

NEWFOUNDLAND AND LABRADOR PHARMACY BOARD

Standards of Pharmacy Practice



Standards for Hospital Pharmacies

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Preface

The purpose of these standards is:

1. To define the scope and responsibility of hospital pharmacy practice;
2. To define the role of the pharmacist in the hospital;
3. To provide directions for identification of priorities and development of pharmacy services;
4. To provide a definition of exemplary pharmacy services, to be used as a reference source for accrediting bodies, other health care organizations and governments.

The 1996 edition of the Canadian Society of Hospital Pharmacists (CSHP) Standards of Practice was used as a basis for compiling this document. In most cases the language and material is directly transposed from the original document.

1. Scope

1.1 These Standards specify the requirements for the practice of pharmacy in hospitals.

1.2 In these Standards, "shall" indicates a mandatory requirement; "should" indicates a recommendation, or that which is advised but not mandatory.

2. Definitions

The following definitions apply in these Standards:

Adverse drug reaction - a reaction that has neither therapeutic, prophylactic nor diagnostic benefit to the patient.

Ambulatory pharmacy services - the provision of pharmacy services to patients who require medical attention yet do not require admission to an institution.

Automatic stop order - the practice of automatically terminating a drug after a specific time period if the physician has not specified a limit to the time or number of doses. The purpose is to avoid prolonged administration of medications which may inadvertently result in harmful consequences to the patient and unnecessary expense.

Continuous quality improvement - a proactive process with the underlying assumption that every process can be improved. The core theoretical constructs are: focus on customers, focus on processes and improve continuously. CQI builds on quality assurance (QA) by extending activities beyond resolution to ongoing improvement in of all key processes involved in patient care/service.

Controlled dosage system - a form of drug distribution, also known as a monitored dosage system, in which medication orders are filled and packaged (e.g., blister cards, cassettes) in accordance with scheduled administration times. Each package contains no less than one day's and no more that approximately one month's supply of medication. This is not a unit dose system.

Cytotoxic drug - usually refers to antineoplastics or drugs used in the treatment of cancer.

Dispense - to provide a medication in response to a medication order but does not include the administration of a medication.

Drug distribution service - a pharmacy-coordinated hospital system used to provide medications to the patient in a controlled manner.

Drug recall - a request for and the subsequent removal of a defective medication from stock. This usually results when a particular lot number of a medication is of substandard quality or when a particular medication produces unexpected side effects.

Drug use control - a system of knowledge, understanding, judgments, procedures, skills, controls and ethics that assures optimum safety in the distribution and use of drugs (Brodie, 1967).

Drug use evaluation - the prospective or concurrent analysis of the pattern of use of drugs against a predetermined set of criteria, followed by assessment, implementation of corrective action, and reassessment.

Drug utilization review - the retrospective analysis of the pattern of use of drugs against a predetermined set of criteria, followed by assessment, implementation of corrective action, and reassessment.

Emergency release drug - a drug not approved for use in Canada and whose use is limited to specific physicians approved by the Health Protection Branch.

Formulary - a dynamic compilation of medications, information, and related policies, approved for use within a hospital, that reflects the current clinical judgment of the medical and pharmacy staff.

Health record - patient's medical chart or medical record.

Hospital - a facility that is approved by a federal, provincial or territorial government, in accordance with the appropriate laws to provide health services treatment to persons suffering from diseases or illness (may also refer to other organized health care settings).

Individual patient prescription system - a form of drug distribution in which medications are dispensed in the pharmacy in patient-specific labelled prescription containers.

Investigational drug - a medication approved by the Health Protection Branch for limited clinical use in Canada by approved investigators.

Medication discrepancy - an event that does not involve the actual administration or omission of a drug to a specific patient, but is a situation where an error in the drug process has been detected and corrected before reaching the patient. This includes the unexplained loss or theft of a medication.

Medication incident - a patient-related event which involves the incorrect administration or omission of a medication to a specific patient.

Medication profile - an ongoing record of patient specific information used to monitor drug therapy.

Night cabinet - a suitable, locked storage area (a cupboard, room, cart, etc.) containing supplies of medications required when the pharmacy is closed.

Non-Formulary drug - a drug not listed in the hospital Formulary.

Patient counselling - counselling of selected patients about their medications. Written information is provided when appropriate to supplement verbal counselling.

Pharmaceutical Care - is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. The process of pharmaceutical care involves designing, implementing and monitoring a therapeutic plan. (Hepler and Strand, 1990)

Pharmacist - one who is licensed to practice in Newfoundland and Labrador.

Pharmacokinetics - the action of drugs in the body over a period of time, including the processes of absorption, distribution, localization in tissue, biotransformation, and excretion.

Pharmacotherapy monitoring - a patient-specific assessment by the pharmacist of medications based on the diagnoses, concurrent therapy, indication, adverse effects, allergies, laboratory tests, and prognosis.

Pharmacy and therapeutics committee - a committee that evaluates the clinical use of drugs, develops policies for managing drug use and drug administration, and manages the formulary system. This committee is composed of physicians, pharmacists and other health professionals selected with the guidance of the medical staff. It is a policy-recommending body to the medical staff and the administration of the organization on all matters related to the therapeutic use of drugs.

Pharmacy service - a system that integrates the application of the pharmacist's specialized knowledge with the distribution of the medication to assure optimal medication therapy for the patient.

Policy - a general statement of principle pertaining to a specific issue, task or service.

Preprinted order - a series of predetermined orders that are accepted by the clinical team for use in the management of a specific diagnosis or following a specific diagnostic procedure. Using the preprinted form the physician can individualize any element of a particular drug order.

Principal functions - the main areas of responsibility for a pharmacy service.

Procedure - detailed guidelines for implementing policy.

Repackage - to remove drugs from manufacturer's original package and place within another form of packaging (e.g., strip packaging, blister packaging, etc.).

Self-administration program - an organized program in which patients are taught how to and allowed to administer their own medications in the hospital, in accordance with hospital and pharmacy policies and procedures.

Telephone drug order - a medication order given over the telephone by a legally qualified prescriber.

Therapeutic interchange - a process where drug products, which are chemically different but considered by the medical and pharmacy staff to be therapeutically equivalent, are interchanged according to hospital policies.

Unit dose distribution - a form of drug distribution in which orders for each patient are filled individually and packaged in unit-of-use dosages.

Verbal drug order - a medication order given verbally, other than by telephone, by a legally qualified prescriber.

Ward stock - those medications which are stocked in the patient care area at all times and are not individually labeled for a specific patient's use.

3. Department Administration

3.1 Provision of Pharmacy Services

- 3.1.1 The hospital shall make provision for the delivery of pharmacy services.
- 3.1.2 The pharmacy service shall be administered in accordance with accepted ethical and professional practices and legal requirements and shall meet the needs of patients
- 3.1.3 The pharmacy service shall be responsible for drug-use control including purchasing, storing, distributing, and ensuring the optimal patient outcomes resulting from the use of medications in the hospital.

3.2 Direction

- 3.2.1 A pharmacist shall direct all pharmacy services.
 - 3.2.1.1 The director of pharmacy services shall be a pharmacist who is experienced in the practice of hospital pharmacy.
 - 3.2.1.2 Site Regional Managers shall be pharmacists who are experienced in the practice of hospital pharmacy.
- 3.2.2 The director of pharmacy, in consultation with the pharmacy staff, shall develop a statement of purpose, goals and objectives for the pharmacy service that are consistent with the mission of the hospital and that assure the safe and appropriate distribution of medications.
 - 3.2.2.1 The statement of purpose, goals and objectives shall be reviewed regularly, revised when necessary and dated accordingly.
 - 3.2.2.2 The goals and objectives shall include, but not be limited to, the following:
 - (a) the practice of pharmacy consistent with the size, location and function of the hospital and the changing needs of the patients and the medical and nursing staff;
 - (b) the provision of pharmacy programs to encourage safe, appropriate and economical medication therapy;
 - (c) the provision of a drug distribution service which ensures safe, appropriate and economical use of medications -- unit dose is the system of choice;
 - (d) the participation with other health care team members in the assessment and medication treatment of the individual patient;
 - (e) the promotion and maintenance of educational and information programs for the hospital staff which are designed to enhance the understanding, recognition, management and prevention of medication-related problems in patients; and,
 - (f) the provision of an environment for the practice of pharmacy which will encourage the growth and development of the individual pharmacy staff member and student in the health care field.

3.3 Organization

- 3.3.1 A written organizational chart for the provision of pharmacy services shall define the relationships and formal lines of communication within the service and relationships of the service with other departments and services within the hospital.
 - 3.3.1.1 The organizational chart shall be available to all pharmacy personnel.

3.3.1.2 The organizational chart shall be reviewed every 3 years, revised as necessary, and dated accordingly.

3.3.2 The pharmacy service shall be represented by a pharmacist in planning, decision making and policy formulation related to the service and to medication therapy. This includes membership on the Pharmacy and Therapeutics Committee and may include membership on other hospital and medical staff committees.

3.4 Staffing

3.4.1 The pharmacy department shall be staffed by sufficient numbers of professional, technical and other support personnel to meet the goals and objectives of the department and of the hospital.

3.4.2 All pharmacists and pharmacy students providing a pharmacy service shall report to the Director of Pharmacy.

3.4.3 There shall be written job descriptions for all pharmacy personnel clearly delineating professional and technical functions.

3.4.3.1 Job descriptions shall be reviewed at least every 3 years, revised as necessary, dated accordingly, and approved in accordance with hospital and pharmacy policies and procedures.

3.4.4 Support personnel shall be used to minimize the direct involvement of pharmacists in technical, clerical and secretarial activities.

3.5 Hours of Pharmacy Service

3.5.1 Hours of pharmacy service shall be adequate to meet the scope and programs of the service and the needs of the customer. They shall depend on the size, location, and the functions of the institution and the availability of staff.

3.5.2 If 24-hour pharmacy is not available on-site, there shall be provision for after-hours (on call) pharmacy service. A secure night cabinet shall be available.

3.6 Policy and Procedure Manual

3.6.1 The pharmacy department shall develop and maintain a complete policy and procedure manual that is well organized, easily accessible to all pharmacy personnel and familiar to all pharmacy personnel.

3.6.2 Written policies which govern drug use control and patient-oriented pharmacy services shall be developed by pharmacists in collaboration with the medical and nursing personnel and other appropriate disciplines, and be approved by the Pharmacy and Therapeutics Committee and other appropriate administrative committees.

3.6.3 The policy and procedure manual shall include information relating to the administrative and procedural aspects of pharmacy services, as well as those guidelines for all medication-related activities in the hospital that have been approved by hospital administration or the Pharmacy and Therapeutics Committee. It shall be reviewed on an ongoing basis and revised, as needed, at least every three years.

3.7 Pharmacy and Therapeutics Committee

3.7.1 Purposes:

The primary purposes of the P&T committee are:

- (a) Policy Development. The committee formulates policies regarding evaluation, selection, and therapeutic use of drugs and related devices.
- (b) Education. The committee recommends or assists in the formulation of programs designed to meet the needs of the professional staff (physicians, nurses, pharmacists, and other health-care practitioners) for complete current knowledge on matters related to drugs and drug use.

3.7.2 Organization and Operation:

While the composition and operation of the P&T committee might vary among specific practice sites, the following generally will apply:

- (a) The P&T committee should be composed of at least the following voting members: physicians, pharmacists, nurses, administrators, quality-assurance coordinators, and others as appropriate. The size of the committee may vary depending on the scope of services provided by the organization. Committee members should be appointed by a governing unit or authorized official of the organized medical staff.
- (b) A chairperson from among the physician representatives should be appointed. A pharmacist should be designated as secretary.
- (c) They should meet regularly, at least four times per year, and more often when necessary.
- (d) The committee should invite to its meetings persons within or outside the organization who can contribute specialized or unique knowledge, skills, and judgments.
- (e) An agenda and supplementary materials (including minutes of the previous meeting) should be prepared by the secretary and submitted to committee members in sufficient time before each meeting for them to review the material properly.
- (f) Minutes of committee meetings should be prepared and maintained in the permanent records of the organization.
- (g) Recommendations of the committee should be presented to the medical staff or its appropriate committee for adoption or recommendation.
- (h) Liaison with other organizational committees, concerned with drug use should be maintained.
- (i) Actions of the committee should be routinely communicated to the various health-care personnel involved in the care of the patient.
- (j) The committee should be organized and operated in a manner that ensures the objectivity and credibility of its recommendations. The committee should establish a conflict of interest policy with respect to committee recommendations and actions.
- (k) In formulating drug use policies for the organization, the committee should be attentive to the content and changes in pertinent guidelines and policies of professional organizations and standards-setting bodies.

3.7.3 Functions and Scope

The following list of committee functions is offered as a guide:

- (a) To serve in an evaluative, educational, and advisory capacity to the medical staff and organizational administration in all matters pertaining to the use of drugs (including investigational drugs).
- (b) To develop a formulary of drugs accepted for use in the organization and provide for its constant revision.

- (c) The selection of items to be included in the formulary should be based on objective evaluation of their relative therapeutic merits, safety, and cost. The committee should minimize duplication of the same basic drug type, drug entity, or drug product.
- (d) To establish programs and procedures that help ensure safe and effective drug therapy.
- (e) To establish programs and procedures that help ensure cost-effective drug therapy.
- (f) To establish or plan suitable educational programs for the organization's professional staff on matters related to drug use.
- (g) To participate in quality-assurance activities related to distribution, administration, and use of medications.
- (h) To monitor and evaluate adverse drug (including, but not limited to, biologics and vaccines) reactions in the health-care setting and to make appropriate recommendations to prevent their occurrence.
- (i) To initiate or direct (or both) drug use evaluation programs and studies, review the results of such activities, and make appropriate recommendations to optimize drug use.
- (j) To advise the pharmacy department in the implementation of effective drug distribution and control procedures.
- (k) To disseminate information on its actions and approved recommendations to all organizational health-care staff.

3.8 Budget

- 3.8.1 The pharmacy department shall be involved in budget preparation for the service.

3.9 Quality Improvement Process

- 3.9.1 The pharmacy department should continuously evaluate the quality of pharmacy services provided.

4. Facilities, Equipment and Supplies

- 4.1 There shall be sufficient space, facilities, equipment, information resources and supplies which are of the type, quality and quantity to:

- (a) support the principal functions and related processes, goals and objectives;
- (b) ensure a safe working environment for pharmacy staff (e.g., consideration for handling antibiotic, cytotoxic, biological and hazardous products); and,
- (c) integrate the pharmacy with the hospital's communication systems.

- 4.2 All equipment used by the pharmacy in the preparation, distribution and administration of medication shall be appropriately and regularly serviced/certified to ensure accurate and safe operation.

- 4.3 There shall be procedures established to authorize and control access to computer information systems.

5. Pharmaceutical Care and Pharmacy Services

5.1 Medication Order Review

- 5.1.1 All medication orders should be reviewed by the pharmacist prior to medication administration to the patient. After-hours or ward stock orders shall be reviewed by the pharmacist at the earliest opportunity.

- 5.1.2 Prior to dispensing any medication, the pharmacist shall review the prescriber's original written order or a direct copy to ensure that the prescriber's medication order is authentic, accurate and appropriate. The pharmacist shall check the medication order for:
- (a) the patient's name, hospital number and location;
 - (b) signature of authorized prescriber;
 - (c) the name of the medication and formulary status;
 - (d) dose, form and strength;
 - (e) route and frequency of admission;
 - (f) duration of treatment, if limited;
 - (g) complete directions for appropriate use;
 - (h) date order was written; and,
 - (i) for verbal and/or telephone orders, the name and signature of the person who received the order and the name of the prescriber.
- 5.1.3 The pharmacist shall ensure that a current computerized medical profile system is available. Patient medication profile should include:
- (a) name of the patient, hospital number and location;
 - (b) admission date;
 - (c) attending physician's name and/or prescriber's name;
 - (d) date of birth;
 - (e) gender;
 - (f) weight (for pediatric/neonatal patients);
 - (g) allergies and/or sensitivities;
 - (h) list of current medication orders;
 - (i) list of medications which have been prescribed since admission to the hospital (in a chronological sequence)
 - (j) for each medication order: medication name, dose, route, dosage form, directions for use and administration times (if not following standardized times);
 - (k) start and stop date of the medication, when applicable;
 - (l) date medications were dispensed, refilled or discontinued; and,
 - (m) signature or initials of the pharmacist or technician entering or verifying the transcription or computerized entry or medication orders into the medication profile.
- 5.1.4 The pharmacist shall have access to the following information, in addition to the medication profile:
- (a) medication history prior to hospital admission;
 - (b) other pertinent monitoring data (e.g., drug serum concentrations, renal function, etc.);
 - (c) other therapies (e.g., parenteral nutrition, enteral nutrition, etc.);
 - (d) diagnosis on admission and updates when applicable; and,
 - (e) selected medical data and diet information relevant to medication profile.
- 5.1.5 The pharmacist shall review the profile information prior to dispensing the patient's medications. The pharmacist shall assess the physician's original medication order, utilizing the patient's medication profile for the detection of:
- (a) duplication of therapeutically similar medications;
 - (b) potential allergic or adverse drug reactions;
 - (c) possible drug-disease incompatibilities;
 - (d) significant drug-drug interactions;

- (e) correct dosage and dosage interval;
- (f) appropriate dosage form and route of administration;
- (g) problems related to intravenous administration including potential incompatibilities, drug stability, volume of intravenous fluid for medication administration and rate of administration; and,
- (h) appropriate length of therapy.

5.1.6 The pharmacist shall resolve any questions regarding the order with the prescriber and shall document the resolution in accordance with policy. Telephone and verbal orders received by the pharmacist shall be reduced to writing immediately on the order form in accordance with and legal requirements.

5.1.7 The use of preprinted medication orders, if considered necessary:

- (a) shall be reviewed and revised as necessary by the P&T committee;
- (b) shall be approved individually by the appropriate hospital committee (e.g., Medical Advisory Committee);
- (c) shall have a copy that can be appended to the medical record; and,
- (d) shall be signed by the prescriber and individualized according to the patient's needs.

5.1.8 Written policies and procedures shall govern the use of p.r.n. medication and automatic stop orders.

5.2 Pharmaceutical Care

5.2.1 The pharmacist should provide pharmaceutical care to all patients. For selective monitoring, if resources are limited, the pharmacist may identify patients using criteria such as:

- (a) patients whose clinical state or condition may affect medication absorption or disposition, alter dosage requirements or predispose them to adverse drug reactions or medication toxicity;
- (b) populations (e.g., geriatrics, pediatrics or pregnancy) where age, weight or physiologic parameters are important considerations in determining appropriate medication therapy;
- (c) patients on multiple drug therapy;
- (d) patients taking medications with a low therapeutic index;
- (e) patients taking investigational or emergency release medications;
- (f) patients taking medications in doses greater or less than recommended by the manufacturer or recognized preferences; and,
- (g) patients on parenteral nutrition.

5.2.2 The pharmacist should discuss the desired outcome of drug therapy with the physician, the patient or delegate and other health care professionals as required. The pharmacist shall actively evaluate patient needs to ensure that the patient is receiving drug therapy that is achieving the desired therapeutic outcome.

5.2.3 For patients monitored under the Pharmaceutical Care Program the pharmacist should:

- (a) identify, prevent and resolve drug-related problems in patients. These include patients:
 - i) needing pharmacotherapy but not receiving it;
 - ii) taking or receiving the wrong drug;
 - iii) taking or receiving too little of the correct drug;
 - iv) taking or receiving too much of the correct drug;
 - v) experiencing an adverse drug reaction;
 - vi) experiencing a drug-drug, drug-food interaction;
 - vii) not taking or receiving the drug prescribed; and/or,

- viii) taking or receiving a drug for which there is no valid medical indication; and,
- (b) document provision of pharmaceutical care in the patient health record in accordance with hospital and pharmacy policies and procedures.

5.2.3.1 The pharmacist should assess the patient for development of drug-related problems throughout the patient's stay by evaluating:

- (a) the patient's response to medication therapy and achievement of the desired therapeutic outcome;
- (b) adverse medication effects including allergies and sensitivities; and,
- (c) changes in the patient's clinical condition (including altered kinetics of drug absorption, distribution, metabolism or excretion) which necessitate an alteration in medication therapy or dosage.

5.2.4 The pharmacist should consider the potential cost implications of drug therapy for the individual patient and the health care system to ensure the most beneficial and most economical therapy is utilized.

5.3 Interprofessional Team Participation

5.3.1 The pharmacist shall participate with other health care team members in the provision of patient care by discussing the patient's medication therapy with other members of the health care team during informal discussions, bedside rounds, interdisciplinary team conferences or meetings.

5.3.2 The pharmacist should participate in the assessment, implementation, monitoring and evaluation of the patient medication self-administration program, where applicable.

5.4 Drug Use Evaluation

5.4.1 The pharmacy department shall coordinate, in cooperation with the medical staff and the Pharmacy and Therapeutics Committee, a system for the ongoing evaluation of medication use within the hospital that may include:

- (a) development of medication use criteria;
- (b) evaluation of medication use against the predetermined criteria;
- (c) identification of problem areas;
- (d) education to correct patterns of inappropriate medication use; and,
- (e) evaluation of such educational programs.

5.4.2 The frequency and depth of evaluation shall depend on the disease and therapy complexity of the patients within the institution, and shall allow an accurate assessment of selected drug use within the institution.

5.4.3 Problems detected during the evaluation process shall be communicated to the responsible bodies.

5.4.4 Recommendations for improvement may include educational programs or structural or procedural modifications.

5.5 Drug Information

5.5.1 The pharmacist shall provide drug information, including patient-specific drug information, to health care personnel.

- 5.5.2 The pharmacy shall have current drug-related reference material either print or electronic. The Recommended Drug Information References will be approved by the NL Pharmacy Board.
- 5.5.3 Access to drug information services shall be available 24 hours a day, seven days a week. During hours the pharmacy is not open and in situations which cannot wait for regular hours of service, drug information shall be provided by the on-call pharmacist.
- 5.5.4 The pharmacist shall provide current information on the assessment, management, prevention of drug poisoning in conjunction with, or in the absence of, a poison control centre.

5.6 Medication Counselling

- 5.6.1 The pharmacist shall counsel selected patients (or their agents), individually or in groups, to provide specific information required for safe and appropriate medication therapy and compliance.
- 5.6.2 Medication counselling service may include information to the patient on the following aspects of medication use:
- (a) the name of the medication and dosage;
 - (b) the purpose of the medication and therapeutic goals;
 - (c) administration and/or use of the medication to include the route and frequency of medication administration, the correct use of special dosage forms, the proper scheduling of doses and the duration of therapy;
 - (d) action to be taken in the event of a dosage omission;
 - (e) instructions on proper storage of medication;
 - (f) a discussion of possible adverse and/or toxic drug reaction which may occur. This may include measures to be taken to avoid their occurrence, their effects on normal activities and the appropriate action to be taken by a patient if an adverse reaction occurs;
 - (g) potential drug-drug or drug-food interactions or other therapeutic incompatibilities;
 - (h) prescription refill information; and,
 - (i) other information unique to the specific patient or medication.
- 5.6.3 Verbal instruction may be supplemented with written information and other aids, (e.g., audio-visual and compliance aids), where appropriate.

5.7 Adverse Drug Reaction Reporting Program

- 5.7.1 The pharmacy department should maintain current information about adverse drug reactions including those occurring in the hospital and those described in the literature.
- 5.7.2 Policies and procedures pertaining to the reporting of adverse drug reactions shall be approved and supported by the Pharmacy and Therapeutics Committee.

5.8 Medication Incident and/or Medication Discrepancy Reporting Program

- 5.8.1 The pharmacy department shall participate in a medication incident and medication discrepancy reporting program.
- 5.8.2 There shall be written policies and procedures to report, document, analyze and follow-up medication incidents and medication discrepancies.

5.8.3 A written report shall be prepared for the designated hospital committee(s) describing medication incidents and medication discrepancies occurring in prescribing, dispensing or administration of a medication.

6. Drug Use Control

6.1 Formulary System

6.1.1 The pharmacy department, in cooperation with the Pharmacy and Therapeutics Committee, shall maintain a formulary system governing the selection and usage of medications in the institution.

6.1.2 The formulary system shall be based on therapeutic and economic considerations of medication use.

6.1.3 The formulary shall be approved by the appropriate hospital committee (e.g., Medical Advisory Committee).

6.1.4 The formulary shall contain:

- (a) the selected drug products approved for use within the hospital; and,
- (b) information about available dosage forms, dosage strengths and unit-of-use quantities.

6.1.5 The formulary shall be available to all professionals prescribing, administering or dispensing medications.

6.1.6 The pharmacy department shall be responsible for the maintenance and control of the formulary system throughout the hospital.

6.1.7 The pharmacy department shall be responsible for the storage and distribution of all investigational and emergency release drugs used for inpatients and outpatients:

- (a) investigational drugs shall be used only under the authorization of the principal investigator;
- (b) investigational drugs shall be approved for use by the appropriate hospital committees;
- (c) policies and procedures shall be available which describe the approval process for the use of emergency release drugs;
- (d) drug information on these medications shall be readily available; and,
- (e) the pharmacy shall maintain utilization records.

6.2 Drug Procurement

6.2.1 The purchasing of all medications shall be a function of the pharmacy department and shall be under the supervision of the Director of Pharmacy.

6.2.2 The pharmacist shall use professional judgment and any other sources of information in medication product selection to ensure drug quality.

6.2.3 The pharmacy department shall establish procedures for obtaining emergency supplies of medications.

6.3 Drug Inventory Management

6.3.1 The pharmacist shall be responsible for maintaining records of all drug transactions, including those required by law to maintain adequate inventory control and accountability.

6.3.2 The pharmacist shall maintain an adequate inventory control system.

6.3.3 All pharmaceuticals shall be delivered unopened to the pharmacy department upon receipt in the hospital receiving area.

6.3.4 Medication storage, including investigational drugs, within the pharmacy and throughout the hospital shall be the responsibility of the pharmacy department.

6.3.4.1 All medications shall be stored under proper conditions of sanitation, temperature, light, humidity, ventilation, regulation and security.

6.3.4.2 Access to medication storage areas shall be restricted to designated personnel.

6.4 Medication Distribution Service

6.4.1 Dispensing

6.4.1.1 Dispensing shall be restricted to the pharmacist or other authorized personnel under the direction and supervision of the pharmacist.

6.4.2 Medication Labelling

6.4.2.1 The pharmacy department shall use standardized format, terminology, SI units and generic nomenclature on all medication labels.

6.4.2.2 Other labelling considerations shall include when appropriate:

- (a) appropriate directions for medications requiring dilution or reconstitution;
- (b) expiration date and proper storage conditions;
- (c) acceptable route of administration for parenteral medications; and,
- (d) use of non-proprietary names.

6.4.2.3 Medication labels shall be typed or machine printed and shall be free from erasures and strikeovers and shall be firmly affixed to the container.

6.4.2.4 Only pharmacists shall alter medication container labels.

6.5 Medication Preparation

6.5.1 Sterile Product Preparation

6.5.1.1 A pharmacy-based intravenous admixture program is the system of choice for drug admixing parenteral products. The pharmacy should aseptically prepare those sterile drug products required to meet the specific needs of the patient, in accordance with the CSHP Guidelines for the Preparation of Sterile Products in Pharmacies.

6.5.1.2 All personnel working in aseptic areas shall receive training in aseptic technique.

6.5.1.3 Cytotoxic drugs shall be handled and prepared in accordance with the CSHP Guidelines for the Handling and Disposal of Hazardous Pharmaceuticals (Including Cytotoxic Drugs).

6.5.1.4 Parenteral admixtures and solutions shall be prepared in a laminar air flow hood equipped with a high efficiency particulate air (HEPA) filter to prevent contamination with microorganisms and particulate matter. Cytotoxics shall be prepared in a Class II, biological safety cabinet, as per current NIOSH guidelines.

- 6.5.1.5 All completed parenteral admixtures and solutions prepared by technical personnel shall be checked by the pharmacist.
- 6.5.1.6 The pharmacist shall ensure:
- (a) the dosage calculations are correct for all orders;
 - (b) the label correctly states the contents of the package;
 - (c) hygienic packaging;
 - (d) stability and compatibility of contents; and,
 - (e) all completed parenteral solutions are inspected for particulate matter, signs of incompatibilities, degradation or contamination before they are dispensed.
- 6.5.1.7 Parenteral admixtures and solutions shall be labelled in a standard format.
- 6.5.1.8 A program of environmental monitoring should be used to ensure standards are maintained.

7. Specialized Pharmacy Services

7.1 General Principles

- 7.1.1 The pharmacy shall provide specialized programs in response to the needs of patients and the hospital.

7.2 Ambulatory Patient Services

- 7.2.1 The pharmacy shall provide pharmacy services to ambulatory patients such as dispensing of medications, medication counselling, maintenance of patient profiles, medication history taking and medication therapy monitoring, when appropriate.
- 7.2.2 The pharmacist shall participate as a member of the home care team, when appropriate.
- 7.2.3 The pharmacist should provide services to the emergency and ambulatory clinics, as required, to meet the pharmaceutical needs of the patients.

8. Education and Staff Development

- 8.1 All staff involved in pharmacy services shall be provided with educational and staff development programs including orientation, inservice education and continuing education programs.
- 8.2 Pharmacy staff shall be encouraged to attend meetings or seminars relevant to the function of the department or their particular service.

9. Research

- 9.1 The pharmacy staff should be encouraged to participate in research activities, recognizing this as an important contribution to the knowledge of the profession and the development of institutional pharmacy practice.
- 9.2 Communication of research should be considered an integral component of the process.