

# ***Health Professions Act – BYLAWS***

## **SCHEDULE F**

### **PART 2 – Hospital Pharmacy Standards of Practice**

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## Application

1. This Part applies to all registrants providing pharmacy services in a hospital pharmacy or a hospital pharmacy satellite.

## Definitions

2. In this Part:

**“bulk/batch drug repackaging”** means the repackaging in a single process of multiple units, not for immediate use;

**“bulk compounding”** means the preparation of products which are not commercially available in anticipation of a practitioner’s order;

**“Community Pharmacy Standards of Practice”** means the standards, limits and conditions for practice established in Part 1 of this Schedule;

**“final check”** means ensuring that:

- (a) the prescription product and the prescription product label match the product information with respect to:
  - (i) drug,
  - (ii) dosage form,
  - (iii) strength, and
  - (iv) quantity;
- (b) the drug is not expired and will not expire within the duration of use; and
- (c) a pharmacist has completed a clinical assessment of the prescription after reviewing the patient profile.

**“hazardous drugs”** means pharmaceutical preparations in which the concentration, toxicity, environmental persistence, degradation characteristics, flammability, corrosiveness, or reactivity represents a risk to the health of humans or other living organisms;

**“hospital pharmacy”** has the same meaning as in section 1 of the bylaws of the college under the *Pharmacy Operations and Drug Scheduling Act*;

**“hospital pharmacy satellite”** has the same meaning as in section 1 of the bylaws of the college under the *Pharmacy Operations and Drug Scheduling Act*;

**“individual patient prescription system”** means a form of drug distribution in which drugs are dispensed in patient-specific labelled drug containers;

**“master formula”** means a set of instructions outlining in detail the materials, equipment, and procedures required to produce a specific quantity of a product;

**“multiple pouch packaging”** means a pouch containing drugs to be administered at a particular time;

**“unit dose distribution”** means a form of drug distribution in which orders for each patient are dispensed individually and packaged in unit-of-use packages containing one dose;

**“ward stock”** means drugs that are stocked in a patient care area and are not labelled for a particular patient.

### **Drug Distribution**

3. (1) The pharmacy’s manager must establish a drug distribution system that
  - (a) provides drugs in identified dosage units ready for administration whenever possible and practical,
  - (b) protects drugs from contamination,
  - (c) provides a method of recording drugs at the time of administration, and
  - (d) eliminates or reduces the need to maintain ward stock.
- (2) A unit dose, monitored dose, multiple pouch packaging or individual patient prescription drug distribution system must be used for dispensing drugs.
- (3) Sterile products must be prepared and distributed in an environment that is in accordance with
  - (a) the Canadian Society of Hospital Pharmacists’ Guidelines for Preparation of Sterile Products in Pharmacies,
  - (b) the USP Pharmaceutical Compounding – Sterile Products Guidelines, and
  - (c) such other published standards approved by the board from time to time.
- (4) Hazardous drugs must be handled and prepared in accordance with the Requirements for the Safe Handling of Antineoplastic Agents in Health Care Facilities published by the Workers Compensation Board of British Columbia and such other published standards approved by the board from time to time.

### **Preparation of Prescription Product**

- 3.1 (1) A registrant who prepares a prescription product must ensure that:
  - (a) the prescription product label matches the product information with respect to:
    - (i) drug,
    - (ii) dosage form,
    - (iii) strength,
    - (iv) quantity; and
  - (b) the drug is not expired and will not expire within the duration of use.

## Patient Identification

- 3.2 Unless dispensing to staff, outpatients or the general public under section 4(5), all registrants must use at least two person-specific identifiers to confirm the identity of a patient before providing any pharmacy service to the patient.

## Drug Label

4. (1) Drug container labels must include
- (a) the generic name of the drug, strength and dosage form, and
  - (b) hospital approved abbreviations and symbols.
- (2) Only hospital pharmacy staff may alter a drug container label.
- (3) Inpatient prescription labels must include
- (a) a unique patient name and identifier,
  - (b) the generic name of the drug, strength and dosage form,
  - (c) parenteral vehicle if applicable, and
  - (d) hospital approved abbreviations and symbols.
- (4) The following information must be included on the inpatient prescription label if not available on the medication administration record:
- (a) the frequency of administration;
  - (b) the route of administration or dosage form;
  - (c) auxiliary or cautionary statements if applicable;
  - (d) the date dispensed.
- (5) All drugs dispensed to staff, outpatients or the general public from a hospital pharmacy or hospital pharmacy satellite must be labeled and dispensed according to the *Community Pharmacy Standards of Practice*.
- (6) Prior to releasing a prescription product, a registrant must perform a final check of the prescription product and record his or her identity in writing as required by section 17.

## Returned Drugs

5. (1) Unused dispensed drugs must be returned to the hospital pharmacy.
- (2) Previously dispensed drugs must not be re-dispensed unless
- (a) they are returned to the hospital pharmacy in a sealed dosage unit or container as originally dispensed,
  - (b) the labeling is intact and includes a legible drug lot number and expiry date, and

- (c) the integrity of the drug can be verified.

### **Drug Transfer**

- 6. A registrant who supplies a Schedule I drug to another registrant or practitioner must comply with section 8(3) and (4) of the *Community Pharmacy Standards of Practice*.

### **Inpatient Leave of Absence and Emergency Take-Home Drugs**

- 7. (1) A system must be established to provide drugs to an emergency department short stay patient requiring take-home drugs, who is unable to obtain them from a community pharmacy within a reasonable time frame.
- (2) All take-home drugs issued from the emergency department must be documented in the patient's health record.
- (3) All inpatient leave of absence drugs must be documented in the patient's health record.
- (4) Labels for inpatient pass and emergency department take-home drugs must include
  - (a) the hospital's name,
  - (b) the patient's name,
  - (c) the practitioner's name,
  - (d) the drug name, strength and directions for use,
  - (e) identification of the person preparing the drug, and
  - (f) the date the drug is issued.
- (5) Drugs must be dispensed in a container that is certified as child-resistant unless
  - (a) the practitioner, the patient or the patient's representative directs otherwise,
  - (b) in the registrant's judgment it is not advisable to use a child-resistant container,
  - (c) a child-resistant package is not suitable because of the physical form of the drug or the manufacturer's packaging is designed to improve patient compliance, or
  - (d) child-resistant packaging is unavailable.

### **Investigational and Special Access Program Drugs**

- 8. Registrants must comply with the policies and directives of Health Canada with respect to storage and dispensing of Special Access Program or investigational drugs.

### **Drug Repackaging and Compounding**

- 9. (1) A registrant must supervise all bulk/batch drug repackaging and bulk drug compounding.

- (2) Bulk/batch drug repackaging records must be kept for three years after the repackaging date.
- (3) A master formula record must be kept for each bulk compounded drug product.
- (4) A separate production record must be kept for each compounded bulk product and must include
  - (a) the date of compounding,
  - (b) the lot or batch number assigned to the compounded product,
  - (c) the manufacturer's name and lot number for each raw material used,
  - (d) the identification of each registrant and pharmacy assistant involved in each step of the compounding process,
  - (e) the process including weights and measures performed,
  - (f) the results of all quality control testing,
  - (g) a statement of the final yield,
  - (h) signatures for final verification and authorization for release,
  - (i) a sample label, and
  - (j) the expiry date of the product.
- (5) A production record must be kept for a period of three years after the expiry date of the compounded batch.
- (6) A label must be affixed to the finished bulk/batch repackaged or bulk compounded drug and must contain
  - (a) generic name(s) of the drug,
  - (b) strength and quantity of active ingredients,
  - (c) dosage form,
  - (d) total amount of final product,
  - (e) expiry date of the compound,
  - (f) manufacturer identification and lot number or hospital pharmacy control number,
  - (g) storage conditions, if applicable,
  - (h) auxiliary labels, if applicable, and
  - (i) the name of the hospital.

## **Hospital Pharmacy Technicians**

10. (1) Pharmacy technicians in a hospital pharmacy or hospital pharmacy satellite may prepare, process and compound prescriptions, including
  - (a) receiving and transcribing verbal prescriptions from practitioners,
  - (b) ensuring that a prescription is complete and authentic,
  - (c) transferring prescriptions to and receiving prescriptions from other pharmacies,
  - (d) ensuring the accuracy of a dispensed prescription,
  - (e) performing the final check of a dispensed prescription, and
  - (f) ensuring the accuracy of drug and personal health information in the PharmaNet patient record.
- (2) Despite subsection (1), a pharmacy technician in a hospital pharmacy or hospital pharmacy satellite may dispense a drug but must not
  - (a) perform the task of ensuring the pharmaceutical and therapeutic suitability of a drug for its intended use,
  - (b) do anything described in
    - (i) sections 13, 15 or 16 of this Part
    - (ii) Part 4 of this Schedule, or
  - (c) dispense a drug pursuant to HPA Bylaws Schedule F, Part 5.
- (3) A pharmacy technician must identify his or her registrant class in any interaction with a patient or a practitioner.

## **Hospital Pharmacy Assistants**

11. Specific technical functions may be performed by a pharmacy assistant in a hospital pharmacy or hospital pharmacy satellite after the pharmacy's manager has established written procedures for performing the functions.

## **Patient Record**

12. (1) The registrant must ensure the preparation and maintenance of patient records for each patient for whom drugs are prepared are complete, accurate and current, except patients admitted for less than 24 hours to
  - (a) surgical day care,
  - (b) ambulatory care,
  - (c) emergency short-stay, or
  - (d) other short-stay diagnostic or treatment units.

- (2) The patient record must include
  - (a) the patient's full name and admission date,
  - (b) the hospital number and location,
  - (c) the patient's date of birth and gender,
  - (d) the attending practitioner's name,
  - (e) the patient's weight and height if applicable to therapy,
  - (f) the patient's allergies, adverse drug reactions, intolerances, and diagnoses,
  - (g) a chronological list of drugs which have been prescribed for the patient since admission to hospital, or, if admission is prolonged, for a minimum period of two years, and
  - (h) a list of all current drug orders including
    - (i) the drug name,
    - (ii) the drug strength,
    - (iii) the dosage,
    - (iv) the route,
    - (v) the dosage form,
    - (vi) intravenous diluent if applicable,
    - (vii) the directions for use,
    - (viii) administration time or frequency,
    - (ix) the attending practitioner,
    - (x) the quantity,
    - (xi) the start and stop date, or length of therapy, and
    - (xii) the date drug was dispensed, refilled or discontinued.

### **Patient Oriented Pharmacy Practice**

- 13. (1) During pharmacy hours the full pharmacist must review the drug order before the drug is dispensed.

- (2) The full pharmacist must check the drug order for
  - (a) the patient's name, hospital number and location,
  - (b) the signature of the practitioner,
  - (c) the name of the drug,
  - (d) the dosage form and strength,
  - (e) the route and frequency of administration,
  - (f) the duration of treatment if limited,
  - (g) directions for use,
  - (h) the date and time the order was written, and,
  - (i) in the case of verbal and/or telephone orders, the name and signature of the person who received the order.
- (3) The full pharmacist must review the pharmacy patient record before dispensing the patient's drug and at appropriate intervals thereafter to assess
  - (a) appropriateness of therapy,
  - (b) drug interactions,
  - (c) allergies, adverse drug reactions and intolerances,
  - (d) therapeutic duplication,
  - (e) correct dosage, route, frequency and duration of administration and dosage form,
  - (f) contraindicated drugs,
  - (g) intravenous administration problems including potential incompatibilities, drug stability, dilution volume and rate of administration, and
  - (h) any other drug related problems.
- (4) The full pharmacist must notify the patient's nursing staff immediately if a problem with a prescription for a ward stock item is discovered.
- (5) The full pharmacist must monitor drug therapy to detect, resolve and prevent drug-related problems at a frequency appropriate for the medical condition being treated.
- (6) Monitoring includes but is not limited to
  - (a) a review of the patient record and/or health record,
  - (b) discussion with the patient's practitioner and/or other appropriate individual, and
  - (c) use of physical assessment skills when trained to do so.

- (7) The full pharmacist must provide drug information, including patient-specific information to patients and health care personnel.
- (8) A full pharmacist, or a limited or student pharmacist under the direct supervision of a full pharmacist, must provide drug consultation to an outpatient or the outpatient's representative, or to an inpatient on request, and must
  - (a) confirm the identity of the patient,
  - (b) identify the name and strength of drug,
  - (c) identify the purpose of the drug,
  - (d) provide directions for use of the drug including the frequency, duration and route of therapy,
  - (e) discuss common adverse effects, drug and food interactions and therapeutic contraindications that may be encountered, including their avoidance, and the actions required if they occur,
  - (f) discuss storage requirements,
  - (g) provide prescription refill information,
  - (h) provide information regarding
    - (i) how to monitor the response to therapy,
    - (ii) expected therapeutic outcomes,
    - (iii) action to be taken in the event of a missed dose, and
    - (iv) when to seek medical attention, and
  - (i) provide other information unique to the specific drug or patient.
- (9) If a full pharmacist requests a history from a patient or a patient's representative, the following information must be obtained:
  - (a) medical conditions and physical limitations;
  - (b) allergies, adverse drug reactions, and idiosyncratic responses;
  - (c) past and current prescribed drug therapy including the drug name, strength, dosage, frequency and duration and effectiveness of therapy;
  - (d) compliance with the prescribed drug regimen;
  - (e) Schedule II and III and unscheduled drug use.
- (10) A full pharmacist must provide information about the assessment, management and prevention of drug poisoning within the hospital.

## Medication Administration

14. (1) The registrant must collaborate with nursing and medical staff to develop written policies and procedures for the safe administration of drugs.
- (2) A medication administration record of all prescribed drugs for each patient must be produced from the pharmacy-maintained patient record.
- (3) The medication administration record must include
  - (a) the patient's full name and identification number,
  - (b) the patient's location in the hospital,
  - (c) the presence or absence of known allergies, adverse drug reactions, and intolerances,
  - (d) the date or period for which the drug administration record is to be used,
  - (e) the name, dosage and form of all drugs currently ordered,
  - (f) complete directions for use for all drugs,
  - (g) stop or expiry dates for drug orders for which there is an automatic stop policy (if not reported by another means),
  - (h) predetermined, standard medication administration times for regularly scheduled drugs, and
  - (i) changes to drug orders.

## Residential Care

15. A full pharmacist providing pharmacy care to residential care patients residing in a facility that is not licensed under the *Community Care and Assisted Living Act* must
  - (a) use a monitored dosage, multiple pouch packaging or unit dosage system except where the form of the drug does not permit such packaging,
  - (b) restrict ward stock to drugs that do not have a high potential for toxicity or require a complex dosage titration, and are commonly prescribed on a "when needed" basis,
  - (c) maintain a current patient record for each patient,
  - (d) provide administration records of all current drugs for each patient from the pharmacy maintained patient record within seventy-two hours of admission and at least monthly thereafter,
  - (e) review each patient's drug regimen at least every six months preferably in the setting of multidisciplinary rounds, and
  - (f) maintain a written record of drug reviews in the patient's permanent health record, including the date of each review, identified concerns and recommendations.

## Documentation

16. (1) The full pharmacist must document directly in the patient record all activities and information pertaining to the drug therapy of the patient.
- (2) For the purposes of subsection (1), the documentation must include but is not limited to
  - (a) actual or potential drug-related problems that warrant monitoring,
  - (b) recommendations for changes in drug selection, dosage, duration of therapy, and route of administration,
  - (c) recommendations for monitoring the response to drug therapy,
  - (d) notations of consultations provided to other health care professionals about the patient's drug therapy selection and management,
  - (e) notations of drug-related patient education and/or consultation provided,
  - (f) clarification of drug orders and practitioner's telephone orders received directly by the registrant,
  - (g) allergies, adverse drug reactions and intolerances, and
  - (h) the full pharmacist's signature.
17. Documentation of the identity of any registrant who prepared a prescription product or performed a final check must be in writing, readily available and retained for at least three years after the date on which the prescription product was last dispensed.