

GUIDELINES FOR DRUG-USE CONTROL

PREFACE

These guidelines were originally published by the Canadian Society of Hospital Pharmacists (CSHP) as the CSHP Standards of Practice (1993).

With the revision of the CSHP Standards of Practice in 2000, the 1993 standards became a set of interim Guidelines for Practice. These 2008 Guidelines for Drug-Use Control, which replace in part the Guidelines for Practice, provide the practitioner with information necessary to meet the 2000 CSHP Standards of Practice and to achieve optimum safety in the distribution, control, and use of drugs. CSHP Council approved this document as an official CSHP publication in March 2008.

These Guidelines are intended to describe the optimal level of hospital pharmacy practice and to reflect pharmacists' commitment to providing quality care for the patient. The Guidelines have several purposes:

1. to define the scope and responsibility of pharmacy practice within health care facilities;
2. to define the role of the pharmacist in a health care facility;
3. to provide direction for identifying the priorities of a pharmacy service;
4. to serve as a reference or source of information for faculties and colleges of pharmacy in the development of their curricula; and
5. to provide a definition of exemplary pharmacy services that can be used as a standard for accrediting bodies, other health care organizations, and governments.

Permission was obtained from the Editor of Best Practices for Hospital & Health-System Pharmacy Practice Standards and Quality Division of the American Society of Health-System Pharmacists to adapt material from the ASHP Guidelines on the Safe Use of Automated Medication Storage and Distribution Devices. Where the ASHP Guidelines are the basis for sections of this document, they are cited as such.

1. SCOPE

1.1 Purpose

These Guidelines specify the requirements for the ideal practice of drug-use control by hospital pharmacies. The specific pharmacy services provided will depend on the size, location, and function of the particular hospital. Users of this document are also referred to the Canadian Council on Health Services Accreditation (CCHSA) standards for accreditation purposes.

1.2 Level of detail provided

These Guidelines do not provide detailed information about each aspect of drug-use control provided by pharmacy practitioners in the hospital setting. References providing such information are included in the bibliography.

1.3 Interpretation of the use of "shall" and "should"

In these Guidelines, “shall” indicates a mandatory requirement, and “should” indicates a recommendation, something that is advised but not mandatory.

2. FACILITIES, EQUIPMENT, AND SUPPLIES

2.1 Basic Requirements

The pharmacy service shall have sufficient space, facilities, equipment, information resources, and supplies of the type, quality, and quantity to fulfill the following requirements:

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

2.2 Maintenance of Equipment

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

2.3 Procedures

Procedures shall be established to authorize and control access to computer information systems.

2.4 Automated medication storage and distribution devices[†]

Automated medication storage and distribution devices should be used as tools to improve the medication distribution system with consideration of safety, cost, and the effective use of human resources.¹

2.4.1

When automated processes are implemented, the following factors, among others, should be considered¹:

- (a) compatibility with the organization's strategic plan;
- (b) integration with existing manual and automated systems and processes;
- (c) benefits over the current system, from the perspectives of safety, accuracy, timeliness, and cost;
- (d) responsibilities of the organization and the vendor regarding installation, staff training, maintenance, operations, and troubleshooting;
- (e) leadership of the pharmacy service in the development of policies and procedures for the safe and effective use of the automated devices.

2.4.2

Automated devices should have the following features¹:

- (a) medications are contained in and administered from single-unit or unit-dose packages;
- (b) to the extent possible, the final package for each medication is available to the end-user in a ready-to-administer form;
- (c) the medications are available at the appropriate time;
- (d) medication profiles are readily available to all health care providers;
- (e) assessment of all medication orders is performed by a pharmacist before administration of the first dose (if the first dose is given during regular pharmacy service hours);

- (f) safety of storage, distribution, access, and use by all users is ensured throughout the drug distribution process;
- (g) environmental conditions for maintaining product integrity are met; and
- (h) federal, provincial, and territorial requirements are met.

2.4.3

The pharmacy service shall be responsible for maintaining automated devices, so as to minimize errors and operational delays¹.

2.4.4

Policies and procedures for the safe use of the automated devices should be developed through consultation with physicians, nurses, and all other users and should include the following information¹:

- (a) clear statement of the responsibilities of all personnel involved in operating or using the automated devices;
- (b) methods of identifying potential sources of medication errors;
- (c) methods and tools to minimize medication errors (such as, bar coding);
- (d) methods of restricting access to medications;
- (e) specification of packaging style and labelling format;
- (f) procedures for secure handling of controlled substances
- (g) procedures for ensuring product integrity, including:
 - (i) statement regarding the importance of accuracy and integrity of product labels;
 - (ii) procedures for handling medications that are removed from automated devices but not used;
 - (iii) accountability measures for wasted and spoiled medications;
 - (iv) methods of checking for expired medications;
 - (v) methods for identification and follow-up of tampered products; and
 - (vi) methods for proper storage of products throughout the pharmacy service supply chain to the patient;
- (h) procedures for auditing all transactions;
- (i) procedures for ensuring access to medications in emergency or urgent situations;
- (j) procedures for personnel who are involved with the restocking of medications in the automated system; and
- (k) contingency plan for use during operational interruptions to ensure seamless and secure distribution and documentation of medications.

2.4.5

Initial and ongoing education and training shall be provided to ensure the safe operation of automated equipment. The education and training function shall include the following elements¹:

- (a) providing adequate resources for effective training;
- (b) revising the training and educational material in a timely and responsive manner; and
- (c) regularly evaluating and documenting staff competence in operating the equipment.

2.5 Threats to patient safety related to medication misuse, pilferage, & diversion

The pharmacy service shall ensure that threats to the safety of both patients and staff resulting from medication misuse, pilferage, and diversion are minimized¹.

2.6 Policies & procedures regarding security of drug distribution systems

A policy and corresponding procedures shall be developed that assign responsibility and address security issues.

- (a) The policy should have input from all stakeholders (such as, the pharmacy service, nursing, security, risk management).
- (b) The policy should state that the pharmacy service is responsible for the security of drug distribution systems.
- (c) The policy should clearly state who within the pharmacy service is responsible for the following:
 - (i) resolving computer-interface problems;
 - (ii) resolving operational problems;
 - (iii) ensuring the accuracy of medications in the system;
 - (iv) maintenance of access devices (such as, codes, magnetic cards, fingerprint or retinal readers); and
 - (v) training and retraining of users.

2.7 Assessment & management of medication-use

The health care facility should develop methods for assessing and managing medication-use.

2.7.1

The pharmacy service should work collaboratively with various groups within the health care facility (such as, information systems, admitting, finance) to ensure that automated interfaces, if applicable, are functioning correctly.

2.7.2

The following steps should occur in assessing and managing medication-use:

- (a) identifying the data to be reviewed;
- (b) generating reports;
- (c) assigning the following responsibilities:
 - (i) reviewing reports;
 - (ii) scheduling the frequency of such reviews;
 - (iii) reporting discrepancies;
 - (iv) resolving discrepancies; and
 - (v) following up on resolutions of discrepancies;
- (d) investigating trends in discrepancies.

2.8 Medication discrepancy reports

Medication discrepancy data should be evaluated regularly and used to identify opportunities for improvement.

3. MEDICATION ORDERS

3.1 Medication Order Review

3.1.1

All medication orders shall be documented in the patient's medical record.

3.1.2

Every medication order should be reviewed by the pharmacist before the medication is administered to the patient. After-hours or ward stock orders shall be reviewed at the earliest opportunity.

3.1.3

Before dispensing any medication (except in an emergency situation), a pharmacist shall review the prescriber's original written order or a direct copy (hard copy or electronic) to ensure that the prescriber's medication order is authentic, accurate, and appropriate. The pharmacist shall check the medication order for the following information:

- (a) patient's name, hospital identification number, and location;
- (b) signature of authorized prescriber;
- (c) prescriber's privileges;
- (c) name of the medication and formulary status;
- (d) dose, form, and strength;
- (e) route and frequency of administration;
- (f) duration of treatment, if limited;
- (g) complete directions for appropriate use;
- (h) date and time when the order was written;
- (i) for a verbal or telephone drug order, name and signature of the person who received the order and name of the prescriber; and
- (j) prescriber conformance with hospital-approved and standardized terminology and abbreviations.

Medication orders stating that the patient should resume medications that were being taken before admission (such as, "meds as at home") are not acceptable.

3.1.4

The pharmacist shall ensure that a complete and current medication profile is available for each patient, through either a manual or a computerized system. The patient's medication profile shall include the following information:

- (a) patient's name, hospital identification number, and location;
- (b) admission date;
- (c) attending physician's name or prescriber's name or both;
- (d) patient's date of birth;
- (e) patient's sex;
- (f) patient's height and weight;
- (g) allergies, sensitivities, and other significant contraindications;
- (h) list of current medication orders;
- (i) list of medications that have been prescribed since admission to the hospital (in chronological sequence);
- (j) for each medication order, the medication name, dose, route, dosage form, directions for use, and administration times (if not standardized times);
- (k) start and stop dates of the medication, when applicable;

- (l) date on which medications were dispensed, refilled, or discontinued; and
- (m) signature or initials of the pharmacist or technician entering or verifying the transcription or computerized entry of medication orders into the medication profile.

3.1.5

The following information, as well as other information as appropriate, should also be kept as part of the medication profile:

- (a) medication history before hospital admission, obtained through the medication reconciliation process;
- (b) pertinent monitoring data (such as, drug serum concentrations, renal function);
- (c) other therapies (such as, parenteral nutrition, enteral nutrition);
- (d) diagnosis on admission and diagnostic updates when applicable; and
- (e) selected medical data and diet information relevant to medication therapy.

3.1.6

The pharmacist shall review the medication profile before dispensing the patient's medications. The pharmacist shall assess the physician's original medication order, using the patient's medication profile to detect any of the following situations:

- (a) prescription of therapeutically similar medications;
- (b) potential allergic or adverse drug reactions;
- (c) possible drug-disease incompatibilities;
- (d) clinically significant drug-drug interactions;
- (e) inappropriate dosage or dosage interval;
- (f) inappropriate dosage form or route of administration;
- (g) problems related to intravenous administration, including potential incompatibilities, drug stability, volume of intravenous fluid for medication administration, and rate of administration; and
- (h) inappropriate duration of therapy.

3.1.7

The pharmacist shall resolve any questions regarding the order with the prescriber and shall document the resolution in the patient's medical record.

3.1.7.1

Telephone and verbal drug orders received by the pharmacist from the prescriber shall be transcribed immediately on the order form and shall be countersigned by the prescriber at a later time in accordance with hospital policy and legal requirements.

3.1.7.2

The pharmacist shall resolve questions by reviewing the patient's medical record, researching the literature, or discussing questions with the prescriber, nursing staff, or pharmacy service staff.

3.1.8

The following conditions apply to the use of pre-printed orders:

- (a) pre-printed orders shall be approved individually by the appropriate hospital committee (such as, pharmacy and therapeutics committee, medical advisory committee);
- (b) pre-printed orders shall be reviewed annually and revised as necessary;
- (c) pre-printed orders shall conform to all safe medication practices (such as, no use of abbreviations, no use of trailing zeros);
- (d) pre-printed orders shall include a copy that can be appended to the medical record; and
- (e) pre-printed orders shall be authorized by the prescriber and individualized according to the patient's needs.

3.1.9

To prevent indefinite, open-ended orders, written policies and procedures shall govern the use of automatic stop orders and p.r.n. ("as needed") medications.

3.1.9.1

The pharmacy and therapeutics committee shall determine automatic stop-order policies for all medications, unless a stop date is specified by the physician.

3.1.9.2

Automatic stop-order policies should be developed for specific drug classes for which a limited duration of therapy is usually desirable (such as, antibiotics, post-operative narcotics).

3.1.9.3

Medication orders should be automatically reviewed by the physician when a patient goes to critical care, the delivery room, the operating room, or a different service.

3.1.9.4

The prescriber shall be notified of the impending expiration of a medication order so that appropriate patient reassessment can be completed before the order is renewed. Unintended interruption of treatment should be avoided.

3.1.10

In computerized patient data systems where physicians perform medication order entry, each prescriber should have a unique identifier or code that is clearly displayed on the medication order.

3.1.11

Appropriate records should be maintained to allow for reviews of all processed medication orders to determine the following information:

- (a) date and time of dispensing;
- (b) who prepared the doses;
- (c) how many doses were dispensed; and
- (d) who checked and dispensed the medications.

3.2 Drug-Use Evaluation

3.2.1

The pharmacy service shall coordinate, in cooperation with the medical staff and the pharmacy and therapeutics committee, a system for the ongoing evaluation of medication-use within the hospital, which may include the following components:

- (a) development of medication-use criteria, such as the following, to promote appropriate use:
 - (i) diagnostic criteria (i.e., restricting use of a medication to a specific diagnosis);
 - (ii) prescriber criteria (i.e., restricting use of a medication to physicians in certain specialities, such as infectious disease specialists, cardiologists);
 - (iii) drug-specific criteria (such as, limiting certain long-acting injectable antibiotics to once-daily administration except where approved by an infectious disease specialist);
- (b) development of treatment guidelines (such as, for community-acquired pneumonia, myocardial infarction);
- (c) evaluation of medication-use against the pre-determined criteria;
- (d) identification of problem areas;
- (e) education to correct patterns of inappropriate medication-use;
- (f) evaluation of such educational programs; and
- (g) measurement and comparison of patient outcomes.

3.2.2

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

3.2.3

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

3.2.4

Recommendations for improvement should include educational programs or structural or procedural modifications.

4. DRUG-USE CONTROL

4.1 Formulary System

4.1.1

The pharmacy service, in cooperation with the pharmacy and therapeutics committee, shall maintain a formulary system governing the rational selection and use of medications in the hospital to optimize patient care.

4.1.2

The formulary shall be based on therapeutic and economic considerations related to medication-use, but economic considerations shall not compromise quality of care.

4.1.3

The formulary shall be approved by the appropriate hospital committee (such as, the medical advisory committee).

4.1.4

The formulary shall have the following components:

- (a) a list of the drug products that have been selected and approved for use within the hospital, classified according to pharmacologic and therapeutic use;
- (b) information about available dosage forms, dosage strengths, unit-of-use quantities, and unit cost for each drug product;
- (c) information on the use of the formulary and its management by the relevant hospital committees;
- (d) a cross-index of drug products according to generic and trade names;
- (e) aids for medication-use, such as equivalency tables, dosing charts, and other sources of information; and
- (f) policies and procedures governing additions to and deletions from the formulary.

4.1.5

The formulary shall be available to all health care professionals who prescribe, administer, or dispense medications.

4.1.6

The pharmacy service shall be responsible for the maintenance and control of the formulary system².

4.1.6.1

The pharmacy and therapeutics committee should review the use and therapeutic effects of formulary drugs from several classes annually for the following attributes:

- (a) effectiveness;
- (b) comparison with formulary medications from the same drug class;
- (c) toxicity; and
- (d) cost-effectiveness.

4.1.6.2

The pharmacy and therapeutics committee shall develop a clear process for making changes to the formulary. This process should include the following components:

- (a) an evaluation of the proposed change, prepared by the pharmacy service;
- (b) a summary of the anticipated changes to the quality of patient care;
- (c) a pharmacoeconomic analysis;
- (d) potential implications for other drug therapies; and
- (e) pre-determined reassessment dates to evaluate the impact of decisions to change the formulary, especially when the expected impact of the change in drug therapy on the cost or quality of the patient care is significant or unknown.

4.1.7

The formulary shall be reviewed regularly, revised as necessary, and dated accordingly for purposes of quality improvement.

4.1.7.1

A request for the addition of a drug to the formulary shall be made in writing and shall include the following elements:

- (a) generic name, strength, and dosage form of the drug;
- (b) therapeutic classification, major indications, side effects, precautions, and usual dose of the drug;
- (c) reasons why it should be added to the formulary;
- (d) any restrictions that should be placed on use of the drug;
- (e) drugs currently in the formulary that could be replaced by the new drug; and
- (f) special training or equipment that may be required to administer the drug or monitor use of the drug.

4.1.7.2

Pharmacists should play a primary role in assessing the relative safety and efficacy of drugs that are being considered for the formulary and should ensure that the information presented in support of a formulary recommendation is balanced. The full impact of the addition or deletion of a drug shall be considered, including drug acquisition costs, carrying costs, preparation costs, storage requirements, human resource time, equipment required for administration, anticipated changes to length of stay, estimated frequency and duration of use, and monitoring costs.

4.1.7.3

A proposed formulary change shall be presented at a pharmacy and therapeutics committee meeting for evaluation in a balanced manner.

4.1.7.4

The requesting individual should be invited to attend the pharmacy and therapeutics committee meeting and shall be informed of the committee's decision.

4.1.7.5

The pharmacy and therapeutics committee shall advise the medical, nursing, pharmacy service, and other health care provider staffs in writing of changes to the hospital formulary in a timely and routine manner.

4.1.8

Policies and procedures shall provide for the use of various types of medications within the hospital, including the following:

- (a) formulary medications;
- (b) non-formulary medications;
- (c) sample medications;
- (d) investigational medications;
- (e) Special Access Programme drugs;
- (f) drugs required on an emergency basis;
- (g) patient's own medications;
- (h) specific medications whose use has been restricted to defined therapeutic indications or specialties within the hospital
- (i) generic substitutions; and
- (j) drugs identified through therapeutic interchange.

4.1.8.1

The pharmacy and therapeutics committee should develop policies and procedures for obtaining, using, and evaluating non-formulary drugs.

- (a) The procurement process should be responsive and timely to meet patient care needs.
- (b) The evaluation process should be designed to monitor trends and assist in formulary decisions.

4.1.8.2

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 service.

4.1.8.3

The pharmacy service shall be responsible for the storage and distribution of all investigational and Special Access Programme drugs used for inpatients and outpatients, with the following conditions:

- (a) investigational drugs shall be used only under the authorization of the principal investigator;
- (b) investigational drugs shall be approved for use by the appropriate hospital committees;

- (c) policies and procedures shall be available that describe the approval process for the use of investigational and Special Access Programme drugs;
- (d) information on investigational and Special Access Programme drugs shall be readily available;
- (e) the pharmacy service shall maintain records of the use of investigational and Special Access Programme drugs; and
- (f) the use and control of investigational drugs shall comply with the CSHP Guidelines for Use of Drugs in Clinical Trials in Health Care Facilities.⁴

4.1.8.4

Medications brought to the hospital by patients shall not be administered unless the medications can be verified by a pharmacist or authorized designate. Written or verbal orders to administer a patient's own medications shall be given by the prescriber and shall be clearly documented in the patient's medical record.

4.1.8.4.1

A pharmacist shall dispense a patient's own medication if all of the following conditions apply the:

- (a) identity of the medication is known;
- (b) medication is approved for use in Canada;
- (c) integrity of the medication has not been compromised; and
- (d) established or potential benefits outweigh the established or potential risks of the product.

4.1.8.4.2

Patients should be encouraged to have a family member remove any of their own medications that are not going to be used in the hospital.

4.1.8.4.3

If the patient's medications cannot be sent home during the hospital stay, they shall be stored in a secure space, separate from inpatient medications and in accordance with hospital policy regarding patients' valuables, and returned to the patient at the time of discharge.

4.1.8.4.4

Medications not returned to the patient shall be destroyed by the pharmacy service in accordance with hospital policy and legal requirements.

4.1.8.5

Generic substitution is an acceptable strategy in formulary management.

4.1.8.6

Therapeutic interchange is an acceptable strategy in formulary management. Therapeutic interchanges should meet the following criteria:

- (a) involve the interchange of one drug for another with appropriate dose adjustments, if necessary;
- (b) be routinely reviewed and revised as needed;
- (c) be clearly documented in the patient's medical record when used;
- (d) be monitored and followed up to identify or prevent any unexpected or untoward response;
- (e) be applied consistently; and
- (f) be considered inappropriate if warranted by clinical indications (such as, therapeutic failure on previous exposure to the drug, patient preference).

4.2 Drug Procurement

4.2.1

The purchase of all medications shall be performed under the supervision of a pharmacist.

4.2.2

The pharmacy service should use appropriate practices for medication purchase, including competitive bid purchasing and group purchasing.

4.2.3

The pharmacist shall use professional judgement and appropriate sources of information in making decisions regarding products, quantities, product specifications, and sources of supply.

4.2.3.1

The pharmacist should consider the following features when selecting a product: price, terms and conditions, shipping details, vendor reliability, quality of service, returned-goods policy, packaging, and product quality.

4.2.4

The pharmacy service shall develop and follow procedures for obtaining emergency supplies of medications.

4.2.5

The pharmacy service should develop and follow procedures for obtaining medications through Health Canada's Special Access Programme.

4.3 Drug Inventory Management

4.3.1

Personnel involved in the purchase, receipt, and control of drugs:

- a) shall understand the serious nature of drugs; and
- b) should be well trained in their duties and responsibilities³.

4.3.2

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

4.3.2.1

The duration of retention of records may vary according to local, provincial, or territorial regulations.

4.3.2.2

The pharmacist should be familiar with regulations pertaining to provincial and federal sales taxes, records, and reports. The following are some of the records needed to control inventory³:

- (a) perpetual inventory for controlled substances;
- (b) medication orders and processing records;
- (c) manufacturing and packaging production records;
- (d) pharmacy service workload records;
- (e) purchase and inventory records;
- (f) equipment maintenance records; and
- (g) records of results and actions performed in quality assurance and drug audit programs.

4.3.3

The pharmacist shall maintain an adequate inventory control system that may include, but is not limited to, the following components:

- (a) establishment of minimum and maximum stock levels to avoid the problems of depletion or overstocking of drug products;
- (b) accountability for drug products as they are removed from stock;
- (c) detection and proper disposal of outdated, deteriorated, recalled, discontinued, or hazardous drug products³; and
- (d) analysis and interpretation of medication usage trends and their economic impact³.

4.3.4

All drug products shall be delivered unopened to the pharmacy service upon receipt in the hospital receiving area.

4.3.5

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

4.3.5.1

All medications shall be placed into stock in appropriate storage areas upon receipt.

4.3.5.2

All medications shall be stored safely under proper conditions of sanitation, temperature, light, humidity, ventilation, regulation, segregation, and security to maintain product integrity and staff safety³.

4.3.5.2.1

Medications requiring refrigeration should not be stored with food.

4.3.5.2.2.

Medications intended for external application should be kept separate from medications intended for internal administration.

4.3.5.2.3

Special consideration should be given to the safe storage of poisons and of flammable and dangerous goods.

4.3.5.3

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

4.3.5.4

Medications shall be stored to ensure proper stock rotation in the pharmacy service, in patient care areas, and throughout the institution, including the following sites:

- (a) satellite pharmacies;
- (b) nursing units;
- (c) automated cabinets;
- (d) clinics;
- (e) emergency department;
- (f) operating rooms;
- (g) recovery rooms;

- (h) treatment rooms; and
- (i) night cabinets.

4.3.5.5

Annual inspections shall be made of all medication storage areas and medication centres within the hospital. A written record shall verify that the following conditions are met:

- (a) disinfectants and medications for external use are stored separately from injectable medications and medications for internal use;
- (b) medications requiring special environmental conditions for stability are properly stored;
- (c) no outdated or discontinued medications are stocked;
- (d) narcotics and controlled substances are stored with proper measures of security;
- (e) no medications are being overstocked;
- (f) medications that may be required on an emergency or urgent basis are in adequate supply and properly stored;
- (g) medications that are no longer required by a patient are returned to the pharmacy service;
- (h) standards of neatness and cleanliness are consistent with good medication handling practices; and
- (i) storage equipment performs to the required specifications (such as, refrigerator maintains suitable cold temperature)

4.3.6

Deteriorated, discontinued, and expired medications shall be disposed of in accordance with professional standards and legal requirements, in an environmentally safe and effective manner.

4.3.6.1

All non-usable medications shall be stored in a separate, secure area within the pharmacy service until final disposal.

4.3.7

The pharmacy service shall develop and follow drug and device recall procedures that can be readily implemented.

4.3.7.1

The results of any drug recall shall be documented and communicated to all appropriate departments and areas throughout the organization.

4.4 Medication Distribution Service

4.4.1 *General Principles*

4.4.1.1

The pharmacy service shall develop and provide medication distribution services to meet the needs of patients and to optimize safety, efficiency, and economy.

4.4.1.2

The following requirements shall be considered during the design of the medication distribution system to help reduce the potential for error and the nursing time involved in handling and administering medications:

- (a) reduce or eliminate transcription of medication orders (such as, by means of self-copying order forms or facsimiles);
- (b) provide legible patient and medication order information (such as, by means of computerized physician order entry);
- (c) provide medications in identified dosage units ready for administration, wherever possible and practical;
- (d) protect medications from contamination;
- (e) minimize nursing time required to prepare medications before administration;
- (f) eliminate the drug ticket as a means to identify and schedule medications;
- (g) simplify charting and allow recording of medications at the time of administration;
- (h) provide a means to determine whether or not an individual dose has been administered;
- (i) simplify the recording procedure; and
- (j) eliminate or reduce the need to maintain ward stock.

4.4.1.3

The unit-dose system should be the drug distribution system of choice. Other distribution systems may be used, including but not limited to the following:

- (a) controlled-dosage system;
- (b) individual patient prescription system;
- (c) ward stock system; and/or
- (d) patient self-administration of medication program.

4.4.2 *Dispensing*

4.4.2.1

Dispensing shall be restricted to the pharmacist or other authorized personnel under the direction and supervision of the pharmacist. The accuracy of the dispensed medication shall be verified before administration. (Refer to the CSHP Guidelines for the Delegation of Functions to Pharmacy Technicians.⁵)

4.4.2.2

Special orders (such as, "stat" orders and orders for non-formulary drugs, investigational drugs, and restricted-use drugs) shall be processed and dispensed according to specific written procedures and in accordance with hospital policy.

4.4.3 *Labelling*

4.4.3.1

The pharmacy service shall use a standard format, standard terminology, SI (Système international) units, and generic nomenclature on all medication labels, and all labels shall meet all applicable local, provincial, territorial, and federal regulations.

4.4.3.2

A list of acceptable abbreviations and symbols, approved by the pharmacy and therapeutics committee, shall be maintained by the pharmacy service for use in medication prescribing and labelling; this list shall follow current medication safety recommendations.

4.4.3.3

The label shall include the following information, when appropriate:

- (a) appropriate directions for medications requiring dilution or reconstitution;
- (b) expiration date and proper storage conditions;
- (c) acceptable route of administration for parenteral medications;
- (d) lot numbers or codes of source products for repackaged medications;
- (e) non-proprietary names;
- (f) auxiliary labels as required (such as, "shake well," "refrigerate");
- (g) names of all therapeutically active ingredients in compounded mixtures;
- (h) amount of drug in each dosage unit (such as, 250 mg/5 mL [50 mg/mL], 125 mg per capsule);
- (i) amount dispensed; and
- (j) identifier for the pharmacist responsible for dispensing the medication.

In addition, the following considerations should be taken into account³:

- (a) labels for large volumes of parenteral medications should be firmly affixed in a way that allows visual inspection;
- (b) unofficial names, synonyms, and coined names should not be used; and
- (c) small items may be labelled with the minimum required information (patient name, drug name, drug strength, and prescription number), and the small container can then be put into a larger container that bears the full label with all pertinent information as listed above.

4.4.3.4

Medication labels shall be typed or machine printed, shall be free of erasures and strikeovers, and shall be firmly affixed to the container. Labelling with pen, pencil, or marker is prohibited.

4.4.3.5

Only pharmacy service personnel shall alter or apply labels to medication containers.

4.4.3.6

A label should not be superimposed over an existing label.

4.4.3.7

Any medication label on a drug container that will be used outside the hospital shall include the pharmacy service name, address, and phone number and shall meet all local and provincial regulations.

4.4.4 *Unit-Dose Medication System*

4.4.4.1

Unit-dose packaging shall be consistent with either the CSHP Guidelines for Drug Packaging and Labelling for Manufacturers⁶ or the CSHP Guidelines for Repackaging Medications in Hospitals.⁷

4.4.4.2

Unit-dose carts or medication trays shall be used for storing medications on the ward.

4.4.5 *Controlled-Dosage System*

4.4.5.1

Medications shall be dispensed in individually labelled controlled-dosage packages.

4.4.5.2

The amount of medication dispensed shall be determined by hospital policy.

4.4.5.3

Medication cards or containers shall be labelled with the following information:

- (a) patient's name and location;
- (b) name of the medication;
- (c) strength;
- (d) route of administration;
- (e) accessory or cautionary statements as required; and
- (f) date dispensed.

4.4.6 *Individual Patient Prescription System*

4.4.6.1

Medications shall be dispensed in individually labelled medication containers

4.4.6.2

The amount of medication dispensed shall be determined by hospital policy.

4.4.6.3

Medication containers shall be labelled with the following information:

- (a) patient's name and location;
- (b) name of the medication;
- (c) strength;
- (d) route of administration;
- (e) accessory or cautionary statements as required; and
- (f) date dispensed.

4.4.7 *Ward Stock System*

4.4.7.1

Ward stock medications shall be limited to those medications commonly prescribed on an “as needed” (p.r.n.) basis, or medications that are used in routine patient treatment and that do not have a high potential for toxic effects, are not complex to manipulate, and are not extremely expensive.

4.4.7.2

Staff who are working in patient-care areas should be familiar with the ward stock medications.

4.4.7.3

The pharmacy service shall be responsible for the distribution and control of ward stock medications.

4.4.7.4

Minimum and maximum levels of ward stock medications shall be established for each patient care area by nursing and the pharmacy service.

4.4.7.5

When narcotics and controlled substances are provided through a ward stock system, they shall be stored in accordance with legal requirements, and appropriate records shall be maintained.

4.4.7.6

Medications that may be required on an emergency or urgent basis shall be provided as a special form of ward stock and shall be stored in sealed units. The container that holds emergency medications shall be returned to the pharmacy service for inspection and replacement when the seal has been broken during use or when the stock becomes outdated. The pharmacy and therapeutics committee or another appropriate committee shall determine the medications to be maintained in such emergency stocks³.

4.4.7.7

Medications intended for distribution from the emergency department to outpatients by designated hospital personnel shall be prepared in labelled, safety-capped packages and shall be issued according to hospital policy and provincial regulations.

4.4.7.8

The use of multi-dose vials should be minimized.

4.4.8 *Patient Self-administration of Medication Program*

4.4.8.1

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

4.4.8.2

Self-administration of medications by patients shall be permitted when specifically ordered by the prescriber in accordance with the hospital's policies and procedures.

4.4.8.3

A self-administration of medication program should include, but should not be limited to, the following components:

- (a) education of the patient by the pharmacist, covering the following topics:
 - (i) name and identification of the medication;
 - (ii) indication;
 - (iii) dosage, frequency, and duration;
 - (iv) side effects;
 - (v) documentation procedure for administration; and
 - (vi) requirements for appropriate storage;
- (b) clearly labelled unit-dose packages of medications;
- (c) legible medication administration records for the patient's use;
- (d) patient education material presented in a clear and simple format;
- (e) clear and detailed instructions for the patient and the pharmacy service, medical, and nursing staffs regarding procedures and responsibilities; and
- (f) written policies and procedures approved by the hospital.

4.4.9 *Delivery of Medications*

4.4.9.1

Medications shall be delivered to the patient care area with the least possible delay. Medications may be sent through pneumatic tubes or by dumb waiters, porters, or trolleys.

4.4.9.2

All parts of the transportation system shall be configured to protect medications from pilferage and breakage; locks or other security devices may be used.

4.4.9.3

When appropriate, special procedures for delivery of certain medications (such as, narcotics, controlled substances, investigational drugs, total parenteral nutrition solutions, intravenous admixtures, chemotherapy admixtures) shall be established to ensure that the medications are delivered safely and promptly, that they are intact on arrival, and that they are placed in proper storage areas upon arrival in the patient care area (such as, in a locked storage cupboard or refrigerator).

4.4.9.4

Alternative delivery methods should be developed in case of breakdown or service interruptions for the primary delivery method.

4.4.10 *After-Hours Pharmacy Service*

4.4.10.1

If 24-hour pharmacy service is not available on site, there shall be provision for after-hours pharmacy service.

4.4.10.2

The pharmacy service shall establish policies and procedures clearly describing how medications may be accessed in situations where a drug is to be given before a pharmacist can review and approve the prescription. Such policies and procedures should be made readily available to all hospital staff.

4.4.10.3

Policies and procedures should be implemented to ensure review of all orders initiated without a pharmacist's prior review and approval.

4.4.10.4

Only licensed pharmacists should have access to the pharmacy for obtaining medications.

4.4.10.5

A policy shall be established outlining the procedures to be followed in the event of an emergency occurring when the pharmacy service is closed that necessitates immediate access by designated non-pharmacy-service personnel. Such access shall be documented and communicated to the pharmacist as soon as possible. Examples of emergency situations include fire, flood, and breach of security.

4.4.11 *Night Cabinet*

There shall be a medication night cabinet for after-hours pharmacy service, so that authorized personnel may obtain medications that have been ordered for a patient after regular pharmacy service hours and that are needed for immediate commencement of therapy.

4.4.11.1

The limited number of medications that are to be kept in the night cabinet should be determined by a committee of pharmacists, physicians, and nurses who agree that the clinical need for these drugs outweighs the risk associated with ready availability. This list of medications should be reviewed regularly.

4.4.11.2

The medication night cabinet shall be stocked with a minimum supply of the medications most commonly required for immediate use³.

4.4.11.3

Narcotics and controlled substances may be stocked in the medication night cabinet only if they are secured with a double lock. Procedures for the procurement of narcotics and controlled substances shall be clearly posted, outlined, adhered to, and monitored.

4.4.11.4

The medications in the night cabinet shall be stored in labelled unit-of-use containers with an indexing system to permit rapid access.

4.4.11.5

The pharmacy service shall regularly restock the medication night cabinet with the medications that have been removed.

4.4.11.6

The medication night cabinet shall be checked regularly for expired or missing medications.

4.4.11.7

When the pharmacy service is closed, authorized personnel shall obtain needed medications from the medication night cabinet. All withdrawals from the medication night cabinet shall be documented. The physician's original order or a direct copy should be left with this record, and a pharmacist shall check these documents at the earliest possible time after regular service resumes. The following information shall appear on the record and the order:

- (a) patient's name, hospital identification number, and location;
- (b) complete description of the medication;

- (c) prescriber's name;
- (d) name and signature of the authorized nurse;
- (e) number of doses taken; and
- (f) date and time the doses were taken.

4.4.11.8

In the event that a required medication is not available in the medication night cabinet or drug information is required before a drug is withdrawn from the medication night cabinet, a designated pharmacist shall be available for consultation after regular pharmacy service hours.

4.5 Return of Medications

4.5.1

Medications dispensed for administration but not used shall be returned to the pharmacy service.

4.5.2

Procedures for crediting and returning medications to stock shall take into account the integrity of packaging of the returned drug and the proper storage of the medication in the patient care area.

4.5.3

The following medications shall be discarded when returned to the pharmacy service:

- (a) opened topical medications (such as, creams, ointments, lotions, and ophthalmic, otic, or nasal drops or ointments);
- (b) used inhalation products, unless they have been cleaned and sterilized;
- (c) opened multi-dose and single-dose vials;
- (d) opened liquid products;
- (e) medications that have been handled by patients;
- (f) medications that have been returned by ambulatory patients;
- (g) medications that have been stored improperly; and
- (h) all oral dosage forms, unless packaged in unit-dose containers.

4.6 Repackaging of Medications

4.6.1

The pharmacy service shall, when necessary, repackage medications for use within the medication distribution system according to the CSHP Guidelines for Repackaging Medications in Hospitals.⁷

4.6.2

Written policies and procedures, including guidance on maintaining quality control records, shall be in place for the repackaging of medications.

4.6.3

Precautions shall be taken to meet the following requirements:

- (a) ensure that the label correctly states the contents of the package;
- (b) ensure hygienic packaging;
- (c) ensure stability;
- (d) prevent cross-contamination of drugs; and
- (e) use appropriate techniques for special medications (such as, cytotoxic drugs).

4.6.4

Auxiliary labels, instructions, Workplace Hazardous Materials Information System (WHMIS) labels, and cautionary statements shall be used where appropriate.

4.7 Preparation of Medications

4.7.1 *General Principles*

4.7.1.1

The pharmacy service shall prepare dosage forms, dosage strengths, and medication delivery systems as required to meet the specific needs of patients.

4.7.1.2

Written policies and procedures shall be in place for the preparation of medications, including the compounding of medications and the preparation of sterile products and cytotoxic drugs.

4.7.1.3

The pharmacy service shall comply with the CSHP Guidelines for Bulk Compounding of Products in Hospitals.⁸

4.7.2 *Preparation of Sterile Products*

4.7.2.1

An intravenous admixture program, based within the pharmacy service, shall be the system of choice for admixing parenteral products. The pharmacy service shall aseptically prepare sterile drug products as required to meet the specific needs of patients, in accordance with the CSHP Guidelines for Preparation of Sterile Products in Pharmacies.⁹

4.7.2.2

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

4.7.2.3

Cytotoxic drugs shall be handled and prepared in accordance with the CSHP Guidelines for the Handling and Disposal of Hazardous Pharmaceuticals (Including Cytotoxic Drugs).¹⁰

4.7.2.4

Quality control records related to the preparation of medications shall be maintained in a log book or in individual patient records. (Refer to CSHP Guidelines for Preparation of Sterile Products in Pharmacies.⁹)

4.7.2.5

Parenteral admixtures and solutions shall be prepared in a laminar air flow hood equipped with a high-efficiency particulate air (HEPA) filter to prevent contamination with micro-organisms and particulate matter. Cytotoxic drugs shall be prepared in a Class II Type B-2 biological safety cabinet.

4.7.2.6

All completed parenteral admixtures and solutions prepared by technical personnel shall be checked by the pharmacist or delegate:

- (a) the correct medication and quantity has been added to the appropriate solution;
- (b) the appropriate information has been included on the label; and
- (c) the correct label has been affixed to the completed admixture or solution.

4.7.2.7

The pharmacist shall ensure that the following conditions are met for all sterile products:

- (a) the dosage calculations are correct;
- (b) the label correctly states the contents of the package;
- (c) the packaging is hygienic;
- (d) the contents of the package are stable and compatible; and
- (e) all completed parenteral solutions are inspected for particulate matter and signs of incompatibilities, degradation, or contamination before they are dispensed.

4.7.2.8

Parenteral admixtures and solutions shall be labelled in a standard format. (Refer to CSHP Guidelines for Preparation of Sterile Products in Pharmacies.⁹)

4.7.2.9

An end-product testing procedure and acceptance criteria should be developed, and the procedure should be performed in accordance with the CSHP Guidelines for Preparation of Sterile Products in Pharmacies.⁹

4.7.2.10

A scientifically sound program of environmental monitoring should be used to ensure that recognized standards are maintained.

4.8 Administration of Medications

4.8.1

The pharmacy and therapeutics committee shall develop written policies and procedures to govern the safe administration of medications. These policies and procedures shall include the following specifications:

- (a) Medications shall be administered only upon the order of an individual who has been assigned clinical privileges or who is an authorized member of the medical staff.
- (b) Medications shall be administered only by appropriately licensed personnel in accordance with laws and regulations governing such acts.
- (c) In a unit-dose distribution system, medications shall be administered directly from the medication cart (or its equivalent) at the patient's room, and a medication shall not be removed from the unit-dose package until it is to be administered.
- (d) In an individual patient prescription system, medications shall be prepared for administration in a manner that minimizes the potential for error by minimizing the number of transcription steps, by eliminating patient identification cards or tickets, and by using medication carts similar to the process in the unit-dose distribution system.
- (e) In a controlled-dosage system, medications shall be administered directly from the medication controlled-dosage package. The medication shall be removed from the controlled-dose package only when it is to be administered.
- (f) In the absence of the recommended intravenous additive service, precautionary measures for the safe admixture of parenteral products in the patient care area shall be developed, and a distinctive supplementary label shall be affixed to indicate the patient's name, the name and amount of medication added, the date and time of the addition, and the name of the person who prepared the admixture.
- (g) A parenteral drug manual shall be maintained and shall include the hospital's policy with respect to each medication.
- (h) A medication shall be given as close to the specified time as possible (as defined by hospital policy).
- (i) The patient for whom a medication is intended shall be positively identified in accordance with hospital policy (such as, by checking the patient's identification band or hospital number or photograph).

- (j) The person administering the medication shall stay with the patient until the dose has been taken, except for self-administered medications.
- (k) All administered, refused, or omitted medication doses shall be recorded in the patient's medical record, according to established procedure. Information to be recorded shall include:
 - i) the medication name;
 - ii) dose, route of administration;
 - iii) frequency, date and time of administration; and
 - iv) initials of the person administering the dose.
- (l) Procedures should be established for administration of medications by non-nursing personnel (such as, physicians, respiratory therapists, licensed practical nurses).
- (m) All medications that have not been administered to the patient shall be returned to the pharmacy service.
- (n) A detailed policy shall be developed for situations, in which personnel must administer medications that are not usually their responsibility, or by a route that is not usually their responsibility; the policy shall cover the required qualifications of such personnel and the circumstances under which they may act.
- (o) A list should be prepared of specific medications that require two authorized health care professionals to check the prescription and drug before a drug on that list can be administered.

4.8.2

The pharmacy and therapeutics committee should develop a schedule of standard medication administration times.

4.8.3

In circumstances where the administration time is critical to pharmacy service workload planning, the nurse shall notify the pharmacist whenever it is necessary to deviate from the standard medication administration schedule.

DEFINITIONS

The following definitions apply in these Guidelines.

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

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

Controlled-dosage system — a form of drug distribution in which medication orders are filled individually and packaged (such as, in the form of blister cards or cassettes) in accordance with scheduled administration times; also known as a monitored dosage system. Each package contains no less than one day's supply of medication and no more than approximately one month's supply. Not equivalent to "unit-dose system."

Cytotoxic drug — a drug that has a deleterious effect on cells; usually refers to antineoplastics or other drugs used in the treatment of cancer.

Dispense — to provide a medication in accordance with a medication order; does not include administration of the medication.

Drug recall — a request for removal of a defective medication from stock and the subsequent fulfillment of the request. A drug recall usually occurs when a particular lot of a medication is of substandard quality or when a particular medication produces unexpected side effects.

Drug-use control — a system of knowledge, understanding, judgements, procedures, skills, controls, and ethics that ensures optimum safety in the distribution and use of drugs.¹¹

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

Formulary — a dynamic compilation of medications that have been approved for use within a health care institution, along with relevant information and related policies, reflecting the current clinical judgement of the pharmacy and therapeutics committee.

Generic substitution — the use of another product that is chemically identical with the drug form prescribed in terms of strength, concentration, dosage form, and route of administration.

Goal — a statement describing a desired end result. In the context of a hospital department, goals are based on the mission and vision of the department and are presented in proactive, broad, long-range terms. A goal is therefore a general philosophical commitment indicating the conceptual direction of the department over a period of time.

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

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

Investigational drug — a medication approved by Health Canada for limited clinical use by approved investigators.

Medical record — a patient's medical chart or health care record.

Medication discrepancy — a drug-related event in which an error in the drug process is detected and corrected before the situation reaches the patient; does not involve the administration (or lack thereof) of a drug to a specific patient, but does include the unexplained loss or theft of a medication. Compare "medication incident."

Medication distribution service — a hospital system coordinated by the pharmacy service that is used to provide medications to the patient in a controlled manner.

Medication incident — a patient-related event that involves the incorrect administration of a medication to a specific patient or the omission of administration of a prescribed drug. Compare “medication discrepancy.”

Medication night cabinet — a suitable locked storage area (such as, a cupboard, room, cart) containing supplies of repackaged medications that might be required when the pharmacy service is closed.

Medication profile — a record of patient-specific information used to monitor drug therapy. This record includes all medications prescribed and dispensed for the patient.

Medication reconciliation — a process designed to prevent medication errors at patient transition points.

Non-formulary drug — a drug not listed in the hospital formulary.

Objectives — the concrete steps that are required to achieve identified goals. In the context of a hospital pharmacy service, objectives include action plans indicating the person(s) responsible; they have identified start and completion dates; they are realistic and measurable; they are written annually; and they are monitored to determine if they are being achieved.

Patient self-administration of medication program — an organized program in which patients are taught how to administer their own medications in the hospital, in accordance with the policies and procedures of the pharmacy service and the hospital as a whole. [See queries in main document about preferred term for this type of program]

Pharmacist — a person who meets the requirements of a pharmacy regulatory body.

Pharmacy and therapeutics committee — a committee that is composed of representatives from the pharmacy service, medicine, nursing, hospital administration, and other disciplines and that serves as a policy-recommending body on all matters relating to the use of medications in a hospital. May be known by other names, such as, pharmacotherapy committee.

Pharmacy service — a system that integrates the application of the pharmacist’s specialized knowledge with the distribution of medications to ensure optimal medication therapy for patients.

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

Pre-printed order — a document showing pre-determined procedures and actions that are accepted by the clinical team for use in the management of a specific diagnosis or following a specific diagnostic procedure. The physician can use the pre-printed form to individualize any element of a particular drug order.

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

Procedure — detailed guidelines for implementing policy.

Repackage — to remove drugs from the manufacturer’s original package and place within another form of packaging (such as, strip packaging, blister packaging).

Special Access Programme (SAP) — a Health Canada program that provides access to non-marketed drugs for practitioners who are treating patients with serious or life-threatening conditions when conventional therapies have failed, are unsuitable, or are unavailable. The SAP authorizes the manufacturer to sell a drug that cannot otherwise be sold or distributed in Canada. Drugs considered for release by the SAP include pharmaceutical, biologic, and radiopharmaceutical products not approved for sale in Canada.

Telephone drug order — a medication order given over the telephone by a legally qualified prescriber. Compare “verbal drug order.”

Therapeutic interchange — a process in which drug products that are chemically different but considered by the pharmacy and therapeutics committee to be therapeutically equivalent are interchanged according to hospital policies.

Unit-dose distribution — a form of drug distribution in which orders for each patient are filled individually and packaged in unit-of-use packages. Each package contains one dose. Typically, no more than a 24-hour supply of doses is available in the patient care area at any time.

Verbal drug order — a medication order given verbally, other than by telephone, by a legally qualified prescriber. Compare “telephone drug order.”

Ward stock — medications that are stocked in the patient care area at all times and are not individually labelled for a specific patient's use.

Workplace Hazardous Materials Information System (WHMIS) — mechanism whereby suppliers provide information about the hazards of material produced or sold in, imported to, or used within Canadian workplaces to employers and in turn to employees; required by federal legislation.

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† Adapted with permission from the ASHP Guidelines on the Safe Use of Automated Medication Storage and Distribution Devices. *Am J Health-Syst Pharm.* 1998; 55:1403-7."

Additional Resources

Note: The following documents are current at time of printing. Readers should contact the organization publishing the document for any subsequent revisions.

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If you are interested in a current version of this paper, please check CSHP's website: there is no guarantee that such a version exists.

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