meaning and is used interchangeably with the word "drug."

10.12.6 Drug Administration shall mean a procedure in which a prescribed drug or biological is given to a patient by an authorized person in accordance with all laws and regulations governing such procedures. The complete procedure of administration includes removing an individual dose from a previously dispensed, properly labeled container (including a unit dose container), verifying it with the prescriber's orders, giving the individual dose to the patient, seeing that the patient takes it (if oral), and recording the required information, including the method of administration.

10.12.7 Drug Dispensing shall mean a procedure entailing the interpretation of the original or direct copy of the prescriber's order for a drug and, pursuant to that order, the proper selection, measuring, labeling, packaging, and issuance of the drug to a patient or a service unit of the facility, in conformance with all applicable Federal, State, and local rules and regulations.

10.12.8 Drug Distribution Station shall mean an area as defined in Minimum Requirements of Construction and Equipment for Hospital and Medical Facilities, DHEW Publication No. (HRA) 79-14500.

10.12.9 Floor Stock shall mean a supply of drugs provided by the pharmacist to a patient or a service unit in a labeled container in limited quantities, as approved by the Pharmacy and Therapeutics Committee of the facility.

10.12.10 Formulary shall mean a list of all drugs stocked by the facility. It may also list drugs which are considered appropriate for treating specific illnesses, or may list substitutions of chemically equivalent drugs for trade name prescription drugs.

10.12.11 Licensed Nursing Personnel (Licensed Nurse) shall mean registered professional nurses or practical (vocational) nurses licensed in the State of New Jersey.

10.12.12 Licensed Practical Nurse shall mean a person who is licensed by the New Jersey State Board of Nursing.

10.12.13 Medical Record shall mean all records in the facility which pertain to the patient, including radiological films.

10.12.14 Medication Administration Record (MAR) shall mean the documentation of medication administered to a patient.

10.12.15 Medication Error shall mean the administration of the wrong medication or dose of medication, drug, diagnostic agent, chemical, or treatment requiring use of such agents, to the wrong patient, or at the wrong time, or the failure to administer such agents at the specified time, or in the manner prescribed or normally considered as accepted practice. Errors may be classified as "commissions," that is, medications incorrectly administered to the patient, such as unordered medication or medication in the wrong strength; and "omissions," that is, medications not administered at prescribed times.

10.12.16 Medication Profile shall mean a patient profile record system as defined in the New Jersey State Board of Pharmacy Rules, N.J.A.C. 13:39-9.13.

10.12.17 Pharmacist shall mean a person who is registered by the New Jersey State Board of Pharmacy.

10.12.18 Prescriber shall mean a person who is authorized to write prescriptions in accordance with Federal and State laws and the medical staff bylaws, rules and regulations.

10.12.19 Registered Professional Nurse shall mean a person who is licensed by the New Jersey State Board of Nursing.

10.12.20 Self-Administration shall mean a procedure in which any medication is taken orally, injected, inserted, or topically or otherwise administered by a patient to himself or herself. The complete procedure of self-administration includes removing an individual dose from a previously dispensed, labeled container (including a unit dose container), verifying it with the directions on the label,

and taking orally, injecting, inserting, or topically or otherwise administering the medication.

10.12.21 Stop Order shall mean a written, signed, and dated statement by the prescriber mandating the cessation of a written order (except those orders indicated in 10.4.19 - 10.4.19.4).

10.12.22 Supervision shall mean authoritative procedural guidance by a qualified person for the accomplishment of a function or activity within his or her sphere of competence, with initial direction and periodic on-site inspection of the actual act of accomplishing the function or activity.

10.12.22.1 Direct Supervision shall mean the supervision on the premises within view of the supervisor.

10.12.23 Unit Dose Drug Distribution System shall mean a system in which drugs are delivered to the patient areas in single unit packaging. Each patient shall have his or her own medications labeled with his or her name and location in the facility. Each medication shall be individually wrapped and labeled with the generic and trade names and strength of the drug, lot number or reference code, expiration date, dose, and manufacturer's name, and ready for administration to the patient. Cautionary instructions shall appear on the patient's medication administration record (MAR), and the system shall include provisions for noting additional information, such as special times or routes of administration. Delivery and exchange of patient medications shall occur promptly, and at least one exchange of patient medications shall occur daily. The number of doses for each patient shall be sufficient for a maximum of 24 hours.