



# **The Manitoba Pharmaceutical Association**

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## **Manitoba Pharmaceutical Association**

### **Guidelines on**

### **Practice in Hospital Pharmacy**



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## GUIDELINES ON PRACTICE IN HOSPITAL PHARMACY

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## GUIDELINES ON PRACTICE IN HOSPITAL PHARMACY

### PART ONE

#### 1.0 Preface

The MPhA Guidelines for Hospital Pharmacy Standards of Practice were developed by hospital pharmacy directors practicing in Manitoba. In creating this document, standards, guidelines and by-laws from other provinces across Canada were examined. The information was then considered and reviewed by the Standards of Practice Committee and subsequently approved by council.

These Guidelines specify the minimum requirements for the practice of pharmacy in Manitoba Hospitals. The verb "shall," indicates a mandatory requirement; "should," indicates a recommendation, which is advised but not mandatory.

Specific pharmacy services provided in each institution will depend on size, location and function of the hospital. Therefore attempts have been made to modify certain standards for smaller hospital pharmacies.

These standards are subject to periodic review and suggestions for their improvement are welcomed. All comments or inquiries should be directed to the Registrar or Chair of Manitoba Pharmaceutical Association Standards of Practice Committee.

#### 2.0 Definitions

The following definitions apply to these standards:

**Adverse Drug Reaction** - an undesirable, unintended response to a drug that occurs at doses normally used for the diagnosis, treatment or prevention of a disease or the modification of an organic function. The reaction provides neither therapeutic, prophylactic nor diagnostic benefit to the patient.

**After Hours Cabinet/Cart (aka Night Cabinet)** - is a locked storage area (cabinet, cart or automated dispensing machine) secured to a wall or located in a locked room, stocked with a minimum supply of drugs most commonly required for immediate use within the institution when the pharmacy is closed. The drugs are stored in properly labeled containers supplying a sufficient quantity of medication until such time as a pharmacist is on duty.

**Aseptic Preparation/Technique** - is the use of procedures in the preparation of sterile products, which minimizes or prevents the introduction of microorganisms.

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

**Biological Safety Cabinet** - a ventilated cabinet having an open front with inward airflow for personnel protection, a HEPA-filtered downward airflow for product protection and a HEPA-filtered exhaust air for environmental protection. (Class 2, Type B2, externally vented, suitable for antineoplastic preparation, Class 2 Type A/B3, internally vented, suitable for preparation of allergy potentiating medications such as Penicillin)

**Batch preparation** - Compounding or repackaging of multiple units, not for immediate use, in a single process, by the same operator in accordance with a standardized batch preparation procedure.

**Bulk Compounding** - the preparation of compounded products, which are not commercially available, in anticipation of a prescription drug order and produced in quantities based on routine, regularly observed prescribing patterns. Compounds may be produced prior to receiving a valid prescription, provided a history of receiving valid prescriptions, generated solely within an established pharmacist-patient-prescriber relationship, is documented through the maintain of prescription files.

**Certification** - The process by which a nongovernmental agency or association grants recognition to an individual who has met certain predetermined qualifications specified by that agency or association. In pharmacy, technicians may voluntarily choose to become certified through an examination process.

**Class 100 Environment** - describes a level of cleanliness for environments that have concentrations of less than 100 particles (0.5 micron size and larger) per cubic foot of air

**Collaborative Practice Agreement** - is a written and signed agreement between one or more pharmacists and one or more physicians that provides for collaborative pharmacy practice under drug therapy protocols for the purpose of drug therapy management of patients.

**Collaborative Pharmacy Practice** - is a co-operative practice relationship between a pharmacist and physician or practice group which authorizes the pharmacist to implement drug therapy, modify, and initiate drug dosages, dosage forms, and dosing schedules, order laboratory tests pursuant to a drug therapy management agreement. This agreement must be physician, pharmacist and disease specific, according to established protocols for the purpose of drug therapy management of patients.

**Compounding** - is the preparation of a drug or device for individual patients, within a specific patient population, pursuant to a prescription written within an established prescriber-patient-pharmacist relationship. The preparation of products or specialty dosage forms, includes sterile or non-sterile topical, oral or parenteral preparations including IV admixtures and TPN, which are not commercially available in the market place.

**Commercially Available Products** - are pharmaceutical products authorized by Health Canada for use and sale in Canada, after having received a Notice of Compliance and assigned a Drug Identification Number (DIN) for marketing in Canada. Pharmacists may not compound products that are commercially available in a ready to use form, including products requiring reconstitution.

**Non-Commercially Available Products** - includes drugs in dosage forms, strengths and formulations that are not commercially available, but whose active ingredients are commercially available in Canada. Non-commercially available products also include investigational new drugs and drugs that not approved for use in Canada. Pharmacists may compound non-commercially available products, either pursuant to or in anticipation of a prescription.

**Continuous Quality Improvement (CQI)** - a proactive process with the underlying assumption that every process can be improved. The core theoretical constructs: focus on patients; focus on the process and continuous improvement. CQI builds on quality assurance by extending activities beyond problem resolution to ongoing improvement of all key processes involved in patient care. (See definition of Quality Assurance)

**Contract of Supervision** - is a contract of supervision entered into by a clinical assistant and a physician whereby the physician undertakes to supervise the medical services provided by the clinical assistant.

**Controlled Dose System** - a form of drug distribution, also known as a monitored dose system, in which medication orders are filled individually and packaged in blister paks or dosettes, in accordance with scheduled administration times. Each package contains no less than a one-day and no more than 35 days supply of medication.

**Delegation of Function** - is when one health professional delegates to another health professional any function, which forms part of their scope of practice, for which the delegatee is not otherwise authorized to perform. The

delegatee must have training and qualifications to carry out the duties assigned, and remain professionally responsible to a specific delegating medical practitioner.

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

**Drug Allergy** - an allergic manifestation mediated by the immune system that results from previous exposure and sensitization to a particular chemical or to one that is structurally similar. An allergic drug reaction is commonly IgE or immune-complex-dependent.

**Drug Distribution Service** - a pharmacy coordinated hospital system used to provide medications to the patient.

**Drug Recall** - a request for, and subsequent removal, of a medication from stock.

**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 or corrective action, and reassessment.

**Established Pharmacist-Patient-Prescriber Relationship** - A relationship that can be demonstrated to exist between:

- 3.0 a pharmacist and a patient
- 4.0 a pharmacist and a prescriber
- 5.0 a patient and prescriber and/or
- 6.0 a pharmacist, patient and prescriber.

**Establishment License** - are licenses issued by Health Canada to pharmaceutical fabricators/ distributors that solicit business to compound specific drug products; compounds regularly and in inordinate amounts drug products that are commercially available in the market place, or compounds inordinate amounts of drugs in anticipation of receiving prescriptions in relation to the amount of drugs compounded after receiving valid prescriptions.

**Expiration Date** - is the time during which a pharmaceutical may be expected to meet the requirements of the pharmacopeial monograph provided it is kept under the prescribed manufacturer's conditions. This date limits the time during which and article may be dispensed or used and is based on scientifically sound stability studies care out by the manufacturer.

**Extemporaneous Compounding** - is an all encompassing term used to define all forms of compounding, such as non-sterile compounds (creams, ointments, oral liquid preparations, capsules etc), sterile product preparations (pre-filled syringes, IV admixtures, TPN etc.) and sterile compounds (sterile eye drops).

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

**Good Manufacturing Practices (GMP)** - are manufacturing practices stipulated in Part C, Division 2 of the Regulations to the Food and Drug Act.

**Hazardous Waste** - chemicals or pharmaceuticals in which the concentrations, toxicity, environmental persistence, degradation characteristics, flammability, corrosiveness, or reactivity, are dangerous and may represent a risk to the health of humans and/or other living organisms.

**High Efficiency Particulate Air Filter (HEPA filter)** - a filter which removes 99.9% of particles 0.3 microns and greater in diameter (these particles include bacteria, pollen and dust)

**Hospital** - is an institution that is approved or designated by a federal, provincial or territorial government to provide medical and surgical treatment for sick and injured patients suffering from diseases or illness. (Hospitals are synonymous with institutions)

**Hospital Pharmacy Satellite** - any physically separate area used for the provision of pharmacy services that is dependent upon support services from a hospital pharmacy department.

**Individual Patient Prescription System** - a form of drug distribution, also known as a traditional drug distribution system, in which medications are dispensed by the pharmacy in patient-specific labeled prescription containers.

**Laminar Airflow Hood (LAH)** - a ventilated cabinet (with stainless steel surfaces) that provides a linear pattern of airflow through a HEPA filter to create a suitable environment for preparation of sterile Parenteral admixtures. The directional airflow pattern of a laminar airflow hood can be horizontal or vertical providing product protection not personnel protection. In a LAH air is drawn through a pre-filter to remove gross contaminants, then it is pressurized and forced through a HEPA filter. This is considered a Class 100 environment (no more than 100 particles of 0.5 micron size or larger per cubic foot of air).

**Manufacturing** - is the preparation of compounded drugs or devices intended for distribution or sale outside the established prescriber/patient/pharmacist relationship. Manufacturing also includes the preparation and promotion of commercially available products for resale by pharmacies, practitioners, or other persons. Any pharmacy that promotes or advertises that it compounds specific drugs, or compounds inordinate amounts of product in anticipation of an order, would be subject to the Food and Drug Act and Regulations, Good Manufacturing Practice (GMP) and inspection by Health Canada. Only pharmaceutical fabricators/distributor, that meet the requirements of GMP may be licensed under the Establishment Licensing Framework to manufacture drugs in Canada.

**Medication Discrepancy** (patient health not compromised) - an error that does not involve the actual incorrect administration or omission of a drug to a specific patient, but was detected and corrected before reaching the patient. This definition includes the unexplained loss or theft of a medication.

**Medication Incident** (patient health compromised) - a patient-related error that involves the incorrect administration or omission of a medication to a specific patient.

**Medication Order Review** - an analysis by the pharmacist to ensure the prescriber's order is authentic, accurate, appropriate for the condition and compatible with the patient's current medication profile.

**Medication Profile** - an ongoing record of patient specific information used to monitor drug therapy. This record includes all medications currently prescribed and dispensed for the patient.

**Non-Formulary Drug** - a drug not listed in the hospital formulary.

**Patient Counselling** - the counselling of patients about their medications. Written information may be provided 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.

**Pharmacist** - is a person licensed with the Manitoba Pharmaceutical Association to practice pharmacy.

**Pharmacy and Therapeutics Committee** - a committee composed of representatives from pharmacy, medicine, nursing, administration, and other disciplines, which serves as a policy recommending body on all matters relating to the use of medications in the hospital(s). In absence of a Pharmacy and Therapeutics Committee in smaller hospitals, the Medical Advisory Committee may address these issues.

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

**Practice Description** - is a written description submitted by the supervising physician to the College of Physician and Surgeons, setting out the duties and functions of the clinical assistant in relation to the physician's practice.

**Procedure** - detailed guidelines for implementing policy.

**Quality Assurance** - is a monitoring process to ensure adherence to predetermined standards and focusing on problem resolution.

**Region** - is a geographical area, having definable boundaries, serviced by a regional health authority.

**Regional Health Authority** - is an administrative body regulating the allocations of health care resources within a specific region.

**Registration** - The process of making a list or being enrolled in an existing list. Within pharmacy, some provinces have elected to register technicians who have been certified through an examination process to perform tasks above what is permitted for a non-certified technician.

**Repackage** - to remove drugs from the manufacturer's original packaging and place within another form of packaging.

**Repackaging** - the re-distribution of commercially available package sizes in ready-to-administer or ready to dispense units. Repackaged products are not for resale unless repackaging and labeling complies with the guidelines and standards that ensure quality and safety of the pharmaceuticals. Pharmacies may repackage drugs in ready-to-administer or ready to dispense units, for several purposes that include but are not limited to:

- a) providing unit dose drug distribution services
- b) providing supplies of drugs to personal care homes,
- c) to enhance the efficiency of the dispensing

**Restricted Drugs** - are drugs that can only be prescribed under specific conditions or to specific service. (eg. restricted use of Cefotaxime upon approval of Infectious Disease Service)

**Satellite Pharmacy** - is a hospital pharmacy associated and supported in terms of management and/or inventory control services by a main hospital pharmacy. The satellite pharmacy is generally located within the same physical complex as the main pharmacy and encourages innovative pharmacy services while providing special needs to specific units or wards within the hospital. (ie. Neonatal Intensive Care)

**Seamless Care** - The desirable continuity of care delivered to a patient in the health care system across the spectrum of caregivers and their environments. Pharmacy care is carried out without interruption such that when one pharmacist ceases to be responsible for the patient's care, another pharmacist or health care professional accepts responsibility for the patient's care.

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

**Sensitivity** - a state of abnormal responsiveness to stimuli.

**Small Hospital** - an institution servicing less than 25 beds.

**Standards of Practice** - refers to the Manitoba Pharmaceutical Association Standards of Practice.

**Standing Order** - is a prescriber-authorized medication order that is in effect for specific patients upon admission and pre-authorized to be valid without a prescriber's signature.

**Sterile Product Preparation** - is the preparation of sterile products through aseptic manipulation of commercially available sterile pharmaceutical products, and the batch-scale operations for production of sterile products not

commercially available. Products are dispensed directly to patients or administered to patients, provided the compounding pharmacy is operating within a established pharmacist-patient-prescriber relationship.

**Targeted Substances** - are drugs listed in Schedule 1 of the Benzodiazepines and Other Targeted Substances Regulations to the Controlled Drugs and Substances Act.

**Technician** - is pharmacy personnel employed by the hospital to assist pharmacists with the technical aspects of preparing medications for delivery to a patient or patient care area. Duties could include, but are not limited to, the procurement and distribution of medications; the transportation of medications; the maintenance of medication inventories; and the provision of administrative, secretarial, and clerical or other support services.

**Certified Technician** (Implementation stayed pending Statute change)- is a technician registered with the Manitoba Pharmaceutical Association who has successfully completed a challenge examination approved by council, provided evidence of work experience and a letter of qualification from a licensed pharmacist in order to be eligible to perform specific tasks as individually approved by the pharmacy manager.

**Technician Checker** (Implementation stayed pending Statute change)- is a certified technician who has successfully completed a six months of continuous employment under the supervision of a pharmacy manager and undergone a pharmacy technician training program approved by council, with extensive didactic evaluation, practical training, and accuracy verification, to be eligible to perform specific duties as determined by the pharmacy manager.

**Transfer of Function** - is the performance of a medical function by an individual independent of a qualified physician. A transfer of function can only be considered to professional who is certified as being capable to perform the procedure as a result of education, training and examination.

**Unit Dose System** - a form of drug distribution in which orders are filled individually and packaged in non-patient specific unit-of-use packages. Each package contains generally not more than a 48-hour supply of medication is available in the patient care area at any time.

**Verbal Order** - a medication order given verbally, either by telephone or person to person, by a prescriber.

**Ward stock** - medications stocked in a patient care area not individually labeled for a specific patient's use.

### 3.0 ADMINISTRATION

#### 3.1 Hospital Pharmacy Licensing

**The Hospital Pharmacy shall be licensed in accordance with Part 6 of The Pharmaceutical Act. The pharmacy shall be managed by a licensed pharmacist. This pharmacist shall be designated as the pharmacy manager on the pharmacy license.**

3.1.2 Hospital pharmacy satellites within the same physical complex as the supporting hospital pharmacy (sharing the same address) will be covered by the supporting hospital pharmacy license and do not require a separate hospital pharmacy license.

3.1.3 Hospital pharmacy satellites, which are not within the same physical complex as the supporting hospital pharmacy, but receive support in terms of management and/or inventory control services, require a separate pharmacy license. The pharmacist directly responsible for the supervision of the satellite, shall appear on the pharmacy license.

3.1.4 Hospital pharmacies providing service to staff, outpatients and the community, must comply with the standards set out in the Community Pharmacy section of the Standards of Practice.

3.1.5 Hospital pharmacies providing service to personal care homes must comply with standards set out in the Personal Care Home Standards of Practice.

- 3.1.6 Hospital pharmacies providing service to other hospital(s) must comply with standards set out in the Hospital Pharmacy Standards of Practice.
- 3.1.7 An on-site pharmacy providing service to inpatients, staff, outpatients and the general public, not owned or operated by the hospital (Regional Health Authority) shall comply with standards set out in the Community and Hospital Pharmacy Standards of Practice.
- 3.1.8 An on-site pharmacy providing service to outpatients, staff, and the general public, not owned or operated by the hospital (Regional Health Authority) shall comply with standards set out in the Community Pharmacy Standards of Practice.
- 3.1.9 An off-site pharmacy providing service to hospital inpatients, staff, outpatients and the general public, not owned or operated by the hospital (Regional Health Authority) shall comply with standards set out in the Community and Hospital Pharmacy Standards of Practice.

### **3.2 Provision of Pharmacy Services**

- 3.2.1 Pharmacy services shall be provided either by employing pharmacists and support staff within the hospital or by making alternate arrangements with an outside source.
- 3.2.2 The hospital pharmacy manager shall ensure that rational drug therapy is promoted in collaboration with medical, nursing and administrative staff of the hospital.
- 3.2.3 The pharmacy and pharmacy satellites shall operate in abidance with the laws and ethical principles governing the profession of pharmacy to ensure a high level of patient care by practicing in accordance with the following:
- 3.2.3.1 Legal
    - a) Food and Drugs Act and Regulations,
    - b) Pharmaceutical Act of Manitoba and Regulations,
    - c) Controlled Drugs and Substances Act and Narcotic Control Regulations,
    - d) Prescription Drug Cost Assistance Act and Regulations,
    - e) Personal Health Information Act and Regulations, or any other Health Act or Regulations which may have an impact upon the distribution of medication or provision of patient care.
  - 3.2.3.2 Ethical
    - a) Code of Ethics
- 3.2.4 The pharmacy service shall be responsible for purchasing, receiving, storing, distributing and disposal of drugs in the hospital.
- 3.2.4.1 The purchase of all drugs shall be under the supervision of a pharmacist and in accordance with the Formulary Standard.
- 3.2.4.2 The pharmacy department shall establish and maintain adequate records of drug purchases and distribution necessary for inventory control and legal requirements.

### **3.3 Responsibilities of the Pharmacy Manager**

- 3.3.1 The pharmacy manager, in consultation with pharmacy staff, should develop a statement of purpose, goals and objectives for pharmacy services that is consistent with the mission statement of the hospital and assures the safe use and distribution of medications and provision of direct patient care.

*(Refer to CSHP Standards of Practice 3.2.2.2)*

- 3.3.2.1 The statement of purpose, goals and objectives should be reviewed regularly, revised when necessary and dated accordingly.

3.3.2 The pharmacy manager shall:

- a) actively participate in the day-to-day management of the pharmacy.
- b) confirm that staff members who present themselves as pharmacists and employed to practice are registered with the Manitoba Pharmaceutical Association and pharmacists hold a valid patient-care setting license.
- c) notify the Association of any changes in the appointments or resignations of pharmacists to pharmacy staff within seven days.

3.3.3 The pharmacy manager shall submit to the Registrar diagrams, including measurements, of all proposed renovations or additions to pharmacy areas within the institution (pharmacies, satellite pharmacies, medication storage sites, outpatient counselling areas) for review prior to commencement of construction.

3.3.4 The pharmacy manager shall establish policies and procedures for medication use control and patient-oriented pharmacy services; maintain and enforce the policies and procedures in compliance with these standards of practice.

### 3.4 Staffing

3.4.1 The pharmacy service shall ensure the professional and technical staffing levels are commensurate with the workload volume and patient care requirements to safely and competently provide medication distribution and clinical pharmacy services in accordance with the Pharmaceutical Act, Regulations and Standards of Practice.

3.4.2 In the absence of workload measurement data the application of the Manitoba Health Provincial Staffing Guidelines shall be utilized in the determination of appropriate staffing levels until such time as more useful information becomes available. These minimum guidelines would have to be increased depending on the type of drug distribution system, number of pharmacy programs, and hours of service provided.

3.4.3 Pharmacy technicians shall be utilized to reduce the pharmacist's time committed to the mechanics of drug distribution without reducing professional and legal responsibility in accordance with the pharmacist to technician ratio specified in the Regulations to the Pharmaceutical Act.

3.4.4 There shall be written job descriptions for all pharmacy personnel clearly delineating professional and technical functions. Job descriptions shall be reviewed at least every 3 years, revised as necessary and dated accordingly.

*\*Hospital pharmacies servicing <25 beds are exempt.*

### 3.5 After Hours Service

3.5.1 The maximum possible hours of pharmacy service shall be provided based on the needs of the hospital and community on a 24-hour basis. Hours of service will depend on the size, location and functions of the hospital and the availability of pharmacy staff.

3.5.1.1 If the requirements of an individual institution or the availability of pharmacy staff preclude the provision of a 24-hour pharmacy operation, formal policy should state that "**pharmacy service**" will be provided by a designated pharmacist after hours.

*\*Hospital pharmacies servicing <25 bed facilities should develop formal policy stating "**drug information service**" should be provided by a designated pharmacist after hours.*

3.5.1.2 In the event that the designated pharmacist is unavailable, formal policy should be in place whereby an alternate pharmacist(s) would be contacted.

3.5.2 An After Hours Cabinet, located outside the hospital pharmacy, shall be available for after hours pharmacy service in order for patients to commence drug therapy, if necessary, after regular pharmacy hours.

\*Hospital pharmacies servicing <25 bed facilities, using a ward stock drug distribution are exempt from this requirement.

3.5.2.1 The pharmacy service shall regularly restock the after hours cabinet with medications that have been removed, and check for expired or missing medications.

3.5.2.2 When the pharmacy is closed, an authorized nurse shall obtain the needed medication(s) from the cabinet. The prescriber's order or a direct copy, signed and dated by the nurse, shall be left with the withdrawal record or sent to the pharmacy to be recorded. The pharmacist shall check the physician's order and ensure the correct medication was removed, at the earliest opportunity. The following information must be available either by logbook documentation, automated print out or prescriber's order and shall include:

- (a) patient name and location
- (b) drug removed and quantity
- (c) prescriber's name
- (d) signature of authorized nurse
- (e) date of withdrawal

3.5.2.3 The record of after hour withdrawals shall be reviewed periodically to determine if the appropriate medication and quantities are stocked, and medications not used are removed.

3.5.3 On the rare occasion when a required medication is unavailable from the after hours cabinet the designated pharmacist will be contacted to provide pharmacy service.

*\*Hospital pharmacies servicing < 25 beds - the nurse in charge may access the dispensary and remove the stock bottle, or a previously labeled vial containing a few doses prepared ahead of time, and set beside the stock bottle on the pharmacy shelf. All withdrawals shall be recorded. The prescriber's order or a direct copy shall be left with withdrawal record. The pharmacist shall check the physician's order and ensure the correct medication was removed at the earliest opportunity.*

*The nurse shall document the following:*

- a) patient name and location*
- b) drug removed and quantity*
- c) prescriber's name*
- d) signature of authorized nurse*
- e) date of withdrawal*

3.5.3.1 Stock bottles removed from the dispensary which are not ward stock on the ward, must be retrieved or returned to the pharmacy when the pharmacist is on duty.

3.5.3.2 Pharmacy withdrawal records shall be reviewed periodically to determine if selected drugs should be placed in the after hours cabinet, cart or automated dispensing machine.

3.5.4 Incident reports shall be completed and forwarded to the appropriate committee upon unnecessary access to the pharmacy or when withdrawal records for the pharmacy and after hours cabinet are incomplete.

3.5.5 The pharmacy manager shall designate specific non-pharmacy personnel permitted to access the after hours cabinet and pharmacy, after hours and in emergency situations such as fire, flood or security breach. Keys to enter the pharmacy shall be stored in a secure area, with a system in place making it evident whenever pharmacy access is attained. All access shall be documented and communicated to the pharmacy manager as soon as possible.

## **3.6 Policy and Procedure Manual (see Appendix A – sample Policy and Procedure outline)**

- 3.6.1 The pharmacy service shall establish and maintain current written policies and procedures to ensure the Standards of Practice are met and provide pharmacy staff with clear direction on the scope and limitations of their functions and responsibilities.
- 3.6.2 The pharmacy policy and procedure manual shall be developed, either in-house or regionally, by pharmacists in collaboration with other health care disciplines and approved by the Pharmacy and Therapeutics Committee or other appropriate administrative committee.
- \*Hospital pharmacies servicing <25 beds shall be involved in all the planning, decision making and formulation of policies and procedures related to drug use control within the institution.*
- 3.6.3 A comprehensive policy and procedure manual shall contain information relating to all the pharmacy administrative, procedural and medication related activities within the institution.
- 3.6.4 The pharmacy shall communicate the appropriate policies and procedures necessary for the attainment of drug use control, to other departments and professional groups within the institution.
- 3.6.5 The pharmacy manager shall establish written policies and procedures to control access to confidential patient information.
- 3.6.6 The pharmacy service shall be responsible for monitoring compliance to the approved pharmacy policies and procedures throughout the institution. Any detected non-compliance shall be reported to the Pharmacy and Therapeutics Committee or other appropriate administrative committee.
- 3.6.7 The manual shall be well organized, with a copy of the manual being kept in the pharmacy easily accessible and familiar to all pharmacy personnel.
- 3.6.8 Policies and procedures shall identify specific duties carried out by pharmacy personnel.
- 3.6.9 Policies and procedures shall be reviewed at least every three years, revised as necessary, dated accordingly, and approved by the appropriate committee.
- 3.6.10 Policies and Procedures regarding the following shall be included, but not limited to:
- a) formulary drug use
  - b) non-formulary drug acquisition
  - c) additions and deletions to the formulary
  - d) restricted drugs
  - e) automatic stop orders
  - f) use and storage of patient's own medication
  - g) investigational drug use
  - h) emergency release drug acquisition
  - i) drugs required on an emergency basis
  - j) therapeutic substitution of drugs
  - k) drug order review

### **3.7 Pharmacy and Therapeutics Committee**

- 3.7.1 Hospital pharmacies shall be represented by pharmacist(s) on either an in-house or regional Pharmacy & Therapeutics Committee.

*\*Hospital pharmacies servicing <25 beds - shall be represented by a pharmacist on a Pharmacy and Therapeutics Committee or similar administrative committee where pertinent pharmacy issues are discussed.*

- 3.7.2 Pharmacy and Therapeutics Committee membership should include representation from:
- a) pharmacy,

- b) the medical staff, and
- c) other disciplines as required.

3.7.3 The Pharmacy & Therapeutics Committee shall:

- a) ensure pharmacist participation in the development of all drug-related policies and procedures.
- b) review compliance to all relevant policies relating to medication use, administration and direct patient care.
- c) make recommendations to administration and medical staff on the ongoing review and improvement of policies and procedures relative to the safe, effective and economical use of medications.
- d) compile and effectively maintain a formulary suited to the hospital's needs
- e) critically evaluate all requests for formulary additions and deletions.

3.7.4 Pharmacy and Therapeutics Committee shall meet at least quarterly and minutes of the meeting, indicating activities, findings, recommendations and actions resulting from these recommendations, shall be distributed to all members for future reference.

\*Hospital pharmacies servicing <25 beds shall meet at least twice yearly to discuss issues pertinent to pharmacy, and minutes of the meeting distributed to all members for future reference.

3.7.5 All recommended policies shall be ratified by the appropriate medical and administrative committees.

### **3.8 Quality Management/Improvement Process**

3.8.1 The pharmacy service shall have or be part of, an ongoing quality management/improvement programs including, continuous quality improvement, risk management and utilization reviews appropriate for the level of pharmacy services provided. The programs shall monitor pharmacy personnel, performance, equipment, facilities, services and patient care.

3.8.2 The quality management program should include but not be limited to the following:

- a) documentation of periodic audits of the medication distribution process,
- b) appropriateness and consequence of patient-oriented recommendations,
- c) review process of indication, content, format and appropriateness of individual pharmacy documentation notes in the patient's health record,
- d) evaluation process of medication use relative to predetermined criteria, to correct inappropriate medication use and assess follow-up.

3.8.3 The pharmacy service should implement or be part of a continuous quality improvement (CQI) process to evaluate the quality of pharmacy services provided to the patient.

3.8.4 Documentation supporting this process should include, but not be limited to:

- a) identification of pharmacy department's customer
- b) evaluation by those customers of pharmacy services
- c) staff training, specific to CQI
- d) staff involvement in the processes, and
- e) feedback to staff and appropriate customers.

3.8.5 Documentation supporting the CQI process also should include, but not be limited to:

- a) identification of problem or area for improvement
- b) identification of customers relevant to the problem
- c) implementation of quality improvement teams with staff and cross-functional representation
- d) application of relevant tools and techniques (eg. flow charts)
- e) data collection and analysis
- f) identification of key measurements
- g) identification of target levels
- h) analysis of gaps in performance
- i) actions necessary to improve performance or the process, and
- j) implementation and evaluation plan.

- 3.8.6 Outcome indicators to assess the quality of pharmacy services provided to the customers should include, but not be limited to:
- a) organizational pre-requisites (structural)
  - b) operational indicators (processes)
  - c) medication-use indicators, and
  - d) patient-care indicators (outcomes):
    - i) to monitor the most important aspects of pharmaceutical care
    - ii) to evaluate care and identify problems and opportunities for improvement, and
    - iii) to implement actions to resolve problems and improve the quality of patient care and subsequently its effectiveness.

### **3.9 Medication Incident and Discrepancy Reporting Program (see Appendix B & C)**

- 3.9.1 The quality management program must include a Medication Incident and Discrepancy Reporting Program to ensure medications are ordered, prepared and dispensed according to established procedures and provided to the patient in an accurate, safe and timely manner.
- 3.9.2 All medication incident and discrepancies throughout the facility shall be recorded, reported and examined, and written policies and procedures to report, document, analyze, and follow-up on medication incidents and/or discrepancies shall be developed.
- 3.9.3 Monitoring medication incidents and discrepancies is a management responsibility and shall be jointly managed by hospital administration, pharmacy, nursing, medicine, and other disciplines as appropriate. The Pharmacy and Therapeutics Committee or a multidisciplinary committee accountable to the hospital and/or Pharmacy and Therapeutics Committee shall be established to develop, implement and provide ongoing review of the medication incidents/discrepancy reporting program.
- 3.9.4 The purpose of the committee shall be to provide an ongoing assessment of medication incidents and discrepancies in prescribing, dispensing or administration of medication. The resulting information shall be communicated to all pharmacy staff and used as an educational tool with the ultimate objective of enhanced accuracy and patient safety.
- 3.9.5 Upon discovery of a medication incident or discrepancy, the following shall be notified, as soon as possible: head/charge nurse, attending physician, pharmacy manager and other disciplines, as appropriate. The appropriate party shall take immediate corrective action.
- 3.9.6 The person who discovers the incident/discrepancy shall document the medication incident or discrepancy as soon as possible after its discovery.

*(Refer to CSHP Guidelines for Medication Incident and Medication Discrepancy Reporting)*

### **3.10 Adverse Drug Reaction Reporting Program**

- 3.10.1 The pharmacy service shall coordinate, in cooperation with medical and nursing staff and possibly other facilities in the region, an adverse drug reaction program. This shall include:
- a) the identification and immediate reporting of adverse drug reactions to the prescribing physician and pharmacy,
  - b) the investigation and validation of adverse drug reactions including collection of follow-up information, treatment and outcome,
  - c) documentation in the patient's health care record,
  - d) the regular reporting of adverse drug reactions to the Pharmacy and Therapeutics Committee,
  - e) the regular reporting of adverse drug reactions to the Canadian Adverse Drug Reaction Monitoring Program, Bureau of Licensed Product Assessment and the drug manufacturer.
- 3.10.2 Policies and procedures pertaining to the reporting of adverse drug reactions shall be approved by the Pharmacy and Therapeutics Committee.

3.10.3 The pharmacy department shall maintain current information about adverse drug reactions occurring within the hospital and in literature (ie. Canadian Adverse Drug Reaction Newsletter)

### **3.11 Essential Services**

3.11.1 All available avenues must be utilized to achieve agreements before labor disputes disrupt normal hospital function.

3.11.2 Pharmacy managers shall be responsible for ensuring pharmacists and support-staffing levels are commensurate with the workload volume and maintain the provision of safe patient care at all times.

3.11.3 Pharmacy services essential to patient care, including both clinical and distribution services, shall be maintained to ensure the continued patient safety.

## **4.0 HOSPITAL PHARMACY PREMISES**

### **4.1 Facility**

4.1.1 The hospital pharmacy and satellites shall be of sufficient size, but no less than 150 sq.ft. to allow:

- a) safe and proper storage of pharmaceuticals,
- b) a safe working environment for pharmacy staff (e.g., consideration for the handling of antibiotic, cytotoxic, biological, and hazardous products)
- c) the provision of clinical and administrative pharmacy services.

*\*Requirements for satellite pharmacies may be waived depending on the service(s) provided.*

*\*Hospital pharmacies initially licensed prior to February 1<sup>st</sup>, 1994 are exempt.*

4.1.2 The hospital pharmacy, satellite pharmacies and medication rooms shall be well lit, ventilated, and maintained in a clean and orderly manner.

4.1.3 No person shall prepare, compound, dispense, package or store any medication under unsanitary conditions.

### **4.2 Equipment**

4.2.1 The hospital pharmacy and satellite pharmacies shall be equipped for safe and proper medication compounding, dispensing and/or preparation of medication orders, and for the provision of clinical and administrative pharmacy services.

4.2.2 All equipment used in the preparation, distribution, and administration of medication shall be appropriately and regularly serviced to ensure accurate and safe operations.

4.2.3 The hospital pharmacy and satellite pharmacies shall have a sanitary sink, kept in clean condition, easily accessible to the prescription preparation area, not accessible to the public and supplied with hot and cold water.

*\*Satellite pharmacies - individual requirements may be waived depending on the service(s) provided.*

4.2.4 The hospital pharmacy shall also meet the following requirements and contain:

- a) computerized database and printing system with internet access.
- b) prescription balance having a sensitivity of 10mg.
- c) prescription preparation counter area that provides at least 12 square feet of free working space dedicated to the preparation and compounding of prescriptions.
- d) refrigerator
- e) metric graduates (10ml and 100ml)

- f) glass mortar and pestle (250ml)
- g) counting trays and spatulas
- h) ointment slab or pad
- i) container for waste disposal

*\*Hospital Pharmacies servicing < 25 beds - Requirements for a computerized database with internet access may be waived depending on service(s) provided.*

4.2.5 The hospital pharmacies and satellite pharmacies shall contain no products inappropriate to the practice of pharmacy.

### **4.3 Library**

4.3.1 Each hospital pharmacy shall have the following:

- a) MPhA manual containing, or internet access to, current Federal and Provincial Pharmaceutical Acts and Regulations and Standards of Practice,
- b) hospital pharmacy policy and procedure manual revised/reviewed at least every three years,
- c) hospital or regional formulary revised/reviewed at least annually,
- d) access to the latest edition of the CSHP Official Publications.

Each hospital pharmacy shall have access to the following within the institution:

- a) a reference library containing the latest editions of drug information and interaction texts or software, relevant to medication dispensing, compounding and preparation,
- b) current patient-oriented references for the provision of clinical pharmacy services.

*(Refer to the CSHP Recommended Drug Information References in the CSHP Official Publications)*

4.3.2 Each hospital satellite shall have at the minimum the following:

- a) hospital pharmacy policy and procedure manual revised/reviewed at least every three years,
- b) hospital or regional formulary revised/reviewed at least annually.

Each hospital satellite shall have access to the following within the institution:

- a) hospital a reference library containing the latest editions of drug information and interaction texts or software, relevant to medication dispensing, compounding and preparation.
- c) current patient-oriented references for the provision of clinical pharmacy services.

*(Refer to the CSHP Recommended Drug Information References in the CSHP Official Publications)*

4.3.3 Each nursing unit shall have at the minimum the following:

- a) Compendium of Pharmaceuticals and Specialties (CPS) published within last 3 years,
- b) hospital or regional formulary revised/reviewed at least annually, and
- c) Parenteral drug manual

### **4.4 Security**

4.4.1 The hospital pharmacy shall ensure:

- a) secure drug storage satisfactory to the Therapeutic Products Programme.
- b) access to the pharmacy is restricted to authorized personnel only.
- c) all premises are secured with locks and alarms to detect unauthorized entry after pharmacy hours.
- d) procedures are developed and known in the event the pharmacy alarm is triggered.
- e) strict control is placed on the number of keys available to access drug storage sites.

- f) strict control is placed on the number of individuals having knowledge of the safe combination(s)
- g) pharmacy maintenance and cleaning is completed during regular pharmacy hours when pharmacy staff is on duty.
- h) pharmacy stock shipments arriving at the hospital after pharmacy hours are stored in a secure area until such time as a pharmacist is on duty.

4.4.2 The pharmacy, satellites and other drug storage areas should be locked at all times to prevent unauthorized access for the safety and security of medication and pharmacy staff. Doors to the pharmacy and satellites should be closed when occupied during regular pharmacy hours and must be locked when unoccupied. The use of a wicket, window or half door to provide limited access to hospital staff may be a consideration.

4.4.3 When the pharmacist is on duty within the institution, but not necessarily in the pharmacy, or just prior to the arrival of the pharmacist in the morning, technical staff may be left unsupervised for short periods of time. The pharmacist however, must be readily accessible. The pharmacy manager is responsible for implementing policies and procedures for the non-professional functions which may be performed by pharmacy technicians in the pharmacist's absence.

*\*Hospital pharmacies servicing <25 beds, technical staff may be left unsupervised for short periods of time, in a locked (closed) pharmacy when the pharmacist is on duty but not within the institution.*

## 5.0 PATIENT-ORIENTATED PHARMACY SERVICES

### 5.1 Medication Order Review

5.1.1 Provisions shall be made for sending a direct copy or faxed copy of all medication orders to the pharmacy department and subsequently retaining the original medication order on the patient's chart. In hospital pharmacies serviced by off-site pharmacies, provisions shall be made to send the original written order or faxed copy to the pharmacy and direct copy in the patient's chart.

*\*Hospital pharmacies servicing <25 beds using a ward stock Distribution System are exempt*

*\*In direct order entry systems where it is evident that the electronic order was initiated, entered and initialed by a pharmacist or prescriber, medication orders need not to be sent to the pharmacy.*

*\*Until such time as electronic prescriptions are legal a prescription hardcopy is required, kept either on the patients chart or in the pharmacy.*

5.1.2 All medication orders shall be reviewed by the pharmacist to ensure they are authentic, accurate and appropriate. It is the responsibility of the Pharmacy and Therapeutics Committee to prioritize the type of orders that must be reviewed by the pharmacist prior to medication administration. Orders received after pharmacy hours or ward stock medication orders must be reviewed by the pharmacist and acted upon at the earliest opportunity.

5.1.3 Medication orders shall include:

- a) patient name, age, location and hospital number,
- b) medication and dosage,
- c) route and frequency of administration,
- d) duration of treatment, if limited,
- e) identification of authorizing professional,
- f) date order was written,
- g) time order was written, if appropriate,
- h) for verbal orders, the name and signature of the person who received the order followed by the name of the prescriber.

5.1.4 Hospital policy should be implemented requiring the indication be specified on the medication order, thereby lessening the opportunity for misinterpretation of medication orders.

5.1.5 The original written order, direct copy or faxed copy of the medication order shall be initialed by the pharmacist, to indicate the entry into the medication profile has been verified and a medication order review has taken place.

*\*Hospital pharmacies servicing <25 beds using a Ward stock Distribution System - pharmacists may initial the patient's Kardex entries to indicate the entry into the medication profile has been verified and a medication order review has taken place.*

*\*In direct order entry systems where it is evident that the electronic order was entered by a pharmacist, their initials indicate the entry into the medication profile has been verified and a medication review has taken place.*

5.1.6 The pharmacist shall resolve any questions regarding medication orders with the prescriber and shall document all medication order changes in the patient's health care record.

5.1.7 Written medication orders sent to the pharmacy shall be filed by date or patient name for two years from the time it was last dispensed and electronic records kept for seven years, in accordance with the *Regulations to the Personal Health Information Act* interpretation by the provincial ombudsman.

*\*Hospital pharmacies servicing <25 beds using a ward stock Distribution System are exempt.*

5.1.8 Medication orders shall be canceled automatically when a patient goes to surgery and reordered post-operatively.

5.1.9 The pharmacist should review medication orders when a patient changes service.

## **5.2 Verbal Orders**

5.2.1 Prescribers are encouraged to give all verbal orders directly to the pharmacist. When the order is for an inpatient, the pharmacist must ensure the order is placed in the patient's chart.

5.2.2 Only persons authorized to prescribe medications shall issue verbal orders. Verbal orders may be given by a prescriber to a nurse provided the order is:

- a) reduced to writing immediately on the patient's health care record,
- b) signed by the person receiving the verbal order,
- c) clear, understandable, reasonable, logical and safe,
- d) countersigned by the prescriber within 24 hours.

*\*Verbal orders received by pharmacies servicing residential care facilities require orders to be co-signed by the prescriber within seven days.*

5.2.3 Hospital policy shall dictate with whom the responsibility lies to verify verbal orders have been counter-signed by the prescriber within 24 hours.

5.2.4 The pharmacist shall resolve any questions regarding verbal medication orders with the prescriber and document the resolution in the patient's chart. If the medication is a ward stock item, the pharmacist shall take appropriate action to contact the ward immediately prior to the administration of the medication.

## **5.3 Standing Orders**

5.3.1 The use of standing orders, if considered appropriate shall:

- a) be authorized by the prescriber,
- b) be approved by the appropriate hospital committee, reviewed annually and revised as necessary,
- c) state the medication name, route, frequency and duration, with each dose individualized according to patient's need,
- d) be available in a pre-printed format, so that a copy can be appended to the patient's chart, and
- e) be administered by authorized hospital personnel with the appropriate skill, knowledge and experience to determine the correct medication, dose, route and manage any anticipated or unanticipated outcomes.

## 5.4 Medication Profiles

5.4.1 The pharmacist shall ensure a medication profile is available for each patient for whom medication is prescribed, except for patients admitted for less than 24 hours to specified diagnostic or treatment areas such as: day surgery, ambulatory care, and emergency.

*\*Hospital or community pharmacies servicing <25 beds - the requirement to maintain patient profiles may be waived depending on service provided. (ie. Ward stock vs. individual patient prescriptions*

5.4.2 Patient medication profile information shall include:

- a) patient name, location and hospital number
- b) attending physician and/or prescriber's name
- c) date of birth
- d) gender
- e) weight and height, if applicable to therapy
- f) allergies, sensitivities or adverse drug reactions
- g) medication(s) name, dose, quantity, route, dosage form and directions for use
- h) dates medications were dispensed, refilled and discontinued,
- i) alcohol
- j) drug samples
- k) initials of the pharmacist or technician entering the information into the computer

5.4.3 The following information should also be included in the medication profile, but not limited to:

- a) a list of all the medications prescribed since admission including:
  - i. prn medication (not one time dose)
  - ii. standing orders (not one time dose)
  - iii. emergency/investigational drugs
- b) medical condition(s) diagnosis on admission and updates when applicable,
- c) medication history,
- d) other pertinent data (e.g. drug serum concentrations, renal function, smoking, alcohol use),
- e) other therapies (e.g. parenteral nutrition, enteral nutrition, etc.),
- f) diagnosis on admission and updates when applicable, and
- g) selected medical data and diet information relevant to medication therapy.

5.4.4 The pharmacist shall review medication orders, utilizing the patient's medication profile prior to releasing the medication and intervene when appropriate. It is the responsibility of the Pharmacy and Therapeutics Committee to prioritize the type of orders that must be reviewed prior to medication administration. For orders received after pharmacy hours or wardstock orders, where the patient profile and medication order review is not possible at time of dispensing, orders shall be reviewed and acted upon at the earliest opportunity.

## 5.5 Direct Patient Care

The pharmacist shall adopt the practice philosophy of pharmaceutical care in the provision of direct patient care to patients, by taking responsibility for the achievement of desired outcomes.

5.5.1 The pharmacist shall provide medication order reviews for all patients receiving medications. For selected patients, the pharmacist shall provide direct patient care, and identify patient using the following criteria:

- 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 such as geriatrics, pediatrics, or pregnant, 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 references,
- g) patients on Parenteral nutrition.

*(Refer to An Information Paper on Optimizing the Use of Limited Resources to Provide Pharmaceutical Care in CSHP Official Publications)*

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

*(Refer to the CSHP Information Paper on Pharmaceutical Care: Responsibility for Outcomes)*

5.5.3 The pharmacist should:

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

*(Refer to the CSHP An Information Paper on Documentation of Pharmaceutical Care in the Health Care Record)*

5.5.4 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 desired therapeutic outcomes,
- 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 of medication therapy or dosage.

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

## **5.6 Medication History Service**

5.6.1 The pharmacist shall review medication histories on selected patients or their agent, when needed. Patient consent to access the DPIN system to obtain medication histories, shall be documented, if not received upon admission.

Medication histories should include, but not be limited to the following:

- a) adverse drug reactions, allergies and sensitivities,
- b) past and currently prescribed medication including the name of the medication, dose, dosage form, frequency of administration, indication and duration of therapy.
- c) compliance with prescribed medication regimen, and
- d) non-prescription, herbal and homeopathic medication use.

5.6.2 The pharmacist should evaluate the information by correlating the history of medication use with the patient's present medical condition(s) and current medication regimen by assessing:

- a) the possibility of adverse drug reaction, including drug-induced disease and/or sensitivity,
- b) the potential for drug-drug, drug-food, or drug-lab test interaction,

- c) the presence of drug dependency,
- d) treatment failure due to non-compliance,
- e) the patient's knowledge of the medication therapy,
- f) other habits or practices which may lead to medication-related problems.

5.6.3 The pharmacist should resolve any problems or potential problems with the physician, in consultation with the patient.

5.6.4 The pharmacist should document medication histories, consultations and recommendations resulting from the evaluation process, in the patient's health record.

*(Refer to CSHP Guidelines for Documentation of Pharmacists' Activities in the Patient's Health Record)*

## **5.7 Medication Counselling**

5.7.1 The pharmacist shall counsel selected patients or their agents, individually or in groups, to provide specific information required for the safe and appropriate medication therapy and compliance.

5.7.2 Medication counselling should provide information 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,
- d) the correct use of special dosage forms,
- e) the proper scheduling of doses
- f) duration of therapy,
- g) action to be taken in the event of a dosage omission,
- h) instruction on proper storage of medication,
- i) a discussion of possible adverse drug reactions which may occur including measures to be taken to avoid their occurrence, their effects on normal activities and the appropriate action to be taken by the patient if an adverse reaction occurs,
- j) potential drug-drug or drug-food interactions or other therapeutic incompatibilities,
- k) prescription refill information, and
- l) other information unique to the specific patient or medication.

5.7.3 Patient counselling shall be provided in a confidential and private manner.

5.7.4 Verbal instructions should be supplemented with written information and other aids, (e.g. audiovisual and compliance aids), where appropriate.

5.7.5 The pharmacist should evaluate the effectiveness of counselling on the patient's medication knowledge through questioning and/or follow-up.

5.7.6 The pharmacist should document the occurrence of medication consultation and any drug-related problems, concerns or recommendations in the patient's health care record.

*(Refer to CSHP Guidelines for Documentation of Pharmacists' Activities in the Patient's Health Record)*

## **5.8 Documentation**

The pharmacist shall document directly in the patient's healthcare record activities and information pertaining to the drug therapy of the patient in accordance established hospital policy and procedure.

5.8.1 Activities and information to be documented should include but not limited to:

- a) medical history,
- b) recommendations for changes in medication selection, dosage, duration of therapy, and route of administration,

- c) recommendations for monitoring drug therapy including identification of clinical or laboratory tests,
- d) recommendations for monitoring the response to drug therapy.
- e) patient's physical assessment or clinical status
- f) consultations provided to other health-care professionals regarding the patient's medication therapy selection and management
- g) medication-related patient education and/or counselling provided.
- h) clarification of medication orders and physician's telephone orders received directly by the pharmacists.
- i) actual or potential drug-related problems that warrant surveillance,
- j) the provision of pharmaceutical care
- k) pharmacokinetic assessment of the drug therapy
- l) verbal orders subsequent to a discussion with prescriber

*(Refer to the CSHP An Information Paper on Documentation of Pharmaceutical Care in the Health Care Record)*

*(Refer to CSHP guidelines for Documentation of Pharmacists Activities in the Patient's Health Record)*

## **5.9 Seamless Care**

- 5.9.1 The pharmacist should become actively involved, with community pharmacists and other health care professionals, in the provision of seamless care to discharged patients to ensure continuity of care within the health care system.
- 5.9.2 The pharmacy should develop tools for information sharing (including profiles, care plans and communication systems) to facilitate the dissemination of relevant patient information and proper implementation of the treatment plan.
- 5.9.3 The information system should be time-efficient, standardized, and consistent, providing detailed information on changes made to drug therapy during hospitalization, reasons for changes, information on any potential or unresolved drug related problems, and suggestions for management and follow-up.
- 5.9.4 Co-operation is required of all members of the health care team and patients play a critical role. Prior to release of any information a patient consent form must be signed and patient confidentiality must be ensured.
- 5.9.5 Pharmacists may transfer written medication orders to community pharmacies verbally or by fax provided a proper written order, signed by the prescriber instructing a stated amount of drug is to be dispensed to a patient for a specific period of time beyond hospital stay. The order must be assigned a number and filed in a readily retrievable manner.

## **5.10 Collaborative Pharmacy Practice – (Implementation Stayed pending legislative changes)**

### **5.11 Clinical Assistants**

- 5.11.1 Pharmacists may consider registration as a Clinical Assistant in accordance with the Clinical Assistants Regulations to the Medical Act, to extend the ability of one or more supervising physicians to provide medical care to patients, particularly in remote isolated communities where medical and pharmacy services are limited.
- 5.11.2 Pharmacist(s) may apply for registration as a:
- a) Non-Certified Clinical Assistant by having completed a degree in pharmacy and licensed with the Manitoba Pharmaceutical Association or,
  - b) Certified Clinical Assistant by having graduated from a physician assistant training program and passed the examination set for physician assistants.
- 5.11.3 A pharmacist who becomes a clinical assistant must enter into a *contract of supervision* with one or more supervising physicians and a *practice description*, setting out the duties and function of the clinical assistant in relation to the physician's practice, must be submitted for approval to the College of Physician and Surgeons.

5.11.4 Pharmacists as Clinical assistants may issue prescriptions, which the supervising physician has determined the assistant is qualified to prescribe in accordance with the approved *practice description*.

## **6.0 NON-PATIENT CARE PHARMACY SERVICES**

### **6.1 Interdisciplinary Team Participation**

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

6.1.2 The pharmacist should contribute to the education of all health care professionals by participating or initiating in-services, seminar programs, information newsletters or bulletins and pharmacy student/intern or pharmacy technician student training programs.

### **6.2 Drug Use Evaluations**

6.2.1 The pharmacy department should 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.

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

6.2.3 Problems detected during the evaluation process should be communicated to the responsible bodies.

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

### **6.3 Drug Information Service**

6.3.1 The pharmacist shall provide drug information, including patient-specific drug information, to health care professionals and patients.

*(Refer to CSHP Guidelines on the Provision of Drug Information Services)*

6.3.2 The pharmacist shall select from the current drug literature those reference sources which will meet the drug information needs of their specific area of practice and the pharmacy shall have the latest editions of these reference materials.

*(Refer to the CSHP Recommended Drug Information References)*

6.3.3 The pharmacy should develop a system of classification and organization that facilitates the rapid retrieval of drug information.

6.3.4 The pharmacist shall provide information on medications and medication therapy when:

- a) providing information related to a specific patient's pharmacotherapy,

- b) attending patient rounds and patient-care conferences,\*
- c) responding to drug-related questions posed by staff or patients,
- d) recommending drug-related references for use by the hospital, and
- e) participation on the Pharmacy and Therapeutics Committee.

*\* Hospitals servicing <25 beds are exempt from attending patient rounds and patient-care conferences.*

6.3.5 The pharmacist shall evaluate and analyze relevant drug and therapeutic information in the literature and provide professional expertise and judgment in processing drug information requests by:

- a) obtaining necessary background information so that the request is received in a complete and understandable,
- b) interpreting the drug information request,
- c) systematically and thoroughly conducting a literature search,
- d) evaluating the literature in an accurate unbiased manner,
- e) formulating relevant, coherent and informative response, and
- f) communicating the response in a verbal and/or written format.

6.3.6 The pharmacist should provided drug information services through the preparation of newsletters, patient information handouts, seminars and in-service presentations.

6.3.7 Access to drug information services shall be available 24 hours a day, seven days a week. After hours drug information a designated pharmacist shall provide services or "pharmacy consultation". Where the pharmacy cannot provide on-call services, the pharmacist must make arrangements in advance for the provision of information services after hours and in their absence.

6.3.8 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.

#### **6.4 Self-Administration Programs**

6.4.1 The pharmacy service, in cooperation with the medical and nursing staff, shall develop policies and procedures approved by the hospital, regarding patient medication self-administration programs. The pharmacist shall be involved in the assessment, implementation, monitoring, and evaluation of the patient medication self-administration education program.

6.4.2 Self-administration of medications by patients shall be permitted when specifically ordered by the prescriber.

### **7.0 DRUG USE CONTROL**

#### **7.1 Formulary System**

**The pharmacy service, in cooperation with the Pharmacy and Therapeutics Committee, shall develop and maintain a formulary system, based on both the therapeutic and economic considerations of drug use, governing the selection and usage of medication in the hospital, or hospitals within a regional health authority.**

7.1.1 The formulary shall be approved by the appropriate hospital or regional hospital committee.(e.g. Regional Health Authority)

7.1.2 The formulary shall be available to all professionals prescribing, administering, or dispensing medications within the hospital.

7.1.3 The formulary shall be reviewed regularly, revised as necessary, and dated indicating date of last review or revision.

7.1.5 The minimum requirements for a hospital formulary are:

- a) a written list of selected drug products approved for use within the hospital, classified according to pharmacologic-therapeutic use,
- b) information about available dosage forms and strengths,
- c) information on the use of the formulary and its administration by the relevant hospital committees,
- d) policies and procedures governing the use of medications within the hospital.

7.1.6 A formal published hospital formulary should contain, in addition to the above information the following:

- a) a cross-index of selected medication products according to generic and trade names,
- b) aids for medication use, such as tables, dosing charts, and equivalency/comparison charts,
- c) a list of abbreviations and symbols approved for use within the hospital.

7.1.7 Policies and Procedures that shall be included in the formulary:

- a) formulary drug use
- b) non-formulary drug acquisition
- c) additions to the formulary
- d) deletions to the formulary
- e) use and store of patient's own medication
- f) medications for self-administration
- g) therapeutic substitution of drugs
- h) automatic stop orders
- i) sample use within the hospital
- j) emergency release drug acquisition
- k) investigational drug use
- l) restricted drug use

## 7.2 Drug Procurement

7.2.1 The pharmacist shall direct the purchasing of all medications within the institution, using professional judgment to ensure all medications are of acceptable quality and quantity.

7.2.2 The pharmacy manager shall ensure procedures are in place to obtain emergency supplies of medications, when needed.

## 7.3 Inventory Management

7.3.1 Policy and procedures shall be developed requiring incoming medication shipments to be delivered forthwith by authorized personnel to:

- a) the hospital pharmacy,
- b) the receiving area and subsequently delivered to the pharmacy,
- c) a secure storage area until such time as a pharmacist is on duty, or
- d) a secure medication storage area under the control of the pharmacist.

7.2.1 Policy and procedures shall be developed to ensure incoming medication shipments are received and stored in a secure manner until such time as required for distribution.

7.2.2 The pharmacist shall be responsible for maintaining records of all drug transactions, for at least two years to provide adequate inventory control and accountability.

7.2.3 The pharmacist shall maintain or be involved in maintaining an inventory control system to ensure:

- a) detection, segregation and proper disposal of outdated, deteriorated, recalled, obsolete or hazardous drugs,
- b) medication storage within the pharmacy and throughout the hospital is the responsibility of pharmacists,
- c) medications are stored under proper conditions of sanitation, temperature, light, humidity,
- d) ventilation, regulation and security.

e) access to medication storage areas is restricted to authorized personnel only.

7.3.5 Inventory control procedures should include, but not be limited to:

- a) the establishment of minimum and maximum stock levels,
- b) procedures to ensure proper stock rotation,
- c) accountability for medications as they are removed from stock,
- d) analysis and interpretation of medication usage trends and their economic impact.

7.3.6 Non-usable and expired medications shall be stored in a separate, secure area under the control of the pharmacy, until final disposal.

7.3.7 There shall be drug recall procedures that can be readily implemented and documented. All repackaged product that has been recalled, lacking lot numbers, shall be removed from all drug storage areas.

#### **7.4 Automated Medication Dispensers**

7.4.1 Pharmacies using automated dispensers shall ensure written policies and procedures are developed to ensure:

- a) a verification system to ensure the proper drug has been loaded into the appropriate cell.
  - i) a double check should occur when loading a cell and at least two people should be involved with the verification of contents.
  - ii) the verification is to be documented and initialed by all personnel involved in the loading process.
- b) drug name, strength, DIN, manufacturer, lot no. and expiry date are to appear on each cell.
- c) the DIN on the stock bottle and the displayed dosage form in the compartment must match the medication in the stock bottle.
- d) procedures are in place to separate placement of look-a-like drugs and drugs with multiple strengths to prevent medication errors.
- e) policies are in place regarding the practice of "topping up" cells and returning stock to cells.
- f) containers are to be empty of stock before being refilled to prevent a mixing of lot numbers and expiry dates and stock bearing different markings.
- g) stock lacking lot numbers and expiry dates are not to be returned to cells.
- h) stock with lot numbers and expiry dates are to undergo a double check procedure prior to being added to cells, and
- i) regular maintenance schedules should be in place to ensure proper functioning.

#### **7.5 Narcotic and Controlled Drugs**

7.5.1 Narcotic and controlled drugs shall be stored in a secure manner throughout the hospital. Access to all narcotic storage areas shall be kept to a minimum and restricted to authorized personnel only. Keys and safe combinations shall be strictly controlled.

7.5.2 Narcotic and controlled drugs stored in medication carts shall be in a locked drawer. The count book shall be stored out of sight when not in use, so as not to advertise narcotics are stored within. The entire medication cart should be locked whenever a nurse is not in direct attendance and when not in use, should be locked to the wall or inside a locked medication room.

7.5.3 Narcotics and controlled drugs stored in the medication room shall be in a locked cabinet, safe or drawer. The keys to medication room and narcotic storage site must be kept secure at all times, generally transferred directly from one charge nurse to another at shift end. Keys to the narcotic cabinet shall never be left unattended.

7.5.4 Narcotic and Controlled Drug Perpetual Inventory Records shall be maintained for all narcotic and controlled drug orders. Targeted substances, subject to abuse, should also be monitored on the running inventory. Completed inventory records shall be returned to the pharmacy forthwith.

- 7.5.5 Breakage, wastage, discontinued or out-dated Narcotic, Controlled and Targeted Substances, other than unserviceable injectables, shall be returned to the pharmacy for destruction where a pharmacist or supervised hospital employee will destroy the drugs in the presence of a second health care professional. Inventory records shall be maintained of all drugs returned for disposal, signed and where possible, co-signed by a second health care professional. For these purposes a health care professional is defined as the person in charge of the hospital, a pharmacist, practitioner, nurse, pharmacy intern, certified pharmacy technician or an inspector with the Manitoba Pharmaceutical Association.
- 7.5.6 Breakage, wastage of unserviceable injectables Narcotic, Controlled and Targeted Substances, such as partial ampoules, shall be destroyed by a health care professional. Inventory records shall be maintained of all drugs destroyed, signed and where possible, co-signed by a second healthcare professional. For these purposes a health care professional is defined as the person in charge of the hospital, a pharmacist, practitioner, nurse, pharmacy intern, certified pharmacy technician or an inspector with the Manitoba Pharmaceutical Association.
- 7.5.7 Physical counts of Narcotic and Controlled substances on the wards shall be performed and documented on the perpetual inventory record not less than once a week. The count shall be signed by the person conducting the count and, where possible, co-signed by another health care professional.
- 7.5.8 Physical counts of Narcotic and Controlled substances in the pharmacy shall be performed and documented on the perpetual inventory record quarterly. The count shall be signed by the person conducting the count and, where possible, countersigned by another health care professional.
- 7.5.9 Should discrepancies be identified during inventory counts, steps shall be initiated to identify the cause of the shortage, the responsible staff person and corrective actions documented. An incident report shall be completed and kept on record at the pharmacy. Significant shortages or diversion incidents must be reported to the pharmacy manager, the Manitoba Pharmaceutical Association and Health Canada.
- 7.5.10 Pharmacy shall ensure procedures are in place for Narcotic and Controlled substances to be delivered to the ward with the least amount of delay, safely, promptly, intact and placed in the proper storage area upon arrival to the patient care area and receipt thereof signed for by a registered nurse.

## **7.6 Drug Disposal**

- 7.6.1 Hospital pharmacy departments shall take responsibility, through policies and procedures, for environmental practices by efficiently managing the disposal of wastes in the pharmacy area. Handling and disposal procedures relating to pharmaceuticals shall be the responsibility of the director of pharmacy or a designate.
- 7.6.2 Every attempt shall be made to minimize the amount of pharmaceutical waste generated.
- 7.6.3 Pharmacists should investigate municipal and provincial legislation regarding disposal in sewers and landfills. All non-useable and expired medications shall be disposed of in accordance with professional standards and legal requirements. (*ie Dangerous Goods Handling and Transportation Act and Waste Reduction and Prevention Act*)
- 7.6.4 In developing recycling policies, pharmacist shall ensure that confidentiality of patient records is respected.
- 7.6.5 Pharmacists should investigate the existence of local recycling programs and monitor their availability as environmental management initiatives continually change.
- 7.6.6 Incineration shall be the preferred method of disposal as it results in the destruction of organic compounds, which includes the majority of pharmaceuticals.
- 7.6.7 Disposal of small amounts of unused pharmaceuticals or excreted pharmaceuticals and their metabolites into the sewer system should not present a hazard. However, the sewer system shall

not be excessively or indiscriminately used, as it may result in contamination of the water supply and disruption of the sewer processes.

7.6.8 Secure chemical landfills may be used to dispose of pharmaceuticals although this is the least desirable method of disposal.

7.6.9 Pharmaceuticals shall be disposed of in such a manner to render them unusable.

7.6.10 Disposal of Narcotics, Controlled and Targeted Substances shall be in accordance with federal legislation and prior approval from Health Canada. Destruction shall be conducted by two health care professionals under the supervision of a pharmacist. For these purposes a health care professional is defined as the person in charge of the hospital, a pharmacist, practitioner, nurse, pharmacy intern, certified pharmacy technician or an inspector with the Manitoba Pharmaceutical Association.

*(Refer to CSHP Guidelines for the Handling and Disposal of Hazardous Pharmaceutical)*

## **7.7 Drug Storage Site Inspections (see Appendix D - Drug Storage Site Audit)**

7.7.1 A minimum of quarterly inspections shall be completed, under the direction of the pharmacist, of all medication storage areas within the hospital. A written record shall verify:

- a) medications are stored securely on the ward and available to authorized personnel only.
- b) narcotic and controlled drugs are stored with proper measures of security,
- c) standards of neatness and cleanliness are consistent with good medication handling practices,
- d) reconstituted medications are properly labeled with expiry and preparation date,
- e) worn or illegible labels are replaced,
- f) liquid bottles are clean and free of spills,
- g) patient's own medications are stored securely and separately,
- h) disinfectants and drugs for external use are stored separately from internal and injectable medications,
- i) medications are stored properly and medications requiring special environmental conditions for stability are properly stored,
- j) non-pharmaceuticals are stored separately from medications in medication room fridge,
- k) multi-dose vials are dated upon first puncture,
- l) expired or obsolete medications are not stocked,
- m) medications no longer required are returned to the pharmacy,
- n) medications are not being overstocked,
- o) medications which may be required on an urgent or emergency basis are in adequate supply and readily available (Emergency Box, Crash Carts),
- p) medication room door/cart is closed when supervised and locked when unsupervised.

7.7.2 This record shall be distributed to the Nursing Administrator when policies and procedures are not adhered to.

## **7.8 Medication Distribution Service**

7.8.1 The pharmacy department shall develop and provide medication distribution services to meet the needs of the patients and to optimize safety, efficacy and economy. In designing the medication distribution system for an institution, the following methods to reduce the potential for medication error should be considered:

- a) reduce or eliminate transcription errors (ie. physician direct order entry),
- b) provide medication in identified dosage units ready for administration,
- c) eliminate medication cups and medication ticket as a means to store, identify and schedule medications and,
- d) minimizing the need to maintain ward stock.

The system shall also:

- a) utilize the original or direct copies of physician's orders (ie. self-copying order forms or faxed copies.
- b) protect medication from contamination,
- c) minimize nursing time required to prepare the medication prior to administration,
- d) provide a safe and effective method of recording medications at the time of administration.

## **7.8.2 Ward stock Distribution System**

Total Ward stock Distribution Systems are associated with the greatest potential for error, are poor from a drug control perspective and the least desirable form of drug distribution. Therefore, ward stock medications should be limited to those medications:

- a) commonly prescribed on a "as needed" basis,
- b) of low potential for toxicity,
- c) required on an urgent basis, and
- d) that are bulky in size.

7.8.2.1 The pharmacy shall establish a list with minimum and maximum levels of ward stock medications for each patient care area and that list shall be reviewed on an annual basis by the pharmacy.

7.8.2.2 Narcotic, controlled and targeted drugs provided as ward stock shall be maintained on a running inventory system.

7.8.2.3 Medications required on an urgent or emergency basis shall be readily available and stored appropriately. Procedures shall be established specifying individuals responsible For checking the emergency drug storage unit and replacing stock:

- a) after each use, and
- b) inspecting the unit quarterly for outdated product.

## **7.8.3 Traditional System (Individual Patient Prescription)**

Medications shall, be dispensed in individually labeled prescription containers. The amount of drug dispensed shall be determined by hospital policy. Medications shall be prepared for administration in a manner to minimize the potential for error. This would involve minimizing the number of transcription steps by eliminating patient identification cards/tickets and by using medication carts.

## **7.8.4 Controlled/Monitored Dose System**

Medications shall, when possible, be dispensed in individually labeled controlled dose cards/containers. The system shall be designed in order for each dose to be administered at a specific time directly from the medication card/container. Medication shall not be removed from the controlled dose package until it is to be administered. The amount of medication supplied shall be determined by hospital policy.

## **7.8.5 Unit Dose Medication System**

Medications shall, when possible, be dispensed in single unit-of-use labeled packages, removed from the package and administered directly to the patient. The number of doses supplied at any one time shall be determined by hospital policy.

7.8.5.1 Medication carts shall be used for medication storage on the ward. When applicable, medication drawers or bins shall be labeled in a manner so as to identify the patient and location and yet maintain patient confidentiality.

7.8.5.2 Policy and procedures must be in place whereby medications prepared by the pharmacy department, are delivered to the ward and verified by a nurse prior to administration to the patient.

### **7.8.6 Automated Medication Distribution System**

Medications shall, when possible, be dispensed in single unit-of-use labeled packages, removed from the package and administered directly to the patient.

7.8.6.1 Automated Dispensing Units shall be used for medication storage on the ward.

7.8.6.2 Policy and procedures must be in place whereby medication prepared by the pharmacy department is delivered to the ward and verified by a nurse prior to administration to the patient.

### **7.9 Patient's Own Medication**

7.9.1 The pharmacy shall develop policies and procedures with respect to the use of patient's own medications, and the return of patient's medications to the patient upon discharge.

7.9.2 Medications brought to the hospital by the patient shall not be administered unless written orders to administer the medication are given by the prescriber. The medication must be examined by a pharmacist with respect to identity and integrity at the earliest opportunity and a mark or initial placed on the container indicating the product has been checked.

7.9.3 Where the identification of herbal remedies, homeopathic medicines or other alternative therapies is impossible, concerns in regards to product safety, efficacy, quality and possible drug interactions exist. Pharmacists are encouraged to use the pharmaceutical care approach and consider the patient's overall care and anticipated outcome, instead of considering the medicinal product alone.

7.9.4 A pharmacist upon determining a patient's own medication cannot be identified and dispensed, the pharmacist shall communicate this decision to the prescriber and provide factual unbiased information about the medicinal product as required.

7.9.5 Patient's own medication not used during their stay, shall be stored in a secure manner, separate from hospital medication storage areas.

7.9.6 Hospital policies and procedures shall be developed specifying which medications (ie. creams, drops etc.) may be given to patients upon discharge and which medications are not to be given to patients upon discharge. Medications not sent with the patient shall be returned to the pharmacy for destruction in accordance with hospital policy.

### **7.10 Alcoholic Substance Control**

7.10.1 Policies and procedures shall be established regarding the use, control, distribution and storage of alcoholic substances for compounding and dispensing within the institution. Policies with respect to the beverage alcohol need not preclude patient's from bringing in their own supply, but must state:

- a) written orders must be received from the physician prior to administration to the patient,
- b) the information is placed on the patient's medication profile,
- c) pharmacy must obtain a special Manitoba Liquor Control Commission permit for alcohol purchased by the hospital for patients,
- d) patient's own alcohol is to be returned to the patient upon discharge or sent to the pharmacy for disposal.

### **7.11 Drug Samples**

7.11.1 The use of sample medications in the hospital shall be discouraged. If sample medications are

brought into the hospital, they shall be controlled, stored and distributed by the pharmacy.

## **7.12 Investigational Drugs**

7.12.1 Investigational drugs shall be:

- a) stored in, and distributed by the pharmacy,
- b) approved for use by the appropriate hospital committee,
- c) used according to an approved protocol, under the direct supervision of the principal investigator,
- d) dispensed on the receipt of a written order from the authorized investigator,
- e) administered by personnel only after they have received appropriate information on the drug.

7.12.2 The pharmacy shall develop policies and procedures, which address the approval process, handling, and record keeping requirements for investigational drugs.

7.12.3 The pharmacy shall maintain drug information on all investigational drugs prescribed in the hospital.

*(Refer to CSHP Guidelines for the Use of Investigational Drugs in Hospitals)*

## **7.13 Special Access Drugs (Emergency Release Drugs)**

7.13.1 Emergency release drugs shall be:

- a) stored in, and distributed by the pharmacy,
- b) approved for use by the appropriate hospital committee,
- c) dispensed on the receipt of a written order,
- d) used according to an approved protocol,
- e) administered by personnel only after they have received appropriate information on the drug.

7.13.2 The pharmacy shall develop policies and procedures which address the approval process, acquisition, handling, and record keeping requirements for emergency release drugs.

7.13.3 Pharmacy shall maintain drug information on all Special Access Drugs prescribed in the hospital.

*(Refer to the Compendium of Pharmaceuticals and Specialties, Clin-Info L-19)*

## **8.0 DISPENSING**

8.1 Dispensing shall be restricted to the pharmacist or pharmacy technicians under the direction and supervision of the pharmacist.

8.2 An automatic stop-order procedure shall be developed for antibiotics, narcotics and other classes of drugs for which a limited duration of therapy is desirable. There shall be a system in place to notify the physician of the impending expiration of a medication to ensure the appropriate patient reassessment is completed.

8.3 Stat orders shall be processed and dispensed according to specific written procedures in accordance with hospital policy.

8.4 The pharmacist may substitute therapeutically equivalent products without consulting with the prescriber provided the substitution has been approved by the Pharmacy and Therapeutics Committee. (i.e. therapeutic interchange, equivalent oral dosage form substitution, dosage interval substitution, etc.)

## **9.0 MEDICATION LABELING**

### **9.1 Inpatient Medication**

There shall be standardized format, terminology, metric units, and generic labeling on all inpatient medication labels. A list of abbreviations and symbols approved by the Pharmacy and Therapeutics committee for use within the facility shall be readily available in the hospital formulary to all professionals prescribing, dispensing or administering medications.

9.2 Medication labels shall be typed or machine printed, shall be free from erasures and strikeovers and firmly affixed to the container. Only pharmacy personnel shall alter medication labels.

9.3 Other labeling considerations should include, when appropriate:

- a) acceptable route of administration for Parenteral medications
- b) directions for medications requiring dilution or reconstitution
- c) dosage, frequency and/or flow rate
- d) drug classification
- e) expiration
- f) lot numbers or codes for repackaged medications
- g) proper storage conditions
- h) accessory or cautionary statements

**9.4 Ward stock medications** not provided in the original manufacturer's packaging shall be labeled with, but not limited to:

- a) pharmacy name and address
- b) drug and strength
- c) lot number and expiry date

**9.5 Individual Patient Prescriptions** shall be labeled with, but not limited to:

- a) pharmacy name and address
- b) patient name and location
- c) drug and strength
- d) date dispensed

**9.6 Controlled/Monitored Dose** blister cards/containers shall be labeled with, but not limited to:

- a) pharmacy name and address
- b) patients name and location
- c) drug and strength
- d) date dispensed

**9.7 Unit-of-Use packages** shall be labeled with, but not limited to:

- a) drug and strength
- b) lot number and expiry date

### **9.8 Outpatient Prescription**

All medications leaving the institution, such as outpatients, staff and/or prescriptions to the general public, shall be labeled and dispensed in accordance with Standards of Practice for Community Pharmacies and respective of Section 19(1) and 25 of the Pharmaceutical Act Regulations regarding labeling and child resistant containers.

### **9.9 After Hours Cart/Cabinet Medication Labeling**

9.9.1 Medications for in-patient use only, shall be labeled in accordance with inpatient medication labeling requirements.

9.9.2 Emergency outpatient starter packs supplied from the After Hours Cabinet shall be labeled and dispensed according to the standards for community pharmacy practice.

*(see Section 13 - Emergency Department Outpatient Medications)*

## 10.0 DELIVERY

- 10.1 Medications shall be delivered with the least amount of delay, safely, promptly, intact and placed in the proper storage areas upon arrival to the patient care areas. All parts of the transportation process shall protect medications from pilferage and breakage.
- 10.2 When appropriate special procedures for delivery of selected medications (i.e. narcotics, controlled, investigations drugs, TPN solutions and IV admixtures, chemotherapy admixtures shall be established.

## 11.0 Return of Medications

- 11.1 Medication distributed from the pharmacy, but no longer required, shall be returned to the pharmacy.
- 11.2 Procedures for returning medications to stock shall be developed. Medications must not be returned to stock unless integrity of the medication and proper storage of the medication in the patient care area is confirmed.
- 11.3 All topical, liquid or injectable medication shall not be re-dispensed upon return to the pharmacy unless the previously dispensed product is in a sealed dosage unit. The following medications shall be discarded upon return to the pharmacy:
- a) opened ophthalmic/otic/nasal drops/ointments
  - b) opened creams, ointments, lotions
  - c) opened liquid medications
  - d) used inhalation products, unless cleaned and sterilized
  - e) opened multi-dose and single-dose vials
  - f) used IV admixtures
  - g) medications handled by patients
  - h) medications returned by ambulatory patients

## 12.0 IN-PATIENT PASS MEDICATIONS

- 12.1 Every attempt shall be made administer medications just prior to leaving and/or upon return to the institution. Failing this the pharmacy shall be notified 24 hours in advance in order for medications to be repackaged in accordance with regulation. Where advance notice is not possible, medications may be repackaged on the ward provided packaging and labeling requirements are maintained.
- 12.2 Procedures shall be developed to ensure leave of absence/pass medications are prepared correctly and in accordance with section 19(1) of the Pharmaceutical Act Regulations. The label shall include:
- a) Pharmacy name and address
  - b) PASS MEDICATION (Optional)
  - c) Patient:\_\_\_\_\_ Prescriber:\_\_\_\_\_
  - d) Instructions for use
  - e) Drug, strength and manufacturer
  - f) Date:\_\_\_\_\_ Price: \$0.00
  - g) Initials of staff member checking the medications
- 12.3 Pass medications shall be dispensed in child resistant containers in accordance with Section 25 of the Regulations to the Pharmaceutical Act. The prescriber, patient or person acting on their behalf may declare they do not want a child resistant container. The person providing the prescription shall inform the patient/caregiver and make the appropriate documentation in the patient care record.

12.4 Hospital policy shall indicate the ultimate responsibility for verifying the accuracy of all pass medications repackaged on the ward, prior to release to the patient, rests with the prescriber unless a Delegation of Functions Agreement has been signed. (See Section 17 and Appendix E)

12.5 The provision of all leave of absence/pass medications shall be documented in the patient care record.

### **13.0 Emergency Outpatient Medications**

13.1 Emergency patients in urgent need of medications, who are unable to have prescriptions filled within a reasonable time frame, may be provided with sufficient quantities of medication until such time as the prescription can be filled at another pharmacy.

13.2 The pharmacy department shall prepackage the medication and place the following information on the label in accordance with section 19(1) and 25 of the Pharmaceutical Act Regulations. Nurses may assist by filling in the blanks on the label, however the final check of the medication prior to its release to the patient rests with the prescriber unless a Delegation of Functions Agreement has been signed. (See Section 17 and Appendix E)  
The label shall include:

- a) Pharmacy name and address
- b) EMERGENCY OUTPATIENT SUPPLY (Optional)
- c) Patient: \_\_\_\_\_ Prescriber: \_\_\_\_\_
- d) Instructions for use
- e) Drug, strength and manufacturer
- f) Date: \_\_\_\_\_ Price: \$0.00 or amount, if applicable
- g) Initials of staff member checking the medication

13.3 Should a price be charged for emergency outpatient starter packs, a receipt shall be made available to enable patients to seek reimbursement if desired, in accordance with the Prescription Drug Cost Assistance Act.

13.4 Emergency outpatient medications shall be dispensed in child resistant containers in accordance with Section 25 of the Regulations to the *Pharmaceutical Act*. The prescriber, patient or person acting on their behalf may declare they do not want a child resistant container. The person providing the prescription shall inform the patient/caregiver and make the appropriate documentation in the patient care record.

13.5 The provision of emergency outpatient medications shall be documented in the patient care record.

13.6 Sales reportable narcotic and controlled drugs shall not be dispensed as emergency outpatient medications.

13.7 Emergency outpatient medications shall be stored securely in a suitable locked cabinet or cart and present in appropriate quantities, clearly separated from other medications.

13.8 Hospital policy shall indicate the ultimate responsibility for verifying the accuracy of all Emergency Outpatient medications rests with the prescriber unless a Delegation of Functions Agreement has been signed. (See Section 17 and Appendix E)

### **14.0 MEDICATION PREPARATIONS**

14.1 The pharmacist shall be responsible for all medication preparation ensuring established policies and procedures are used in the preparation of repackaged or compounded creams, ointments; sterile compounds such as eye drops; and sterile products like TPN, IV admixtures and Cytotoxic drugs.

14.1.2 The pharmacist shall have knowledge of the ingredients, equipment, possible problems such as compatibility and stability, and correct technique needed to compound sterile and non-sterile extemporaneous prescriptions.

14.1.3 Hospital pharmacies may enter into service provider arrangements with other hospitals or community pharmacies (within the same province) for non-commercially available products in accordance to *Health Canada's Policy Framework on Manufacturing and Compounding of Drug Products in Canada*. A formal

agreement must be signed between the pharmacies, stipulating respect for the Standards of Practice and the patient population to be served. Services may include repackaging, the preparation compounded and/or sterile drug products.

## 14.2 Repackaging Medications

The pharmacy department shall, when necessary, repackage medications in ready to administer or ready to use units, for use within the medication distribution system. All repackaging shall be conducted under the direction of a pharmacist.

14.2.1 Written policies and procedures for repackaging and labeling shall be in place to minimize:

- a) the potential for contamination of the drug and packaging,
- b) health and safety concerns of staff, (i.e. Cytotoxic drugs), and
- c) the potential for the addition of any extraneous material

14.2.2 Repackaging records should be maintained for multiple units, not for immediate use, prepared in anticipation of an order. Records shall be kept for a period of one year after the expiry date of the repackaged product. The repackaging record shall include:

- a) drug name and strength
- b) dosage form
- c) manufacturer
- d) pharmacy control number or manufacturer's lot number
- e) date of repackaging
- f) expiry date
- g) number of units repackaged
- h) quantity in repackaged unit
- i) initials of pharmacy personnel that did repackaging and checking

14.2.4 The label of the finished repackaged medication shall include:

- a) hospital name and address
- b) drug name and strength
- c) dosage form
- d) quantity
- e) manufacturer identification
- f) expiry date
- g) lot no. or pharmacy control no.

14.2.5 Other labeling considerations should include, when appropriate:

- a) directions for medications requiring dilution or reconstitution
- b) proper storage conditions
- c) auxiliary labels, accessory or cautionary statements

14.2.6 The packaging of the finished product shall:

- a) be appropriate for the dosage form,
- b) protect the product from light and moisture, as necessary
- c) minimize the potential for interaction between drug and container.

14.2.7 Repackaged pharmaceuticals shall not be repackaged more than once due to the lack of stability information and the difficulty in tracking repackaged doses.

*(Refer to CSHP Guidelines for Repackaging Products in Health Care Facilities)*

## 14.3 Compounding

Compounding falls within the professional scope of practice of pharmacists. Pharmacists are therefore not expected to comply with the Good Manufacturing Practices or meet the requirements of the Establishment

Licensing Framework, as long as they are compounding and not manufacturing. While compounding is regulated by the provincial regulatory authorities, manufacturing is regulated by Health Canada, which requires the full provision of the Food and Drug Act to be applied to any pharmacy that:

- a) promotes or advertises that it compounds specific drugs or drug classes,
- b) compounds products intended for distribution outside the established pharmacist/patient/prescriber relationship and/or
- c) compounds inordinate amounts of product in anticipation of receiving prescriptions.

14.3.1 Patients should continue to have access to individualized drug therapy, which in some cases requires custom compounded medications. The pharmacy service should, when necessary, compound dosage forms, dosage strengths, and sterile medication products required to meet the anticipated needs of their patient population. Based on the existence of a pharmacist/patient/prescriber relationship and the presentation of a valid prescription, pharmacists should compound, in reasonable quantities, drug products that are not commercially available in the market place.

14.3.2 Pharmacists may compound drugs, prior to receiving a valid prescription, in quantities based on routine, regularly observed prescribing patterns provided a history of receiving a valid prescription exists and provided prescription files are maintained. The compounding of inordinate amounts of drugs in anticipation of receiving prescriptions without any historical basis is considered manufacturing and, an Establishment License is required, a DIN must be obtained and all the Regulations of the Food and Drug Act pertaining to labeling and GMP must be met.

14.3.3 The pharmacist is responsible for:

- a) reading and interpreting the written prescription,
- b) determining if more information is needed before the prescription can be filled,
- c) contacting the patient and/or prescriber, if needed and documenting any discussion(s),
- d) identifying the use of the product for the patient,
- e) locating the source of formulas through knowledge of standard reference sources,
- f) using resources to determine whether there are any physical or chemical incompatibilities,
- g) calculating the required quantities of all ingredients,
- h) knowing the medicinal and pharmaceutical function of each ingredient,
- i) verifying the dosage calculations for each order and patient condition,
- j) developing policies and procedures to compound prescriptions,
- k) using the appropriate equipment and techniques to compound the prescription (prescription balances, dilution techniques, trituration and levigation)
- l) ensuring proper maintenance, cleanliness and use of all equipment used in prescription compounding process,
- m) labeling the prescription in accordance to the regulations to the Manitoba Pharmaceutical Act,
- n) attaching auxiliary label(s) when appropriate (ie. swallow whole, refrigerate, shake well, external use only),
- o) determining stability and expiry date of compounded preparations,
- p) choosing the appropriate container and closures for compounded products,
- q) determining the storage conditions appropriate for the product,
- r) inspecting, approving or rejecting all drug components and processing materials,
- s) preparing and reviewing all records to ensure no errors have occurred in the compounding process,
- t) ensuring quality control procedures are in place.

14.3.4 Pharmacists should be knowledgeable in the preparation of the following:

- a) solutions
- b) suspensions
- c) emulsions
- d) ointments
- e) creams
- f) pastes

- g) colloids/keratolytics
- h) dermatologicals
- i) suppositories

#### **14.3.5 Personnel**

All pharmacists who engage in the compounding of drugs shall be proficient in the art of compounding by possessing the knowledge, experience and ability to assume the responsibility. Pharmacists shall maintain that proficiency through continuing competency and training programs.

14.3.6 All compounding shall be conducted by the pharmacist or under the direction of a pharmacist using technical personnel, when applicable, who have received the proper training.

14.3.7 All completed products prepared by technical personnel shall be checked by the pharmacist or certified technician checker, in accordance with the regulations to the Pharmaceutical Act of Manitoba to ensure:

- a) the correct medication and quantity has been added to the appropriate products,
- b) all completed compounds are inspected for particulate matter, signs of degradation, incompatibilities, or contamination,
- c) the appropriate information has been included on the label,
- d) the correct label has been affixed to the completed product.

14.3.8 The hygiene of all personnel participating in compounding should be guided by policy and procedures. Any person shown at any time (either by medical exam or pharmacist determination) to have an apparent illness or open lesion(s) that may adversely affect the safety or quality of the drug product being compounded shall be excluded from direct contact until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of the product(s).

#### **14.3.9 Apparel**

Personnel engaged in compounding shall wear clean clothing appropriate to the operation being performed. Protective apparel, such as lab coats/jackets, apron or gloves shall be worn as necessary to protect drug products from contamination during processing or packaging and to help protect employees.

#### **14.3.10 Area**

Pharmacies engaging in compounding shall have a specifically designated area for the orderly placement of equipment and materials to be used. The compounding area for sterile products shall be separate and distinct from the area used for compounding of non-sterile drug products. The area designated for compounding shall be:

- a) maintained in a clean, sanitary condition,
- b) permit effective cleaning of all surfaces
- c) conducive to the orderly flow of work.
- d) in a good state of repair to minimize the potential for contamination of the drug or the addition of any extraneous material to the product.

14.3.11 Only personnel authorized by the responsible pharmacist shall be permitted in the immediate vicinity of the drug compounding operation/area.

14.3.12 Adequate lighting and ventilation shall be provided in all drug compounding areas. Fresh distilled water or boiled water shall be used in compounding and reconstitution. Adequate washing facilities, easily accessible to the compounding area of the pharmacy shall be readily available. These facilities shall include, but not be limited to, hot and cold water, soap or detergent, air-driers or single use towels. Trash shall be held and disposed of in a timely and sanitary manner.

### **14.3.13 Equipment**

Equipment used in compounding of drug products should be of appropriate design, composition, size and suitably located to facilitate operations for its intended use, cleaning and maintenance. Equipment and utensils used for compounding should be cleaned and sanitized to prevent contamination that would alter safety, quality and purity of the drug compound.

14.3.14 Automatic, mechanical, or electronic equipment, or other types of equipment or related systems that perform the function satisfactorily may be used in the compounding process. Each piece of equipment used, shall be routinely inspected, subject to preventative maintenance procedures, or checked regularly for proper functioning and calibration to ensure proper performance. Routine equipment maintenance, calibration, and certification should be defined, carried out and documented.

14.3.15 The equipment used in compounding should:

- a) permit effective cleaning,
- b) minimize the potential for contamination of the drug
- c) minimize the potential for the addition of any extraneous material,
- d) be operated only for its intended use.

### **14.3.16 Special Precaution Products**

When drug products with special precautions for contamination, such as penicillin or anti-neoplastics, are involved in compounding, appropriate measures, including dedicated equipment or meticulous cleaning of contaminated equipment prior to its return to inventory, must be used to prevent cross-contamination.

### **14.3.17 Raw Materials**

Bulk drugs and other materials used in the compounding of drugs must be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration. Drug components shall be received, handled and stored in a manner to prevent contamination of product and staff in accordance with official compendia WHMIS Guidelines. Material Safety Data Sheets (MSDS) area available from manufacturers with detailed information on safe use and employee protection.

14.3.18 Bagged or boxed raw materials used in compounding of drugs shall be stored in such a manner as to permit cleaning and inspection.

14.3.19 Drug substances for compounding must be made in licensed establishments approved by Health Canada.

### **14.3.20 Policies and Procedures**

Policies and procedures shall be in place to minimize:

- a) the potential for contamination of the compound and packaging,
- b) health and safety concerns of staff (i.e. Cytotoxic drugs), and
- c) the potential for the addition of any extraneous material.

14.3.21 Written procedures should be in place for the compounding of drug products to ensure that the end product will meet the specifications for that product such as identity, strength, quality, and purity.

Such procedures shall include a listing of ingredients, with respect to amounts in weight or volume, the order of addition, and description of the compounding process. Equipment and utensils and container and closure type, relevant to the sterility and stability of the intended use of the drug shall be listed. These written procedures shall be followed in the execution of the drug compounding process.

14.3.22 Each ingredient shall be accurately weighed, measured, or subdivided as appropriate. The compounding pharmacist shall assume responsibility for the final check and carry out or delegate appropriate checks at critical steps in the process to ensure that each weight or volume is correct as stated in the written compounding procedures.

14.3.23 If an ingredient is removed from an original container to another container, the new container shall be identified with the ingredient name, weight or volume.

14.3.24 To assure reasonable uniformity and integrity of compounding products, written procedures shall be established and followed, that describe the tests or examinations to be conducted on products being compounded (ie. compounding of capsules). Such procedures that may be responsible for causing variability in the final product include, but are not limited to:

- a) capsule weight variation
- b) sufficient mixing of ingredients to ensure uniformity
- c) clarity, completeness or pH of solutions

14.3.25 Policies and procedures shall be in place to minimize:

- a) the potential for contamination of the compound and packaging,
- b) health and safety concerns of staff (i.e. Cytotoxic drugs)
- c) the potential for the addition of any extraneous material

14.3.26 Policies and procedures for use and maintenance of such equipment should be in readily available.

14.3.27 Written procedures for cleaning the compounding area should include:

- a) the cleaning interval
- b) cleaning agents and their concentration, and
- c) disposal of waste material and debris

#### **14.3.28 Labeling**

The label of the finished compound shall contain the following information prior to dispensing:

- a) hospital name and address
- b) compound name and strength
- c) quantity and dosage form
- d) lot no., batch no. or pharmacy control no.
- e) preparation date and time, if applicable
- f) expiration date

14.3.29 Other labeling considerations shall include, when appropriate:

- a) directions for medications requiring dilution or reconstitution
- b) proper storage conditions
- c) auxiliary labels, accessory or cautionary statements

14.3.30 In cases where a quantity of compounded drug product is prepared in excess of that dispensed, the excess product shall be referenced to a complete list of ingredients or labeled with a complete list of ingredients, and the following information:

- a) compound name,
- b) preparation date, and
- c) assigned expiry date

#### **14.3.31 Packaging**

Containers and closures used in compounding shall be handled and stored in a manner to prevent contamination. Bagged or boxed containers and closures used in the compounding of drugs shall be stored off the floor in such a manner as to permit cleaning and inspection.

14.3.32 Drug product containers and closures shall not be reactive, additive or absorptive so as to alter the safety, identity, strength, quality or purity of the compounded product beyond the desired result. Container and closures shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug product. Drug product containers and closures shall be clean, and where indicated sterilized and processed to remove pyrogenic properties to ensure that they are suitable for their intended use.

#### 14.3.33 End Product Testing for Non-sterile Products (Under review)

#### 14.3.34 Storage

The storage of compounded products made in anticipation of a prescription order and where a quantity of compounded drug product is prepared in excess of that dispensed, the product shall be stored and accounted for under conditions dictated by its composition and stability characteristics (ie. clean, dry place on a shelf or in the refrigerator) to ensure its strength, quality and purity.

#### 14.3.35 Expiration date

Expiration dates should be derived using any of the following:

- d) the manufacturer's expiry date of the product with the shortest expiration,
- e) pharmaceutical compendia
- f) professional literature
- g) in-house stability and/or sterility studies

#### 14.3.36 Documentation

All records to be maintained in compliance with these standards shall be readily available for inspection during the retention period at the establishment where the activities described in the record occurred.

14.3.36.1 A **master formula** shall be kept for each compounded product prepared in anticipation of a prescriber's prescription. The master formula should indicate:

- a) compound name and strength
- b) name, manufacturer and lot no. of each raw material
- c) quantity and dosage form
- d) formulations stating:
  - i. weights and measures of each raw material, and
  - ii. theoretical yield,
- e) source of the formula, if available
- f) equipment required
- g) description of each step and equipment used in the compounding process
- h) which steps or measurements must be verified by a pharmacist or a second person,
- i) expiry date
- j) stability data, if available.
- k) storage requirements
- l) prepared by/check by initials
- m) specific packaging requirements
- n) sample label, including auxiliary labels when applicable,
- o) usual dosage range
- p) advice for the patient
- q) quality control testing to be performed, when applicable.

14.3.36.2 A **production record** shall be maintained for each batch of a compound prepared in anticipation of a prescriber's order. Production records shall be kept for a period of one year after the expiry date

of the compounded product. The production record should indicate:

- a) compound name and strength,
- b) name, strength, manufacturer and lot no. of each raw material
- c) preparation date
- d) expiry date of the product with the shortest expiration date
- e) final yield
- f) expiry date of the finished product
- g) check off of each step in the compounding process
- h) initials of pharmacy personnel compounding and checking
- i) lot. no, batch no. or pharmacy control no. assigned to compound
- j) results of all quality control or end product testing

14.3.37 Documentation of personnel validations tests, environmental monitoring, cleaning and maintenance procedures should be kept and reviewed on a regular basis.

#### **14.4 Sterile Product Preparation**

The pharmacy department should aseptically prepare sterile drug products required to meet the specific needs of their patient population. All sterile product preparation in the pharmacy shall be conducted under the direction and supervision of the pharmacist and in accordance with CSHP Guidelines for Preparation of Sterile Products in Pharmacies.

##### **14.4.1 Personnel**

A pharmacist with sufficient training and/or experience shall supervise sterile product preparation and should be knowledgeable in the following areas:

- a) aseptic technique and contamination factors
- b) environmental monitoring, equipment and supplies,
- c) parenteral routes of drug administration
- d) methods and equipment for administration of drugs
- e) preparation, compounding, distribution and storage of sterile products,
- f) quality control testing procedures
- g) sterilization techniques and process validation
- h) chemical, pharmaceutical and clinical properties of ingredients in sterile products

14.4.2 The pharmacist shall ensure:

- a) the dosage calculations are correct for all orders
- b) stability and compatibility of contents
- c) quality control procedures are in place

14.4.3 The pharmacist shall be responsible for the training and evaluation of technicians involved in sterile product preparation. Technicians shall receive suitable didactic and practical training in aseptic technique, proper gowning and gloving and preparation area procedure, and demonstrate competency through written and practical evaluation.

14.4.4 The pharmacist retains the responsibility for the delegated function. The decision whether a pharmacy technician may safely assume a delegated function ultimately rests with the pharmacist. Therefore all sterile products prepared by technical personnel shall be checked by the pharmacist or certified technician checker, in accordance with the regulations to the Pharmaceutical Act of Manitoba to ensure:

- a) the correct medication and quantity has been added to the appropriate products
- b) all completed parenteral solutions are inspected for particulate matter, signs of degradation, incompatibilities, or contamination,
- c) the appropriate information has been included on the label,

d) the correct label has been affixed to the completed product.

#### **14.4.5 Apparel**

Special clean, low particulate generating disposable garments, with a solid front, back closing, long sleeves, tight fitting cuffs and neck shall be worn. Personnel shall also remove wristwatches, and jewelry and wash their hands and arms up to the elbows with antimicrobial skin cleanser. Sterile, powder free gloves shall be worn and disinfected regularly with 70% isopropyl alcohol. Gloves shall be changed after each session or when their integrity has been compromised. Head and facial hair coverings are to be used, covering the ears and all the hair to minimize particulate shedding. Face masks are optional if working in a hood with a vertical glass barrier.

14.4.6 Garments shall be donned prior to entering the aseptic preparation area and removed upon exiting the area. The garments shall not be worn outside the preparation area.

#### **14.4.7 Area**

An area shall be dedicated solely to the preparation of sterile products. This area must have limited access, be secluded from general traffic to minimize air turbulence, be well lit, with nonporous washable floors, walls and counters. Untrained personnel shall not enter the aseptic preparation area unless they are supervised and informed of procedures to follow to maintain the aseptic environment.

14.4.8 All work surfaces shall be cleaned and disinfected after each hood start up and daily before and after each production sequence with water for injection or irrigation and a small amount of cleaner and disinfected with 70% isopropyl alcohol before each aseptic manipulation.

#### **14.4.9 Equipment**

All sterile products shall be prepared in a Grade A, horizontal or vertical laminar air flow hood (capable of maintaining a Class 100 environment) equipped with a HEPA filter to prevent contamination with microorganisms and particulate matter. The hood should be kept running continuously. If turned off, it should not be used for at least 30 minutes after being turned on, or as specified by the manufacturer. A qualified technician shall certify the hood at least annually.

14.4.10 Ingredients and vehicles shall be checked for defects, expiration date and damage before use. All materials essential for processing should be placed in the hood prior to processing. Drugs, containers, equipment such as tubing and filters etc., which come in direct contact with the sterile preparation area shall be properly disinfected with alcohol or other suitable antimicrobial agent before introduction into the critical area.

14.4.11 Activities and materials shall be arranged in the hood so as not to interrupt the airflow. All processing shall occur 15 cm. inside the hood or within the limits specified by the manufacturer. The number of manipulations required for the production of the sterile product shall be kept to a minimum.

#### **14.4.12 Policies and Procedures**

The pharmacy shall prepare written policies and procedures regarding all aspects of sterile product preparation and be responsible for adherence to these policies and procedures. Policies should include but not be limited to:

- a) medication information
- b) protective apparel and equipment
- c) handling technique training
- d) receiving and shipping
- e) preparation
- f) drug administration
- g) storage

- h) labeling
- i) transportation
- j) waste collection and disposal

14.4.13 Methods of cleaning, sterilizing, and processing to remove pyrogenic properties shall be written and followed for drug product containers and closures used in the preparation of sterile pharmaceuticals.

14.4.14 Quality assurance policies and procedures shall be developed and include appropriate sterility testing to evaluate the efficacy of the laminar air flow hood and performance of aseptic technique.

#### **14.4.15 Labeling**

The label of the finished compound shall contain the following information prior to dispensing:

- a) hospital name and address
- b) compound name and strength
- c) quantity and dosage form
- d) route and rate of administration, when applicable
- e) lot no., batch no. or pharmacy control no.
- f) preparation date and time, if applicable
- g) expiration date and time, when applicable

14.4.16 Other labeling considerations shall include, when appropriate:

- a) directions for medications requiring dilution or reconstitution
- b) proper storage conditions
- c) auxiliary labels, accessory or cautionary statements,

14.4.17 In cases where a quantity of compounded drug product is prepared in excess of that dispensed, the excess product shall be referenced to a complete list of ingredients or labeled with a complete list of ingredients, and the following information:

- a) compound name,
- b) preparation date, and
- c) expiration date

#### **14.4.18 Packaging**

Containers and closures used in compounding shall be handled and stored in a manner to prevent contamination. Bagged or boxed containers and closures used in the compounding of drugs shall be stored off the floor in such a manner as to permit cleaning and inspection.

14.4.19 Drug product containers and closures shall not be reactive, additive or absorptive so as to alter the safety, identity, strength, quality or purity of the compounded product beyond the desired result.

14.4.20 Container and closures shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination or the compounded drug product. Drug product containers and closures shall be clean, and where indicated sterilized and processed to remove pyrogenic properties to ensure that they are suitable for their intended use.

#### **14.4.21 End Product Testing for Sterile Products**

Quality assurance sterility testing should be implemented to evaluate the efficacy of the laminar air flow hood and performance of aseptic technique. Sterility tests should be performed randomly on compounded sterile products.

#### **14.4.22 Storage**

The storage of compounded products made in anticipation of a prescription order and where a quantity of compounded drug product is prepared in excess of that dispensed, the product shall be stored and accounted for under conditions dictated by its composition and stability characteristics (ie. clean, dry place on a shelf or in the refrigerator) to ensure its strength, quality and purity.

#### 14.4.23 Expiration Date

Expiration periods shall be established for each type of sterile product, derived using any or all of the following references:

- a) manufacturer's recommendations
- b) pharmaceutical compendia
- c) professional literature
- d) in-house stability and/or sterility studies

#### 14.4.24 Documentation

All records to be maintained in compliance with these standards shall be readily available for inspection during the retention period at the establishment where the activities described in the record occurred.

14.4.25 A **master formula** shall be kept for each sterile product prepared in anticipation of a prescriber's prescription. The master formula should indicate:

- a) compound name and strength
- b) name, manufacturer and lot no. of each raw material
- c) quantity and dosage form
- d) formulations stating:
  - e) weights and measures of each raw material, and
  - f) theoretical yield,
- g) source of the formula, if available
- h) equipment required
- i) preparation procedure
- j) steps or measurements to be verified by a pharmacist or technician checker,
- k) expiry date
- i. stability data, if available
- ii. storage requirements
- iii. specific packaging requirements
- iv. sample label, including auxiliary labels when applicable,
- v. usual dosage range
- vi. advice for the patient, if applicable
- vii. quality control testing to be performed, when applicable.

14.4.26 A **production record** shall be maintained for each batch of sterile product prepared in anticipation of a prescriber's order. Production records shall be kept for a period of one year after the expiry date of the compounded product. The production record should indicate:

- a) compound name and strength,
- b) name, strength, manufacturer and lot no. of each raw material
- c) check off of steps in the preparation process
- d) final yield
- e) prepared by/checked by initials
- f) equipment used
- g) container specifications and lot. no.
- h) preparation date
- i) expiry date of the product with the shortest expiration date
- j) lot. no, batch no. or pharmacy control no. assigned to the product
- k) quality control or end product testing results, if applicable

14.4.27 Documentation of personnel validations tests, environmental monitoring, cleaning and maintenance procedures should be kept and reviewed on a regular basis.

## **14.5 Cytotoxic Drug Preparation**

### **14.5.1 Personnel**

All pharmacy personnel involved in any aspect of Cytotoxic agent handling shall be trained in appropriate handling techniques, preparation, reconstitution, administration and disposal of Cytotoxic agents. Staff shall demonstrate knowledge, understanding of and competence in these techniques prior to working with Cytotoxic agents and regularly thereafter. Evaluation of aseptic technique shall include direct observation, on-the-job performance and aseptic technique testing.

14.5.2 All pharmacy staff shall be informed about the health hazards of working with Cytotoxic agents, and handling of Cytotoxic agents by pregnant, breastfeeding women or individuals actively try to conceive or father a child should be prohibited. The effect of exposure to hazardous drugs on human reproduction is not fully understood. The pharmacy shall implement and maintain Cytotoxic agent handling records and ensure the availability of a medical surveillance program for all staff routinely handling Cytotoxic agents.

### **14.5.2 Apparel**

All personnel handling Cytotoxic agents shall wash their hands before and after the preparation session and wear protective clothing as described in the Sterile Product Preparation Standard however the disposable, powder free gloves should be changed hourly or when contaminated or punctured.

### **14.5.3 Area**

Cytotoxic agents shall be prepared in an appropriately designed area, secluded from general traffic to minimise air turbulence. An eyewash station should be located within 7 meters of the work area.

### **14.5.4 Equipment**

In addition to Sterile Product Preparation standards, Cytotoxic agents shall be prepared in the pharmacy in a Class II, Type B2 (100% external venting), vertical flow Biological Safety Cabinet, under the direction and supervision the pharmacist and handled accordance with the CSHP Guidelines for the Handling and Disposal of Hazardous Pharmaceuticals.

14.5.6 Biological Safety Cabinets shall be cleaned and disinfected before and after each preparation session with water for injection or irrigation and a small amount of cleaner and disinfected with 70% isopropyl alcohol before any aseptic manipulation. The cabinet shall be certified annually by a qualified technician and decontaminated just prior to each time it is turned off.

### **14.5.7 Policies and Procedures**

The pharmacy shall have written policies and procedures in place regarding all aspects of Cytotoxic agent handling and be responsible for adherence to these policies and procedures. Policies should include, but not be limited to:

- a) medication and hazard information
- b) protective apparel and equipment
- c) handling technique training
- d) receiving and shipping
- e) preparation
- f) drug administration

- g) storage
- h) labeling
- i) transportation
- j) waste collection and disposal
- k) emergency procedures for treating accidental contact
- l) exposure records and medical surveillance
- m) hazardous spill management
- n) quality assurance

14.5.8 A complete information file on all Cytotoxic medications shall be readily available in preparation and administration areas and include:

- a) indication
- b) dose and administration information
- c) preparation
- d) acute and chronic toxicities
- e) solubility and stability
- f) compatibilities
- g) chemical inactivators
- h) storage
- i) information on responding to accidental contact
- j) handling of spills and disposal

14.5.9 The pharmacist shall provide basic patient oriented clinical support services for cancer patients such as medical histories, medication monitoring and patient counselling thereby reinforcing compliance to treatment regimens.

14.5.10 In addition to standard aseptic technique described under sterile product preparation, protective aseptic technique includes:

- a) ensuring Cytotoxic ampoule heads are clear of liquid,
- b) wrapping the ampoule neck with an alcohol swab before cracking,
- c) dissolving powders in ampoules and vials by introducing diluents slowly down the wall (wetting minimizes dusting)
- d) measuring final volumes before removing the needle from the vial,
- e) wrapping the needle and vial top with an alcohol swab before withdrawing the needle to minimize aerosol escape and removes last drop from needle tip.
- f) using syringes and IV infusion administration sets with luer-loc fittings.
- g) Attaching and priming IV infusion administration sets prior to adding Cytotoxic agent, and
- h) needles shall not be recapped or clipped after use, but discarded directly into a designated Cytotoxic sharps container to prevent accidental skin punctures.
- i) using a negative pressure technique by injecting a small amount of air into a vial permitting the removal of the required volume.

14.5.11 All cases of exposure to Cytotoxic agents must be reported and documented. Detailed treatments shall be developed and available in the event of Cytotoxic exposure via skin puncture, skin or eye contact or inhalation. An incident report must be completed documenting the cause and corrective action taken.

14.5.12 A clearly defined, formal procedure for handling Cytotoxic agent spills must be developed. Clearly labeled spill kits must be kept in or near all preparation, administration and storage areas. All broken containers, contaminated packaging and cleanup materials must be disposed of appropriately in Cytotoxic waste containers.

14.5.13 Cytotoxic waste must be handled separately from other trash, and disposed of in accordance with CSHP Guidelines for the Handling and Disposal of Hazardous Pharmaceuticals.

#### 14.5.14 Label and Packaging

Cytotoxic agents must be properly labeled as specified in sterile product preparation and dispensed in leak-proof packaging for transportation.

#### 14.5.15 Storage

All shelves and bins where Cytotoxic agents are stored should be designed to minimize the risk of breakage (ie. bins with lips and carts with rims). Shipments of Cytotoxic agents must be sealed in plastic bags, cushioned in a sturdy carton and labeled on all sides with a "Cytotoxic" warning label.

### 14.6 Vinca Alkaloid Administration

In setting where a patient has an order for a lumbar puncture and a combination of intrathecal and intravenous therapy, the following procedures must be in place:

- a) ensure that vinca alkaloids (vincristine, vinblastine, vindesine, etc) are NEVER in the same treatment area where a lumbar puncture is being performed.
- b) prevent cross labelling in the pharmacy by physically separating intrathecal and intravenous doses during all stages of preparation and labelling. Use separate set up trays and clear the hood of all intravenous medications prior to mixing drugs for intrathecal use.
- c) physically separate vinca alkaloids from intrathecal medications during transportation and delivery to the treatment area. If possible, arrange to prepare and send vinca alkaloids after the intrathecal medications have been administered to the patient.
- d) prominently warn that vincristine and other vinca alkaloids are fatal if given intrathecally. Ensure the warning label is affixed DIRECTLY to the label on the syringe barrel, as well as on any protective wrapping or outer packaging. (ie. WARNING: FATAL IF GIVEN INTRATHECALLY)

### 14.7 Potassium Chloride Injections

Potassium chloride (KCl) injection infused too rapidly or given by direct IV can cause cardiac arrest. KCl polyamps have been mistaken for normal saline, sterile water and heparin. KCl concentrate shall be removed from all nursing units, including medication storage sites, medication carts, unit dose carts, and after hours cabinets.

Strategies to remove KCl concentrate could include:

- a) educating prescribers and nursing staff about the risks and potentially fatal consequences of KCl medication errors,
- b) encourage prescribers to use oral KCl whenever possible,
- c) premixed KCl large volume Parenteral and minibags are commercially available. The increased cost far outweighs the potential consequences of a KCl error.
- d) prohibit the addition of KCl concentrate to premixed KCl solutions. KCl concentrate can pool at the injection port, effectively delivering a "bolus" of KCl to the patient.
- e) use automatic substitution orders (eg. For orders for 1-30mmol KCl/L, substitute premixed 20mmol KCl/L. For orders >30mmol KCl/L, substitute premixed 40mmol KCl/L)
- f) update the hospital' KCl IV monograph. The monograph should note the use of premixed solutions only, the maximum IV infusion rate, the use of an infusion device to prevent "runaway" infusions of KCl etc.

### 14.8 Non-Sterile Cytotoxic Products

Generally dispensing of oral, solid dosage forms in multi-use packages is acceptable provided products are not manipulated by bare hands, capsules are not opened and tablets not crushed. Irrespective of whether tablets or capsules are packaged, the equipment used must be thoroughly cleaned after use.

14.8.1 Unit dose packaging of solid oral dosage forms poses additional hazards due to dust dispersion when handling large volumes of tablets. Personnel must wear respirators and gloves during packaging and cleaning procedures.

14.8.2 Non-sterile liquids, powders, creams and ointments should be prepared in a Biological Safety Cabinet. Reusable supplies must be wiped with alcohol prior to leaving the cabinet, cleaned and rinsed with copious amounts of water.

## 14.9 Parenteral Nutrition

In addition to the standards for sterile product preparation, preparation of Parenteral nutrition (PN) solutions requires the formation of a Parenteral nutrition committee with representatives from the departments of medicine, surgery, pharmacy, nursing and dietary. The committee shall develop standardized policies and procedures for :

- a) the education of hospital personnel involved in PN therapy
- b) the indication for PN therapy
- c) the ordering of PN therapy
- d) the formulation, preparation and administration of PN solutions
- e) the monitoring of patients receiving PN therapy

14.9.1 The pharmacist shall evaluate the PN order for the following:

- a) appropriate route and rate of administration
- b) appropriate solution and dosage of constituents
- c) stability and/or compatibility of constituents

Any potential problems encountered shall be communicated to the physician and resolved prior to the preparation of the PN solution.

14.9.2 The pharmacist shall be responsible for assuring the dosage calculations are correct for all PN orders. Specific PN order sheets and standard base solutions should be used with an option of individualized PN base solutions for special patient populations.

14.9.3 The preparation of PN solutions shall be performed in a clean air environment to prevent contamination with microorganisms and particulate matter. The minimum requirements shall be the use of a laminar airflow hood equipped with a "high efficiency particulate air" (HEPA) filter.

14.9.4 Parenteral Nutrition Solutions, and the solutions involved in preparations thereof, shall be stored under proper conditions of sanitation, temperature, light and humidity. At room temperature (15-30 °C) solutions should be completely administered within 24 hours after final admixture. If solutions are refrigerated (2-8°C) they should be removed one-half hours prior to administration and started within 24 hours of rewarming to prevent bacterial growth. Refrigerated solutions must be completely administered within seven days.

14.9.5 All completed PN solutions shall be inspected for particulate matter before they are dispensed for administration to patient. Filters shall be used when infusing nutritional admixtures to remove microorganisms and possible calcium phosphate precipitate that might be present.

14.9.6 There shall be a uniform standard for labelling PN solutions. The following information shall be included on the label:

- a) patient name and location
- b) type of base solution
- c) name and amount of each additive
- d) route of administration - central or peripheral
- e) date of preparation
- f) expiration date and time

14.9.7 All completed PN solutions and PN base solutions prepared by technical personnel shall be checked by the pharmacist or technician checker to ensure:

- a) the correct additives and quantity of additives have been added to the appropriate intravenous solution or PN base solution
- b) the appropriate information has been included on the label
- c) the correct label has been affixed to the completed PN solution or PN base solution

14.9.8 The pharmacist shall monitor patients and their PN therapy for the detection of any problems related to the therapy. A monitoring form should be developed to include all pertinent patient data including laboratory results. Any concerns shall be communicated to the physician.

14.9.9 The quality assurance program shall include appropriate sterility testing to evaluate the efficiency of the laminar air flow hood and performance of aseptic technique. Quality control testing shall be periodically conducted to monitor established procedures for the preparation of PN solutions for possible in-process microbial contamination.

## **15.0 MEDICATION ADMINISTRATION**

- 15.1 The pharmacist should collaborate with nursing and medical staff to develop written policies and procedures governing the safe administrations of medications and should include the following:
- a) medications should be administered upon the order of an individual who has been assigned clinical privileges or who is an authorized member of the house staff.
  - b) medications should be administered by appropriately licensed personnel in accordance with laws and regulations governing such acts.
  - c) in the absence of an IV admixture service, precautionary measures for the safe admixture of Parenteral products in the patient care area should be developed. A distinctive supplementary label shall be affixed to the Parenteral product when medications are added to indicate the patient name, name and amount of medication added, the date and time of addition, and name of person who prepared the admixture.
  - d) an IV manual shall be available and include hospital policies and procedures with respect to each Parenteral medication.
  - e) medications should be given as near to the specified time as possible.
  - f) the patient for whom the medication is intended should be positively identified in accordance with hospital policy.
  - g) the person administering the medications should stay with the patient until the dose has been taken, except for self-administered medications.
  - h) all administered, refused or omitted medication doses should be recorded in the patient's health care record according to established procedure. Information to be recorded should include the medication name, dose, route of administration date and time of administration and initials of person administering the dose.
  - i) procedures should be developed for the administration of medications by non-nursing personnel (ie. respiratory technologists)

## Hospital Pharmacy Policy and Procedure Manual

### Sample Outline

#### 1. General Policies

- a. Organizational Chart
- b. Departmental Goals
- c. Departmental Objectives
- d. Philosophy
- e. Facilities
- f. Locations
- g. Responsibility and Scope of Practice
- h. Hours of Service
- i. After Hours Pharmacy Service
- j. Night Medication Cupboard/Cabinet
- k. Access to Pharmacy
- l. 24 Hour Medication Clock
- m. Metric System Conversion
- n. Standard Abbreviations
- o. Transfer of Function to Nursing
- p. List of Medical Staff and Sample Signatures
- q. Manufacturer Representatives
- r. Pharmaceutical Display
- s. Department Tours

#### 2. Administration

- a. Responsibilities of the Director of Pharmaceutical Services
- b. P&T Committee membership
- c. Maintenance of Formulary
- d. Hospital Formulary System
- e. Restricted Antimicrobial Agents
- f. Dispensing of High Cost Medications
- g. Adding New Drugs to the Formulary
- h. Maintenance of IV Manual
- i. Departmental Telephone Use/Taking and Giving Information via the Telephone
- j. Release of Patient Information to Police or Other Individuals
- k. Shredding Confidential Information
- l. Workload Measurement

#### 3. Committee Activities

- a. Departmental Committees Terms of Reference
- b. Pharmacy & Therapeutics committee
- c. Infection Control Committee
- d. Drug Utilization Committee
- e. Nutritional Support Committee
- f. Intensive Care Committee
- g. Emergency Care Committee
- h. Palliative Care Committee
- i. Patient Education Committee
- j. Medical Audit and Utilization Committee
- k. Workplace Safety and Health Committee
- l. Product Evaluation Committee

#### **4. Reporting Systems**

- a. Adverse Drug Reaction Reporting
- b. Medication Incident/Discrepancy Reporting
- c. General Incident Reports
- d. Drug Information Request Reporting
- e. Poison Control Reporting
- f. Blood Products Record Keeping
- g. Employee Accident Reports
- h. Monthly Financial Report
- i. Year End Report
- j. Quality Assurance Report
- k. Continuing Education Report

#### **3. Personnel Policies**

- a. Pharmacist's Role in Patient Care Planning
- b. Position/Job Descriptions
- c. Staff Orientation
- d. Performance Appraisals
- e. Personnel Files
- f. Scheduling of Staff and Report of Hours
- g. Notification of Absence from Work
- h. Inservices and Continuing Competency
- i. Pharmacy Service for Employees
- j. Dress Code
- k. Prohibition of Smoking
- l. Volunteer Services to Pharmacy
- m. Time Card
- n. Overtime Authorization

#### **4. Drug Procurement/Inventory Control/Materials Management**

- a. Budgeting Process
- b. Capital Requisition
- c. Drug and Supply Purchasing/Ordering
- d. Contingency Purchases
- e. Non-Formulary Drug Purchases
- f. Receiving Procedure
- g. Authorization for Payment/Signing Authority
- h. Handling of Pharmacy Invoice Discrepancies
- i. Drug Importation
- j. Drug Recall Procedures/Urgent Drug Recall Procedures
- k. Inventory Control
- l. Order/Reorder Alert
- m. Drug Price Books
- n. Return and/or Disposal of Drugs
- o. Returns due to Product Failure
- p. Medication Returns from Inpatient Wards
- q. Disposal of Hazardous Waste
- r. Handling and Disposal of Sharps
- s. Restocking the Dispensary
- t. Drug Samples for Use by Hospital Patients
- u. Resale of Pharmaceuticals
- v. Drug Storage
- w. Perishable Drug Control
- x. Wardstock
- y. Labelling of Drug Containers

- z. Prepackaging Records

## 5. Fire and Safety

- a. Fire Alarm Response Plan/Procedure
- b. Fire Alarm Response Plan/Procedures After Hours
- c. Bomb Threat Plan/Procedures
- d. Safety Contingency Plan
- e. Search for Missing Person
- f. Evacuation Orders
- g. Preventive Maintenance of Laminar Flow Hood
- h. Robbery – Cash or Drugs
- i. Adverse Weather Contingency Plan
- j. External Disaster Plan
- k. Telephone Fan Out
- l. Security Restrictions

## 6. Inpatient Drug Distribution Services

- a. Hours of Services
- b. Prescriptive Authority
- c. Prescription Form and Required Information
- d. Medication Containers
- e. Drug Quantities
- f. Screening Prescriptions
- g. Inpatient Computer System procedures
- h. Signing On and Off
- i. Patient Demographics
- j. Profiling and Monitoring
- k. How to view a Patient History
- l. Medication Review
- m. New Order Processing
- n. Repeat Order Processing/Repeat Orders
- o. Multiple Ingredient Order Processing
- p. Drug Order Clarification Notice
- q. Filling Prescriptions
- r. Preparation of Prescription Labels
- s. Contingency Plan for Computer Failures
  - i. Filling Prescriptions – Non-Computerized
  - ii. Repeat Orders – Non-Computerized
  - iii. Preparation of Prescription Labels – Non-Computerized
  - iv. System Recovery
- t. Telephone Orders
- u. Verbal Orders
- v. Final Checking of Prescriptions
- w. Signed Physician Orders
- x. Canceling or Discontinuing Orders
- y. Resumption of Pre-Op Medications
- z. Dispensing Records
- aa. Distribution Times
- bb. Drug Administration Schedules
- cc. Drug Administration Checks
- dd. Automatic Stop Orders
- ee. Therapeutic Equivalent Dispensing
- ff. Automatic Substitution
- gg. Generic Equivalent Dispensing
- hh. Restricted Antimicrobial Agents
- ii. Dispensing of High Cost Medications
- jj. Clozapine Dispensing

- kk. Alcoholic Beverages
- ll. Investigational Drugs and Emergency (Special Access Medications)
- mm. Additions/Deletions to Wardstock Medications
- nn. Filling Wardstock Drug Orders
- oo. Final Check of Wardstock Drug Orders
- pp. Packaging Drugs for Transport
- qq. Issue and/or Delivery of Drugs by Messengers
- rr. Intramuscular Drug Administration
- ss. Intravenous Drug Administration
- tt. Addition of Drugs to Blood
- uu. Bedside Medication
- vv. Patient Self-Medication
- ww. Patient's Own Medication
- xx. Safekeeping of Personal Medications
- yy. Handling of Medication on Discharge
- zz. Topical Preparations to Patients upon Discharge
- aaa. Leave of Absence/Pass Medications
- bbb. Reuse of Aerochambers and Aerochambers with Masks
- ccc. Ward/Drug Storage Site Inspections

## **7. Clinical Pharmacy Services**

- a. Areas of Service
- b. Clinical Privileges
- c. Documentation in the Patient Medical Record
- d. Medication History Service
- e. Patient Monitoring
- f. Toxic Drug Conc. Monitoring Service
- g. Medication Counselling/ Patient Education
- h. Participation in Medical Service Rounds
- i. Pharmacokinetic Services
- j. Therapeutic Consults
- k. Drugs requiring Serum Creatinine Monitoring
- l. Drugs requiring PT/PTT Monitoring
- m. Drug Utilization Review/Drug Use Evaluation
- n. Pharmacist Involvement in CPR Team
- o. Student Teaching Program

## **8. Drug Information Services**

- a. Hours of Service
- b. Maintenance of Drug information resources
- c. Responding to Drug Information Requests
- d. Maintenance of Drug Information Statistics
- e. Library Loans
- f. Drug Information Postings/Newsletters
- g. Poison Control Service
- h. Antidote Information and Supplies
- i. Maintenance of Pharmacological Nursing Reference Manual
- j. Maintenance of Formulary
- k. Suspected Drug Reactions Reporting Program

## **9. Education Services**

- a. Hospital Pharmacy Residency Program
- b. Undergraduate Teaching Program
- a. Staff/Resident Drug Information Training
- c. Orientation to Pharmacy Department
- d. Staff Training and Inservice Education
- e. Staff Continuing Education

## 10. Outpatient Drug Distribution Services

- a. Hours of Service
- b. Patient Eligibility
- c. Prescriptive Authority
- d. Prescription Forms and Required Information
- e. Reimbursement for Prescription Services
- f. Drug Quantities
- g. Medication Containers/Child Resistant Containers
- h. Receiving Prescriptions
- i. Screening Prescriptions
- j. Outpatient Computer System Procedures
- k. Signing On/Off
- l. Patient Demographics
- m. Patient Medication Profiles
- n. Discontinuing Previous Orders
- o. How to View Patient History
- p. New Order Processing
- q. Repeat Order Processing
- r. Multiple Ingredient Order Processing
- s. Filling Prescriptions
- t. Dispensing Records
- u. Preparation of Prescription Label
- v. Contingency Plan for Computer Failure
  - i. Filling Prescriptions – Non-Computerized
  - ii. Repeat Orders – Non-Computerized
  - iii. Pricing Prescriptions – Non-Computerized
  - iv. Preparation of Prescription Labels – Non-Computerized
  - v. Uncollectible Accounts Receivable (Bad Debt) – Non-Computerized
  - vi. System Recovery
- w. Final Checking of Prescriptions
- x. Dispensing Oral Liquids and Provision of Measuring Devices
- y. Printing Patient Information
- z. Medication Counselling
- aa. Prescription Filing
- bb. Verbal Orders
- cc. Telephone Orders
- dd. Discharge Orders
- ee. Providing Prescription Copies
- ff. Pricing Prescriptions
- gg. Verbal Authorization for Third Party Billings
- hh. Updating Billing Plans
- ii. Uncollectible Accounts Receivable (Bad Debt)
- jj. Cash Register Procedures
- kk. Delivery Service
- ll. Mailing Prescriptions
- mm. Returning Unclaimed Prescriptions to Stock
- nn. OTC Sales
- oo. US Currency Exchange

## 11. Narcotic, Controlled or Targetted Drug Distribution

- a. Narcotic, Controlled or Targetted Drugs Prescription Regulations
- b. Maintenance of Narcotic Inventory Records (Acquisition/Distribution)
  - i. Receiving Narcotic, Controlled and Targetted Drugs (Acquisition)
  - ii. Withdrawal Records of Narcotic, Controlled and Targetted Drugs from Main Pharmacy
  - ii. Disbursements of Narcotic, Controlled and Targetted Drugs to Wards

- c. Prescription forms and required information
- d. Medication Containers
- e. Filling Narcotic, Controlled or Targetted Drugs Requests
  - i. Individual prescriptions
  - ii. Ordering Ward Stock Narcotics
  - iii. Outpatient prescriptions
  - iv. Narcotic, Controlled or Targetted Drugs for Patient on Pass
- f. Prepackaging Narcotic Wardstock
- g. Preparation of Narcotic Delivery Cart
- h. Delivery of Narcotics to Wards (Individual Patient Prescriptions and Wardstock)
- i. Transporting Narcotic, Controlled or Targetted Drugs outside of scheduled delivery times
- j. Drug Security/Storage in Pharmacy and on Ward
- k. Returning Narcotic Medication from the Ward
- l. Returning/Processing Completed Narcotic Recording Sheets (Drug Usage Records)
- m. Reconciliation of Narcotic Issues
- n. Obtaining Credit for Narcotic, Controlled and Targetted Substances
- o. Disposal/Destruction of Unusable Medications
- p. Diversion/Drug Abuse by Staff
- q. Methadone Programs

## 12. Manufacturing Services

- a. Hours of Service
- b. Responsibilities of Manufacturing Pharmacist
- c. Apparel
- d. Housekeeping
- e. Calculations
- f. Manufactured Products - Reference Manual
- g. Preparation of Labels
- h. Definitions
  - Bulk Compounded Product
  - Extemporaneously Compounded Product
- i. Preparation of Bulk Compounded Product
- j. Extemporaneous Manufacturing
- k. Compounding by technicians.

## 13. Sterile Product Services - General

- a. Hours of Service
- b. Access to Sterile Product Preparation Areas
- c. Apparel
- d. Housekeeping
- e. Hand Washing
- f. Prescription Forms and Required Information
- g. Screening Sterile Product Prescriptions
- h. Stocking Laminar Airflow Hood
- i. Admixture Containers
- j. Infectious Waste Handling
- k. Handling and Disposal of Sharps/Needles
- l. Use of Filter Needles
- m. Expiration Date Establishment
- n. Maintenance of Laminar Airflow Hood
- o. Microbiology Testing
- p. Positive Q.C Tester
- q. Preparation of Sterile Ophthalmic Drops
- r. Preparation of Miscellaneous Sterile Products

**14. Sterile Product Services - TPN**

- a. Hours of Service
- b. Prescribing of Authority
- c. Prescription Forms and Required Information
- d. Verbal TPN Prescriptions
- e. TPN files
- f. Screening TPN Prescriptions
- g. Calculations
- h. Preparation of Labels
- i. Preparation of TPN Solutions
- j. Final Check of TPN Solutions
- k. Packaging for Transport
- l. Delivery
- m. After Hour Request to Adjust TPN
- n. Preparation of Batched Parenteral Nutrition Solutions

**15. Sterile Product Service - Oncology Admixture**

- a. Hours of Service
- s. Access to Sterile Product Preparation Areas
- b. Apparel
- c. Housekeeping
- d. Hand Washing
- e. Stocking the Hood
- f. Screening Admixture Orders
- g. Profiling Admixture Orders
- h. Preparing Admixture Orders
- i. Admixture Containers
- j. Labelling Admixtures Orders
- k. Final Checking of Admixtures
- l. Maintenance of Biological Safety Cabinet
- m. Handling and Disposal of Needles
- n. Handling and Disposal of Antineoplastic Waste
- o. Use of Filter Needles
- p. Packaging Admixtures for Transport
- q. Delivery of Oncology Admixtures by Messenger
- r. Antineoplastic Spill Kits and Reports
- s. Medical Surveillance/Personnel Expose

MEDICATION INCIDENT/DISCREPANCY REPORT SAMPLE  
ABC HOSPITAL

PATIENT INFORMATION

ERROR INFORMATION

Patient Name:	Discrepancy: Error discovered prior to administration	<input type="checkbox"/>
Unit/Ward/Room/Bed:	Incident: Error discovered following administration	<input type="checkbox"/>
Physician: ADDRESSOGRAPH	Date(s) of Occurrence: Time(s):	
Patient's Age:	Date of Discovered: Time	
Sex:	Date Report Completed:	
	Physician's Order:	

SECTION I - TO BE COMPLETED BY PERSON DISCOVERING INCIDENT/DISCREPANCY:

Nature of incident/discrepancy \*Check One Or More Error Types

Incorrect Medication	<input type="checkbox"/>	Incorrect Quantity Supplied	<input type="checkbox"/>
Incorrect Dose/Strength	<input type="checkbox"/>	Incorrect Brand Supplied	<input type="checkbox"/>
Incorrect Dosage Form	<input type="checkbox"/>	Expired/Outdated Medication	<input type="checkbox"/>
Incorrect Patient Name on Label	<input type="checkbox"/>	Incorrect Route/Site	<input type="checkbox"/>
Incorrect Dosage/Directions on Label	<input type="checkbox"/>	Incorrect I.V. Solution	<input type="checkbox"/>
Incorrect Dosage Preparation	<input type="checkbox"/>	Incorrect Rate of Administration	<input type="checkbox"/>
Dose Omission/Unavailable	<input type="checkbox"/>	Incorrect Administration Technique	<input type="checkbox"/>
Extra Dose Given	<input type="checkbox"/>	Incorrect Narcotic Count	<input type="checkbox"/>
Unordered Medication	<input type="checkbox"/>	Drug/Drug Interaction	<input type="checkbox"/>
Incorrect Time/Day Given	<input type="checkbox"/>	Allergic Drug Reaction/Known Allergy	<input type="checkbox"/>
Incorrect Patient Received Medication	<input type="checkbox"/>	Other (specify):	<input type="checkbox"/>

SECTION II - TO BE COMPLETED BY PHARMACIST INVOLVED IN THE INCIDENT/DISCREPANCY:

Possible Contributing Factors To Incident/Discrepancy \*Check one or more

<b>Medication Order Information</b>	<b>Order Processing Related</b>
Illegible Handwriting <input type="checkbox"/>	Wrong or No Addressograph <input type="checkbox"/>
Ambiguous/Incomplete Order <input type="checkbox"/>	Failure to Note Order <input type="checkbox"/>
Error in Recording Verbal Order <input type="checkbox"/>	Error in Transcription <input type="checkbox"/>
Error in Writing Medication in Chart <input type="checkbox"/>	Failure or Delay in Sending to Pharmacy <input type="checkbox"/>
Medication Written in Wrong Chart <input type="checkbox"/>	

<b>Medication Preparation Related</b>	<b>Medication Administration Related</b>
Order/Label Misread <input type="checkbox"/>	Improper Patient Identification <input type="checkbox"/>
Calculation Error <input type="checkbox"/>	Delay or Failure to Record Administration <input type="checkbox"/>
Failure to Clarify Substitution <input type="checkbox"/>	Medication Left at Bedside <input type="checkbox"/>
Failure to Check Expiry Date <input type="checkbox"/>	Medication Ticket System <input type="checkbox"/>
Incorrect Label Place on Medication <input type="checkbox"/>	Medication Misplaced on Unit/Ward <input type="checkbox"/>
Medication Not Received on Unit/Ward <input type="checkbox"/>	Malfunctioning Equipment <input type="checkbox"/>
Incorrectly Removed from After Hours Cabinet <input type="checkbox"/>	Inadequate Monitoring of IV Rate <input type="checkbox"/>
Pharmacy Unnecessarily Accessed <input type="checkbox"/>	Incorrect operation of IV Pump <input type="checkbox"/>
	Chart Not Checked if Previously Given <input type="checkbox"/>

<b>Environment Related</b>	<b>Miscellaneous</b>
Shift Change <input type="checkbox"/>	Sound Alike/Look Alike Drug Names <input type="checkbox"/>
Assignment Conflict <input type="checkbox"/>	Look Alike Drug Products <input type="checkbox"/>
Interruptions <input type="checkbox"/>	Trade/Generic Name <input type="checkbox"/>
Short Staffed <input type="checkbox"/>	Patient Off Unit <input type="checkbox"/>
Distraction <input type="checkbox"/>	

Action Taken To Prevent Reoccurrence


**SECTION III - SECTION TO BE COMPLETED BY PERSON INVESTIGATING ERROR:**

**Medication Incident Risk Index**

Classification of event	Type of Incident/Discrepancy	Route of Administration	Classification of Drug
Incident 5	Omission 2	I.V. 4	
Discrepancy 0	Incorrect Dose 2	I.M./S.C. 3	Specify points according to list below
	Extra Dose 2	P.O. 2	
	Incorrect Patient 5	Inhaler 2	
	Incorrect Drug 5	Eye Drops 2	
	Incorrect Time 1	Other 1	
	Incorrect Route 2		
	Allergy 3		
	Other 1		
Totals:			Grand Total

**Classification Of Drugs/I.V. Solutions**

Antacid 1	Antiemetic 2	Anti-infective 3	Anticoagulant 4	Antineoplastic 6
Antidiarrheal 1	Antidepressant 2	Anticonvulsant 3	Thrombolytic 4	TPN 6
Laxative 1	Anxiolytic 2	Diuretic 3	Bronchodilator 4	Insulin 6
Unmedicated IV 1	Antihistamine 2	Narcotic Analgesic 3	Cardiovascular 4	
Expectorant 1	NSAID 2	Oral Hypoglycemic 3		
Antitussive 1	Hormone 2	Steroid 3		
Acetaminophen 1	Muscle Relaxant 2	Eye/Ear Nose 3		
Vitamin 1	Sedative 2			
	Electrolyte 2			
	Antiparkinson 2			
	Misc. G.I. meds 2			

**SECTION IV - TO BE COMPLETED BY PHYSICIAN**

**Physician's Report \*For Incidents Only**

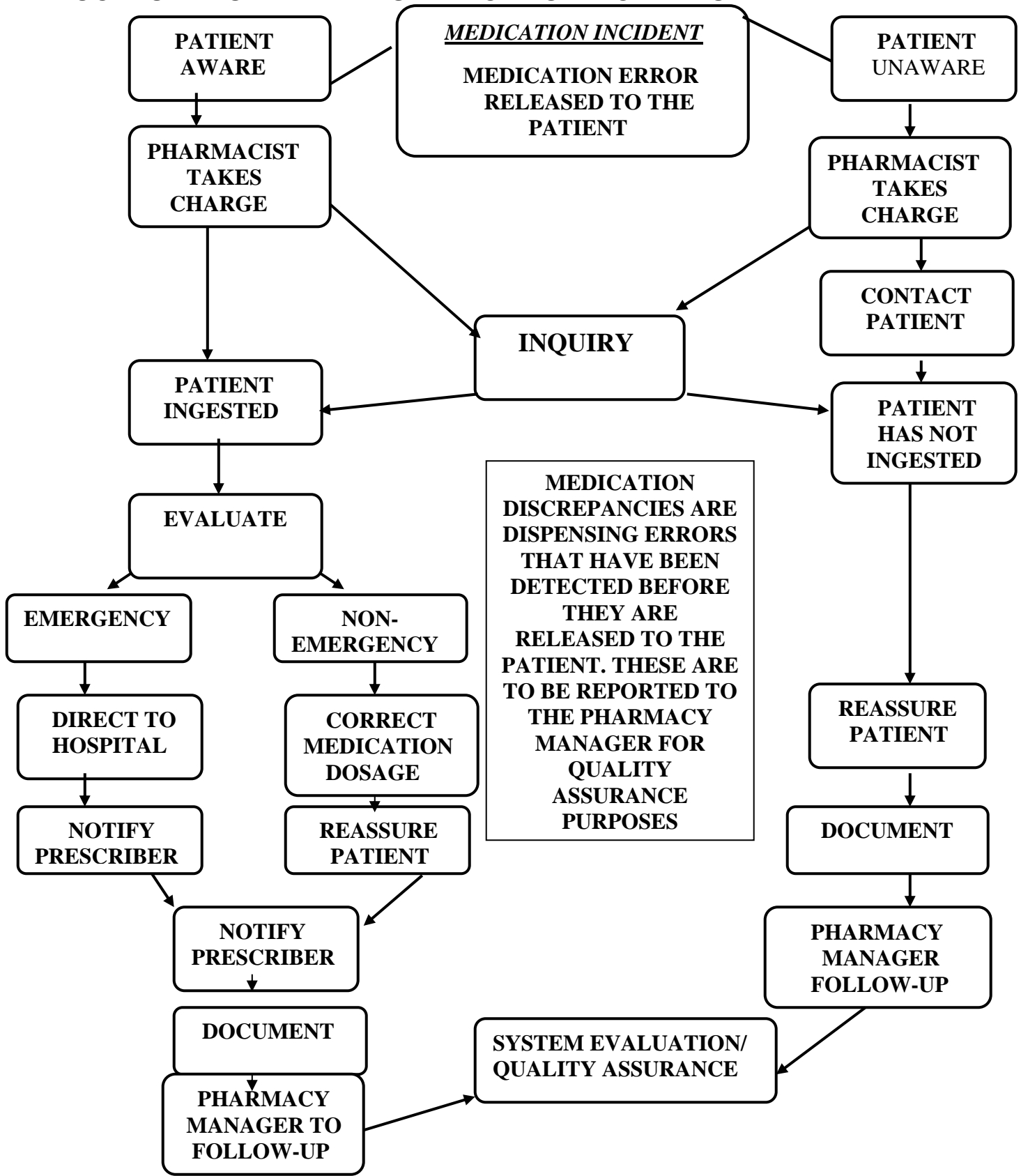
Severity	Assessment
0 No effect	
1 Minor Transient	
2 Minor Permanent	
3 Major Potential	
4 Major Transient	
5 Major Permanent	

**SECTION V - NOTIFICATION SIGNATURES \*WHERE APPLICABLE**

Individual	Notified at: Time/Day	Notified By:	Signature	Date DD/MM/YY
Incident Discovered By:				
Incident Reported By:				
Pharmacist Involved:				
Technician Involved:				
Pharmacy Director:				
Nurse Involved:				
Head/Charge Nurse:				
Director of Nursing:				
Physician:				
QA Coordinator:				

# PROCEDURE FOR HANDLING MEDICATION INCIDENTS

## APPENDIX C



DRUG STORAGE SITE AUDIT  
ABC PHARMACY

LOCATION  
PHARMACIST/TECHNICIAN:

DATE:  
TIME:

1. SECURITY		Y	N	NA
a)	Is medication storage site locked?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b)	If not, is the medication cupboard/cart kept locked?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c)	Are keys carried by registered/license nurse?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. MEDICATION STORAGE		Y	N	NA
a)	Medication storage site neat and clean.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b)	Contents of cupboards/drawers organized.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c)	Contents of the cupboards/drawers properly separated. (i.e. internals from externals, patient's own medications)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d)	Medication containers and cards properly labeled, neat & clean, not worn or illegible	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e)	Labels firmly affixed to containers.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f)	There is no evidence of handwriting on labels.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g)	Wardstock medications accurately labelled with log number (control no.) and expiry date where applicable.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Wardstock rotated to ensure oldest stock is used first.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i)	The wardstock drug list with minimum/maximum quantities posted.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j)	The quota of ward stock reasonable.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
k)	Medications within expiry date.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
l)	Reconstituted drugs properly labeled, dated, and stored.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
m)	Multi-dose vials dated upon first opening and not used past 3 months. (including Salbutamol, Normal Saline, Insulin, eye/ear preparation, etc.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
n)	Bottles of liquid clean and free from spills.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
o)	Deteriorated and discontinued medications removed and returned to the Pharmacy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
p)	Emergency and After-Hours Cabinet medications checked and in date.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. REFRIGERATOR				
a)	Drugs requiring refrigeration properly stored.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b)	Medications are within expiry date.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c)	Refrigerator clean and well organized.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d)	Food and other non-pharmaceuticals stored separately from medication.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e)	Refrigerator clean, free from excess frost, and between 2 and 8 °C.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. NARCOTIC AND CONTROLLED SUBSTANCES				
a)	Narcotic key carried by a registered/licensed nurse.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b)	Narcotic cabinet/drawer locked.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c)	Narcotic and Controlled Substances accurately accounted for.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d)	Quota of narcotic and controlled drugs reasonable.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. LIBRARY				
	The following are readily available on the unit:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a)	Hospital Formulary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b)	IV manual	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c)	CPS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Feb/01  
signature: \_\_\_\_\_

Head/Charge Nurse's

SAMPLE COMPOUNDING WORKSHEET

**MASTER FORMULA:**

**Compound (Formula) Name:**

**Strength:**    % w/v

**Dosage Form:**

**Source of Formula:**

**Preparation Method:**

**Steps to be Checked by Pharmacist:**

<b>Sample Label</b>		
Pharmacy Name and Address		
Rx #:	Dr. Name:	Date
Disp'd:		
Patient Name:		
Sig:		
Qty	Compd Name/ Strength/ Dosage Form	
Batch #	Expiry Date:	

**Equipment Used:**

**Stability Data (if available):**

**Storage Requirements:**

**Packaging Requirements:**

**Quality Control Test(s):**

**Usual Dosage Range:**

**Advice for Patients:**



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