

Pharmacy Operations and Drug Scheduling Act - BYLAWS

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* Note amendment: previously read *Form 2 Community Pharmacy Licence Renewal Notice, Form 3 Hospital Pharmacy Licence Renewal Notice, Form 4 Telepharmacy Services Application/Authorization, Forms 5 and 6* were not included. Amendment will be submitted to MOH in September 2009.

Definitions

1. In these bylaws:

“**Act**” means the *Pharmacy Operations and Drug Scheduling Act*;

“**central pharmacy site**” means a pharmacy authorized under Part IV to provide telepharmacy services;

“**community pharmacy**” means a pharmacy licensed to sell or dispense drugs to the public

“**Community Pharmacy Standards of Practice**” means the standards of practice established under section 19 (k) or (l) of the *Health Professions Act* respecting community pharmacies;

“**controlled drug substance**” means a drug which includes a substance listed in Schedule I, II, III, IV or V of the *Controlled Drugs and Substances Act* (Canada);

“**controlled prescription program**” means a program approved by the board, to prevent prescription forgery and reduce inappropriate prescribing of drugs;

“**dispensary**” means the area of a community pharmacy that contains Schedule I and II drugs;

“**health authority**” means a regional health board designated under the *Health Authorities Act*;

“**hospital**” has the same meaning as in section 1 of the *Hospital Act*;

“**hospital pharmacy**” means a pharmacy licensed to operate in or for a hospital;

“**hospital pharmacy satellite**” means a physically separate area on or outside the hospital premises used for the provision of pharmacy services which is dependent upon support and administrative services from the hospital pharmacy.

“**Hospital Pharmacy Standards of Practice**” means the standards of practice established under section 19 (k) or (l) of the *Health Professions Act* respecting hospital pharmacies;

“**medication**” has the same meaning as drug;

“**outsource prescription processing**” means to request another pharmacy to prepare or process a prescription drug order;

“**patient’s representative**” has the same meaning as in section 61(1) of the bylaws of the college under the *Health Professions Act*;

“**pharmacy assistant**” means a support person;

“**pharmacy education site**” means a pharmacy

- (a) that has Schedule I, II and III drugs, but no controlled drug substances,
- (b) that is licensed solely for the purpose of pharmacy education, and
- (c) from which pharmacy services are not provided to any person;

“**prescription drug**” means a drug referred to in a prescription;

“professional products area” means the area of a community pharmacy that contains Schedule III drugs;

“professional service area” means the area of a community pharmacy that contains Schedule II drugs;

“Residential Care Facilities and Homes Standards of Practice” means the standards of practice established under section 19 (k) or (l) of the *Health Professions Act* respecting residential care facilities and homes;

“telepharmacy” means the process by which a central pharmacy site operates one or more telepharmacy remote sites, all of which are connected to the central pharmacy site via computer, video and audio link;

“telepharmacy services” means prescription processing or other pharmacy services, provided by or through telepharmacy;

“telepharmacy remote site” means a pharmacy providing pharmacy services to the public, or in or for a hospital,

- (a) without a pharmacist present,
- (b) in a rural or remote community, and
- (c) under the supervision and direction of a pharmacist at a central pharmacy site.

PART I - All Pharmacies

Application

1.1 This Part applies to all pharmacies except pharmacy education sites.

Responsibilities of Pharmacy Managers, Owners and Directors

2. (1) A pharmacist may not act as manager of more than one pharmacy location, unless the pharmacy of which the pharmacist is manager includes
 - (a) a telepharmacy remote site,
 - (b) a hospital pharmacy satellite, or
 - (c) a pharmacy education site.
- (2) A manager must do all of the following:
 - (a) actively participate in the day-to-day management of the pharmacy;
 - (b) confirm that the staff members who represent themselves as pharmacists are registrants;
 - (c) notify the registrar in writing of the appointments and resignations of pharmacists as they occur;
 - (d) cooperate with inspectors acting under section 17 of the *Act* or sections 28 or 29 of the *Health Professions Act*;
 - (e) ensure that pharmacist and pharmacy assistant staff levels are commensurate with the workload volume and patient care requirements at all times;

- (f) ensure that new information directed to the pharmacy pertaining to drugs, devices and drug diversion is immediately accessible to pharmacists, pharmacy assistants and pharmacy students;
- (g) establish policies and procedures to specify the duties to be performed by pharmacists, pharmacy assistants and students;
- (h) establish procedures for
 - (i) inventory management
 - (ii) product selection, and
 - (iii) proper destruction of unusable drugs and devices;
- (i) ensure that all records related to the purchase and receipt of controlled drug substances are signed by a pharmacist;
- (j) ensure appropriate security and storage of all Schedule I, II, and III drugs and controlled drug substances for all aspects of pharmacy practice including operation of a pharmacy without a pharmacist;
- (k) ensure there is a written drug recall procedure in place for pharmacy inventory;
- (l) ensure that all steps in the drug recall procedure are documented, if the procedure is initiated;
- (m) ensure that each individual working in the pharmacy wears a badge that clearly identifies the individual's registrant class or other status;
- (n) ensure that confidentiality is maintained with respect to all pharmacy and patient records in accordance with all applicable legislation;
- (o) make reasonable security arrangements in respect of unauthorized access, collection, use, disclosure or disposal of personal information kept on the pharmacy premises;
- (p) notify the registrar as soon as possible in the event that he or she will be absent from the pharmacy for more than eight weeks;
- (q) notify the registrar in writing within 48 hours of ceasing to be the pharmacy manager;
- (r) ensure the correct and consistent use of the community pharmacy operating name as it appears on the community pharmacy licence for all pharmacy identification on or in labels, directory listings, signage, packaging, advertising and stationery;
- (s) ensure that appropriate security is in place for the premises generally;
- (t) in the event of a pharmacy closure or relocation,
 - (i) notify the registrar in writing at least thirty days before the effective date of a proposed closure or relocation, unless the registrar determines there are extenuating circumstances,
 - (ii) provide for the safe transfer and appropriate storage of all Schedule I, II, and III drugs and controlled drug substances,

- (iii) advise the registrar in writing of the disposition of all drugs and prescription records at the time of a closure,
 - (iv) provide the registrar with a copy of the return invoice and any other documentation sent to Health Canada in respect of the destruction of all controlled drug substances,
 - (v) arrange for the safe transfer and continuing availability of the prescription records at another pharmacy, or an off-site storage facility that is bonded and secure, and
 - (vi) remove all signs and advertisements from the closed pharmacy premises;
- (u) ensure sample medications are dispensed in accordance with the requirements in the Drug Schedules Regulation;
 - (v) advise the registrar if the pharmacy is providing pharmacy services over the internet, and provide to the registrar the internet address of every website operated or used by the pharmacy;
 - (w) ensure the pharmacy contains the reference material and equipment approved by the board from time to time;
 - (x) require all pharmacists, owners, managers, directors, pharmaceutical representatives, pharmacy assistants, students and computer software programmers or technicians who will access the in-pharmacy computer system to sign an undertaking in a form approved by the registrar to maintain the confidentiality of patient record information;
 - (y) retain the undertakings referred to in subsection (x) in the pharmacy for 3 years after employment or any contract for services has ended;
 - (z) be informed of the emergency preparedness plan in the area of the pharmacy that he or she manages and be aware of his or her responsibilities in conjunction with that plan.
- (3) Section 2(2)(r) does not apply to a hospital pharmacy, hospital pharmacy satellite or a pharmacy education site.
 - (4) Owners, managers and directors must comply with subsection (2) (d), (e), (j), (n), (o), (r), (s), (t), (v), (w), and (x).
 - (5) An owner or director must appoint a manager whenever necessary, and notify the registrar in writing of the appointment and any resignation of a manager.
 - (6) An owner must ensure that the requirements to obtain a pharmacy licence set out in the *Act* and these bylaws are met at all times.
 - (7) For the purpose of subsection (2)(t), a pharmacy closure includes a suspension of the pharmacy licence for a period greater than 30 days, unless otherwise directed by the registrar.

Sale and Disposal of Drugs

3. (1) Schedule I, II, and III drugs and controlled drug substances must only be sold or dispensed from a pharmacy.
- (2) A pharmacist must not sell or dispense a quantity of drug that will not be used completely prior to the manufacturer's expiry date, if used according to the directions on the label.
- (3) If the manufacturer's expiry date states the month and year but not the date, the expiry date is the last day of the month indicated.
- (4) Every pharmacist practising in a pharmacy is responsible for the protection from loss, theft or unlawful sale or dispensing of all Schedule I, II, and III drugs and controlled drug substances in or from the pharmacy.
- (5) A pharmacist must not sell, dispense, dispose of or transfer a Schedule I drug except as follows:
 - (a) on the prescription or order of a practitioner;
 - (b) for an inventory transfer to a pharmacy by order of a pharmacist in accordance with the policy approved by the board;
 - (c) by return to the manufacturer or wholesaler of the drug;
 - (d) by destruction, in accordance with the policy approved by the board.
- (6) Drugs included in the controlled prescription program must not be sold or dispensed unless
 - (a) the pharmacist has received the prescription on the prescription form approved by both the college board and the College of Physicians and Surgeons of British Columbia, and
 - (b) the prescription form is signed by the patient or the patient's representative upon receipt of the dispensed drug.
- (7) A new prescription from a practitioner is required each time a drug is dispensed, except for
 - (a) a part-fill,
 - (b) a prescription authorizing repeats,
 - (c) a pharmacist-initiated renewal or adaptation, or
 - (d) an emergency supply for continuity of care.
- (8) Subsection (6)* does not apply to prescriptions written for
 - (a) residents of a facility subject to the requirements of the *Residential Care Facilities and Homes Standards of Practice*, or
 - (b) patients admitted to a hospital.

*Note amendment: previously referred to subsection (7), amendment will be submitted to the MOH in September 2009

Drug Procurement/Inventory Management

4. (1) A pharmacist may authorize the purchase of Schedule I, II, or III drugs or controlled drug substances only from the following:
 - (a) a wholesaler or manufacturer licensed to operate in Canada;
 - (b) another pharmacy in accordance with the policy approved by the board,
- (2) A pharmacist must record a transfer of drugs that occurs for any reason other than for the purpose of dispensing in accordance with a practitioner's prescription.
- (3) All drug shipments must be delivered unopened to the pharmacy or a secure storage area.
- (4) Non-usable and expired drugs must be stored in a separate area of the pharmacy or a secure storage area until final disposal.
- (5) A pharmacist must not purchase Schedule I, II and III drugs and controlled drug substances unless they are for sale or dispensing in or from a pharmacy.

Interchangeable Drugs

5. Pursuant to section 25.8 and 25.91 of the *Act*, a pharmacist determines Interchangeability of drugs by reference to Health Canada's Declaration of Equivalence, indicated by the identification of a Canadian Reference Product in a Notice of Compliance for a generic drug.

Returned Drugs

6. No pharmacist may accept for return to stock or reuse any drug previously dispensed except in accordance with section 10(3) of the *Residential Care Facilities and Homes Standards of Practice* or section 5(2) of the *Hospital Pharmacy Standards of Practice*.

Records

7. (1) All prescriptions, patient records, invoices and documentation in respect of the purchase, receipt or transfer of Schedule I, II and III drugs and controlled drug substances must be retained for a period of not less than three years from the date:
 - (a) a drug referred to in a prescription was last dispensed, or
 - (b) an invoice was received for pharmacy stock.
- (2) Pharmacists, pharmacy assistants, managers, directors, and owners must not, for commercial purposes, disclose or permit the disclosure of information or an abstract of information obtained from a prescription or patient record which would permit the identity of the patient or practitioner to be determined.
- (3) Notwithstanding subsection (1) a pharmacist must not destroy prescription or patient records until the completion of any audit or investigation currently underway for which the pharmacist has received notice.

Pharmacy Licences

8. (1) The registrar may issue a licence for any of the following:
 - (a) community pharmacy;
 - (b) hospital pharmacy;
 - (c) pharmacy education site.
- (2) An applicant for a pharmacy licence must submit the following to the registrar:
 - (a) a completed application in Form 1;
 - (b) a diagram to scale of ½ inch equals 1 foot scale including the measurements, preparation, dispensing, consulting, storage, professional service area, professional products area, entrances and packaging areas of the pharmacy;
 - (c) the applicable fee set out in Schedule “A”;
 - (d) for a community pharmacy, proof in a form satisfactory to the registrar that the municipality in which the pharmacy is located has issued a business licence for the pharmacy to the pharmacy’s owner or manager.
- (3) The registrar may renew a pharmacy licence upon receipt of the following:
 - (a) a completed notice in Form 4, 5 or 6, as applicable, signed by the manager and
 - (b) the applicable fee set out in Schedule “A”.
- (4) A pharmacy’s manager must submit to the registrar, in writing, any proposed pharmacy design changes or structural renovations together with a new pharmacy diagram for approval before the commencement of construction or other related activities.
- (5) If a pharmacy will be closed temporarily for up to 14 consecutive days, the pharmacy’s manager must
 - (a) obtain the approval of the registrar,
 - (b) notify patients and the public of the closure at least 30 days prior to the start of the closure, and
 - (c) make arrangements for emergency access to the pharmacy’s hard copy patient records.
- (6) A pharmacy located in a hospital which dispenses drugs to staff, out-patients or the public and which is not owned or operated by a health authority, must be licenced as a community pharmacy.
- (7) Subsections (4) to (6) do not apply to a pharmacy education site.

PART II – Community Pharmacies

Community Pharmacy Manager – Quality Management

9. (1) A community pharmacy's manager must develop, document and implement an ongoing quality management program that
- (a) maintains and enforces policies and procedures to comply with all legislation applicable to the operation of a community pharmacy,
 - (b) monitors staff performance, equipment, facilities and adherence to the *Community Pharmacy Standards of Practice*, and
 - (c) includes a process for reporting, documenting and following up on known, alleged and suspected errors, incidents and discrepancies.

Community Pharmacy Premises

10. (1) In locations where a community pharmacy does not comprise 100 per cent of the total area of the premises, the community pharmacy's manager must ensure that
- (a) the professional products area extends not more than 7.6 meters from the perimeter of the dispensary and is visually distinctive from the remaining areas of the premises by signage, and
 - (b) a sign reading "Medication Information" is clearly displayed to identify a consultation area or counter at which a member of the public can obtain a pharmacist's advice.
- (2) The dispensary area of a community pharmacy must
- (a) be at least 15 square meters,
 - (b) be inaccessible to the public by means of gates or doors across all entrances,
 - (c) include a dispensing counter with at least 3 square meters of clear working space, in addition to service counters,
 - (d) contain adequate shelf and storage space,
 - (e) contain a double stainless steel sink with hot and cold running water, and
 - (f) contain an adequate stock of drugs to provide full dispensing services.
- (3) In all new and renovated community pharmacies, an appropriate area must be provided for patient consultation that:
- (a) ensures privacy and is conducive to confidential communication, and
 - (b) includes, but is not limited to one of the following:
 - (i) a private consultation room, or
 - (ii) a semiprivate area with suitable barriers.

- (4) All new and renovated community pharmacies must have a separate and distinct area consisting of at least 4 square meters reserved as secure storage space.

Operation Without a Pharmacist

11. (1) Except as provided in subsection (2), a community pharmacy must not be open for business unless a pharmacist is present.
- (2) A community pharmacy that does not have a telepharmacy remote site licence may operate without a pharmacist if all the following requirements are met:
 - (a) the registrar is notified of the hours during which a pharmacist is not present;
 - (b) a security system prevents the public, pharmacy assistants and other non-pharmacy staff from accessing the dispensary, the professional service area and the professional products area;
 - (c) Schedule I, II, and III drugs and controlled drug substances in a secure storage area are inaccessible to pharmacy assistants, other non-pharmacy staff and the public;
 - (d) dispensed prescriptions waiting for pickup may be kept outside the dispensary if they are inaccessible, secure and invisible to the public and the requirements of section 11 of the *Community Pharmacy Standards of Practice* have been met;
 - (e) the hours when a pharmacist is on duty are posted.
- (3) When the requirements of subsection (2) have been met, the following activities may be performed at a community pharmacy by anyone who is not a pharmacist:
 - (a) requests for prescriptions, orders for Schedule II and III drugs and telephone requests from patients to order a certain prescription may be placed in the dispensary area by dropping them through a slot in the barrier, and
 - (b) orders from drug wholesalers, containing Schedule I, II and III drugs, may be received but must be kept secure and remain unopened.

Outsource Prescription Processing

12. (1) A community pharmacy may outsource prescription processing if
 - (a) all locations involved in the outsourcing are community pharmacies,
 - (b) all prescriptions dispensed are labeled and include an identifiable code that provides a complete audit trail for the dispensed drug, and
 - (c) a notice is posted informing patients that the preparation of their prescription may be outsourced to another pharmacy.

- (2) The manager of an outsourcing community pharmacy must ensure that all applicable standards of practice are met in processing prescriptions at all locations involved in the outsourcing.
- (3) In this section, “community pharmacy” includes a hospital pharmacy.

PART III – Hospital Pharmacies

Hospital Pharmacy Manager – Quality Management

13. (1) A hospital pharmacy’s manager must develop, document and implement an ongoing quality management program that
 - (a) maintains and enforces policies and procedures to comply with all legislation applicable to the operation of a hospital pharmacy,
 - (b) monitors staff performance, equipment, facilities and adherence to the *Hospital Pharmacy Standards of Practice*,
 - (c) includes a process for reporting, documenting and following up on known, alleged and suspected errors, incidents and discrepancies,
 - (d) documents periodic audits of the drug distribution process,
 - (e) includes a process to review patient-oriented recommendations,
 - (f) includes a process that reviews pharmacist documentation notes in the hospital’s medical records,
 - (g) includes a process to evaluate drug use, and
 - (h) regularly updates policies and procedures for drug use control and patient-oriented pharmacy services in collaboration with the medical and nursing staff and appropriate committees.
- (2) If sample drugs are used within a hospital, the hospital pharmacy’s manager must ensure that the pharmacy oversees the procurement, storage and distribution of all sample drugs.

After Hours Service

14. (1) If continuous pharmacy services are not provided in a hospital, the hospital pharmacy’s manager must ensure that urgently needed drugs and patient-oriented pharmacy services are available at all times by
 - (a) providing a cabinet which must
 - (i) be a locked cabinet or other secure enclosure located outside of the hospital pharmacy, to which only authorized persons may obtain access,
 - (ii) be stocked with a minimum supply of drugs most commonly required for urgent use,
 - (iii) not contain controlled drug substances unless they are provided by an automated dispensing system,

- (iv) contain drugs that are packaged to ensure integrity of the drug and labeled with the drug name, strength, quantity, expiry date and lot number, and
 - (v) include a log in which drug withdrawals are documented, and
- (b) arranging for a pharmacist to be available for consultation on an on-call basis.
- (2) When a hospital pharmacy or hospital pharmacy satellite is closed, the premises must be equipped with a security system that will detect unauthorized entry.

PART IV – Telepharmacy

Telepharmacy Services

15. (1) The registrar may authorize a community pharmacy or hospital pharmacy to provide telepharmacy services, upon receipt of a completed application in Form 2 and if satisfied that the requirements of this section have been met.
- (2) Telepharmacy services may only be provided in or through pharmacies authorized under this Part to provide telepharmacy services.
- (3) A telepharmacy remote site must be under the direct supervision of a pharmacist at the central pharmacy site.
- (4) A telepharmacy remote site must be under the responsibility of the manager of the central pharmacy site.
- (5) The *Community Pharmacy Standards of Practice* apply to a telepharmacy remote site, unless it is located in, or providing pharmacy services for, a hospital in which case the *Hospital Pharmacy Standards of Practice* apply.
- (6) Pharmacists at a central pharmacy site must comply with section 11 of the *Community Pharmacy Standards of Practice* by using video and audio links.
- (7) A sign must be posted at the dispensary counter of a telepharmacy remote site advising patients and staff when the site is operating in telepharmacy mode
- (8) A telepharmacy remote site must not remain open and prescriptions must not be dispensed if
- (a) an interruption in data, video or audio link occurs,
 - (b) a pharmacy assistant is not on duty at the telepharmacy remote site, or
 - (c) a pharmacist is not on duty at the central pharmacy site.
- (9) Prescriptions dispensed at a telepharmacy remote site must be distinguishable from a prescription dispensed at the central pharmacy site and include a unique label and a unique identifier for the prescription.

- (10) There must be a policy and procedure manual which describes the specific telepharmacy operations that are in place to ensure the safe and effective distribution of pharmacy products and delivery of pharmaceutical care.

PART V – Pharmacy Education Sites

Pharmacy Education Site Manager

16. (1) A pharmacy education site’s manager must ensure that only students and instructors are present in the pharmacy education site.
- (2) A pharmacy education site’s manager must comply with sections 2(2)(a), (d), (h), (p), (s) and (t)(ii) and (iii).

PART VI – PharmaNet

Application

17. This Part applies to every pharmacy that connects to PharmaNet.

Definitions

18. In this Part:

“**database**” means those portions of the provincial computerized pharmacy network and database referred to in section 13 of the *Act*;

“**in-pharmacy computer system**” means the computer hardware and software utilized to support pharmacy services in a pharmacy;

“**patient keyword**” means an optional confidential pass code selected by the patient which limits access to the patient’s PharmaNet record until the pass code is provided to the pharmacist;

“**PharmaNet patient record**” means the patient record described in section 10(2) of the *Community Pharmacy Standards of Practice* and in the PharmaNet Professional and Software Compliance Standards as the “patient profile”;

“**PharmaNet Professional and Software Compliance Standards**” means the document provided by the Ministry of Health Services specifying the requirements of an in-pharmacy computer system to connect to PharmaNet;

“**terminal**” means any electronic device connected to a computer system, which allows input or display of information contained within that computer system.

Operation of PharmaNet

19. (1) A pharmacy must connect to PharmaNet and be equipped with the following:
 - (a) an in-pharmacy computer system which meets the requirements set out in the current PharmaNet Professional and Software Compliance Standards;

- (b) a terminal that is capable of accessing and displaying patient records, located in an area of the pharmacy which
 - (i) is only accessible to pharmacists and pharmacy assistants,
 - (ii) is under the direct supervision of a pharmacist, and
 - (iii) does not allow information to be visible to the public, unless intended to display information to a specific patient;
- (c) the computer software upgrades necessary to comply with changes to the PharmaNet Professional and Software Compliance Standards.

Data Collection, Transmission of and Access to PharmaNet Data

20. (1) A pharmacist must enter the prescription information and transmit it to PharmaNet at the time of dispensing and keep the PharmaNet patient record current.
- (2) A pharmacist may collect and transmit patient record information to PharmaNet or access a patient's PharmaNet record only
 - (a) to dispense a drug,
 - (b) to provide patient consultation,
 - (c) to evaluate a patient's drug usage, or
 - (d) for claims adjudication and payment by an insurer.
- (3) A pharmacist must revise information in the PharmaNet database pertaining to corrected billings for prescriptions billed to the patient or a payment agency other than PharmaCare and record the reason for the revision within 90 days of the original entry on PharmaNet.
- (4) A pharmacist must reverse information in the PharmaNet database, for any drug that is not released to the patient or the patient's representative, and record the reason for the reversal no later than 30 days from the date of the original entry of the prescription information in PharmaNet.
- (5) If a pharmacist is unable to comply with the deadlines in subsections (3) or (4), the pharmacist must provide the information required to make the correction to the college as soon as possible thereafter.
- (6) At the request of the patient, a pharmacist must establish, delete or change the patient keyword.
- (7) Where a patient or patient's representative requests an alteration to be made to the PharmaNet information, the pharmacist must:
 - (a) correct the information, or
 - (b) if the pharmacist refuses to alter the information, he or she must inform the person requesting the change of his or her right to request correction under the *Personal Information Protection Act*.

Confidentiality

21. (1) A pharmacist must take reasonable steps to positively identify a patient, patient's representative, pharmacist or a practitioner before providing any pharmacy service, including but not limited to:
- (a) establishing a patient record,
 - (b) updating a patient's clinical information,
 - (c) providing a printout of an in-pharmacy or requesting a PharmaNet patient record,
 - (d) establishing, deleting, or changing a patient keyword,
 - (e) viewing a patient record,
 - (f) answering questions regarding the existence and content of a patient record,
 - (g) correcting information, and
 - (h) disclosing relevant patient record information to another pharmacist for the purpose of dispensing a drug or device, and/or for the purpose of monitoring drug use.