HOSPITAL PHARMACY REVIEW

Contents

♦ If service is provided

Security

Legislation	Requirement(s)
Narcotic Control Regulations s.43	A pharmacist shall take all reasonable steps that are necessary to protect narcotics on his premises or under his control against loss or theft.
PODSA Bylaws s.19(4)	Every registrant practicing 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.?
Benzodiazepines and Other Targeted Substances Regulations - Security 72(2)	A person referred to in subsection (1) who becomes aware of a theft or loss of a targeted substance must provide a written report to the Minister within 10 days after becoming aware of the occurrence.
PODSA Bylaws s.30(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.

Equipment and References

Legislation	Requirement(s)
PODSA s.4.1(3)	A direct owner must give to the registrar 30 days' written notice of any changes respecting the name or layout of the pharmacy.
PPP-59 Policy Statement #2	All hospital pharmacies and hospital pharmacy satellites must be adequately equipped to provide safe and proper medication compounding, dispensing and/or preparation of medication orders, and for the provision of patient-oriented and administrative pharmacy services.
PPP-59 Policy Statement #3	Pharmacy equipment must be clean and sanitary, well-maintained, and properly functioning.
Food and Drugs Act s.8(a)	No person shall sell any drug that was manufactured, prepared, preserved, packaged or stored under unsanitary conditions.
PPP-68	For a drug that requires cold chain management, the pharmacy manager must ensure the following: 1. the drug is maintained in accordance with the manufacturer's requirements and any other applicable requirements; 2. the pharmacy is equipped with cold storage equipment that a) must be purposed for drugs only, b) must maintain only one temperature range enclosed by a door with an air-tight seal (a standard "bar" fridge (combination

	fridge/freezer with one exterior door) is not acceptable as it does not maintain even temperatures), and c) is equipped with a digital thermometer or temperature monitoring system; 3. temperatures of the cold storage equipment are monitored and recorded a) manually at least twice each working day, preferably at opening and closing of the pharmacy, documenting the current temperature, and the minimum and maximum temperatures reached since the last temperature recording, or b) automatically with a temperature monitoring system that i. records temperatures at a frequency that can determine current temperatures, and minimum and maximum temperatures reached at least twice a day, and ii. monitors and notifies pharmacy staff when a temperature excursion occurs; 4. establish written policies and procedures that include processes a) to ensure proper cold chain management, b) to record temperatures of the cold storage equipment in accordance with section 3, c) to determine and document actions taken when a temperature excursion occurs, and d) for regular maintenance that ensures functionality of cold storage equipment and documenting those processes; 5. all pharmacy staff are trained on the policies and procedures necessary to maintain cold chain management; and 6. the following documentation must be retained and easily retrievable for at least three years a) the temperature records of the cold storage equipment required by section 3, and b) the documentation resulting from i. actions taken when a temperature excursion occurs, and ii. regular maintenance that ensures functionality of the cold chain equipment.
PPP-3	All hospital pharmacies and hospital pharmacy satellites must be equipped with, current references relevant to the services provided (examples including but not limited to: Pediatrics, Psychiatric, Geriatric, Oncology and Compounding)
PODSA Bylaws s.23.3(1)	A pharmacy may maintain electronic records containing personal health information if the pharmacy has the equipment, software and systems necessary for the input, storage, use, protection and retrieval of records that are required to be kept under bylaws of the college or other legislation that regulates the practice of pharmacy.

PODSA Bylaws s.23.3(2)	For purposes of subsection (1), the equipment, software and systems must: a) be capable of storing the electronic records for the periods required by applicable law; b) keep the records secure from unauthorized access, use, disclosure, modification and destruction; c) for audit purposes, be capable of uniquely identifying each time an electronic record is accessed and modified; d) be capable of restricting the functions that may be used by an authorized person; e) be capable of tracing alterations to records by identifying the original entry, the identity of the individual who made the alteration and the date of the alteration; f) be capable of searching and sorting electronic prescription records chronologically, and by drug name, drug strength, patient, prescriber, prescription number and transaction number; g) ensure that electronic records can be stored, backed up and recovered in accordance with subsection (3); and, h) provide for a deliberate and auditable procedure to be carried out by the pharmacy manager or by an authorized person prior to the destruction of any electronic record that includes information identifying the pharmacy manager or authorized person who destroyed the record and the date, time and reason for its destruction.

Drug Orders

Legislation	Requirement(s)
HPA Bylaws Schedule F Part 2 s.13(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.
HPA Bylaws Schedule F Part 2 s.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.

Confidentiality

Legislation	Requirement(s)
PODSA Bylaws s.34	A pharmacy must connect to PharmaNet.
HPA Bylaws s.74	A registrant must ensure that all records pertaining to his or her practice, and containing personal information about patients are safely and securely stored at the pharmacy or off site.
HPA Bylaws s.75	A registrant must ensure that records are disposed of or destroyed only by (a) transferring the record to another registrant, or (b) destroying the records in a manner that ensures that they cannot be reconstructed.
HPA Bylaws s.77(1)	A registrant must protect personal information about patients by making reasonable security arrangements against such risks as unauthorized access, collection, use, disclosure or disposal.
HPA Bylaws s.77(2)	A registrant must take reasonable measures to ensure that a third party, including a volunteer, employee or contractor of the registrant, or a limited pharmacist does not access, collect, use, disclose, store or dispose of personal information about patients except in accordance with this Part.
HPA Bylaws s.78	A registrant must ensure that, if personal information about patients is transferred to any person or service organization for processing, storage or disposal, a contract is made with that person which includes an undertaking by the recipient that confidentiality and physical security will be maintained.
HPA Bylaws s.79	A registrant must take appropriate measures to remedy any unauthorized access, use, disclosure or disposal of personal information about patients under this Part as soon as possible after the breach is discovered, including a) taking steps to recover the personal information or to ensure its disposal if it cannot be recovered, b) taking steps to ensure that any remaining personal information is secured, c) notifying (i) anyone affected by the unauthorized access including patients and other health care providers, (ii) the college, and (iii) law enforcement officials, if criminal action may have contributed to the unauthorized action, and d) modifying existing security arrangements to prevent a reoccurrence of the unauthorized access.

Inventory Management – Pharmacy

Legislation	Requirement(s)
PODSA Bylaws s.19(2)	A registrant 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.
PODSA Bylaws s.20(4)	All drug shipments must be delivered unopened to (a) the pharmacy, or (b) an area of the premises other than the pharmacy if the storage of the drug shipment is temporary, safe and secure.
PODSA Bylaws s.20(5)	Non-usable and expired drugs must be stored in the pharmacy in an area separate from other pharmacy stock or drug products until final disposal.
HPA Bylaws Schedule F Part 2 s.5(1)	Unused dispensed drugs must be returned to the hospital pharmacy.
PODSA Bylaws s.22	No registrant may accept for return to stock or reuse any drug previously dispensed except in accordance with section 5(2) of the Hospital Pharmacy Standards of Practice.
HPA Bylaws Schedule F Part 2 s.5(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.

Inventory Management – Nursing Units

Legislation	Requirement(s)
HPA Bylaws Schedule F Part 2 s.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.
PODSA Bylaws s.18(2)(l)	Ensure safe and secure storage of all Schedule I, II, and III drugs and controlled drug substances for all aspects of pharmacy practice, in accordance with the policies approved by the board.

HPA Bylaws Schedule F Part 2 s.14(1)	The registrant must collaborate with nursing and medical staff to develop written policies and procedures for the safe administration of drugs.
HPA Bylaws Schedule F Part 2 s.14(2)	A medication administration record of all prescribed drugs for each patient must be produced from the pharmacy-maintained patient record.
HPA Bylaws Schedule F Part 2 s.14(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.
PPP-68 POLICY STATEMENTS (1) and (4)	For a drug that requires cold chain management, the pharmacy manager must ensure the following: 1. the drug is maintained in accordance with the manufacturer's requirements and any other applicable requirements; 4. establish written policies and procedures that include processes a) to ensure proper cold chain management, b) to record temperatures of the cold storage equipment in accordance with section 3, c) to determine and document actions taken when a temperature excursion occurs, and d) for regular maintenance that ensures functionality of cold storage equipment and documenting those processes.

Narcotics and Controlled Drug Substances

Legislation	Requirement(s)
PPP-65 POLICY STATEMENT 1(a)	A pharmacy manager must ensure that a separate perpetual inventory log for each narcotic drug is maintained for the pharmacy, telepharmacy, pharmacy satellites and all areas of a facility where narcotics are stored.
PPP-65 POLICY STATEMENT 1(b)	A perpetual inventory log may be manual or automated, and must include entries for: purchases, transfers, losses, purchases returned, expired, or destroyed, quantities dispensed and a running balance.

PPP-65 POLICY STATEMENT 1(c)	Each entry in the perpetual inventory log must have an associated record, including but not limited to the following i. purchase record, ii. prescription, iii. loss and theft reports, and iv. record for purchase returned, expired, transferred, or destroyed.
PPP-65 POLICY STATEMENT 1(d)	Any adjustment to an entry in a perpetual inventory log must be documented, including the reason for the adjustment, the date adjusted, the identity of the person who made the adjustment, and the identity of a full pharmacist authorizing the adjustment.
PPP-65 POLICY STATEMENT 2(a)	A pharmacy manager must ensure that physical inventory counts and reconciliations for each narcotic drug are completed for the pharmacy, telepharmacy, pharmacy satellites and all areas of a facility where narcotics are stored: i. at a minimum of every 3 months, ii. after a change of pharmacy manager, iii. after a break and enter or robbery, iv. after an identified drug diversion, v. when a pharmacy closes and ceases to operate its business, and vi. after any event where the security of the narcotic drugs may have been compromised.
PPP-65 POLICY STATEMENT 2(b)(i)	A physical inventory count for each narcotic drug must be conducted prior to each inventory reconciliation in accordance to the following requirements: i. all inventory must be counted, including active inventory, compounded mixtures, and non-usable and expired inventory.
PPP-65 POLICY STATEMENT 2(b)(ii)	A physical inventory count for each narcotic drug must be conducted prior to each inventory reconciliation in accordance to the following requirements: When completing a physical inventory count, the following information must be documented: the name, strength, quantity, and DIN/brand of the drug counted, the date and signature of the person(s) who completed the count, and the date and signature of the responsible pharmacist.
PPP-65 POLICY STATEMENT 2(b)(iii)	The count must not be conducted by the same person who enters narcotic purchases into the records.
PPP-65 POLICY STATEMENT 2(c)	An inventory reconciliation must include the following components: i. the physical inventory count is compared with the perpetual inventory count for accuracy and discrepancies; ii. associated records of the perpetual inventory log are audited for completeness, accuracy and discrepancies; and iii. discrepancies must be investigated, addressed, and documented on a narcotic incident report together with relevant supporting information.
PPP-65 POLICY STATEMENT 2(d)	The completion of each physical inventory count and reconciliation must be verified and signed by the pharmacy manager.

PPP-65 POLICY STATEMENT 3(a)	The perpetual inventory record must be retained for a period of not less than 3 years.
PPP-65 POLICY STATEMENT 3(b)	The physical inventory count and reconciliation documentation must be maintained and retained in chronological order in a separate and dedicated record for a period of not less than 3 years.
PPP-65 POLICY STATEMENT 3(c)	If a loss or theft of a narcotic is discovered, the pharmacy manager must: i. notify the College within 24 hours of the incident; ii. report the loss or theft within 10 days in accordance with Health Canada's requirements; and iii. forward to the College a copy of any report sent to Health Canada.

Dispensed Products

Legislation	Requirement(s)
HPA Bylaws Schedule F Part 2 s.3(2)	A unit dose, monitored dose, multiple pouch packaging or individual patient prescription drug distribution system must be used for dispensing drugs.
HPA Bylaws Schedule F Part 2 s.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.
HPA Bylaws Schedule F Part 2 s.4(2)	Only hospital pharmacy staff may alter a drug container label.
HPA Bylaws Schedule F Part 2 s.4(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.
HPA Bylaws Schedule F Part 2 s.4(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.
HPA Bylaws Schedule F Part 2 s.7(1)	**Inpatient Leave of Absence and Emergency Take-Home Drugs:** 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.

HPA Bylaws Schedule F Part 2 s.7(2)	**Inpatient Leave of Absence and Emergency Take-Home Drugs:** All take-home drugs issued from the emergency department must be documented in the patient's health record.
HPA Bylaws Schedule F Part 2 s.7(3)	**Inpatient Leave of Absence and Emergency Take-Home Drugs:** All inpatient leave of absence drugs must be documented in the patient's health record.
HPA Bylaws Schedule F Part 2 s.7(4)	**Inpatient Leave of Absence and Emergency Take-Home Drugs:** 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.
HPA Bylaws Schedule F Part 2 s.7(5)	**Inpatient Leave of Absence and Emergency Take-Home Drugs:** 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.

Patient Records/Documentation

Legislation	Requirement(s)
PODSA Bylaws s.20(3)	A registrant 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.
PODSA Bylaws s.23(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.

PODSA Bylaws s.23(2)	Despite subsection (1), a registrant must not destroy prescriptions, patient records, invoices and documentation as described in subsection (1) until the completion of any audit or investigation for which the registrant has received notice.
HPA Bylaws Schedule F Part 2 s.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.
HPA Bylaws Schedule F Part 2 s.12(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.
HPA Bylaws Schedule F Part 2 s.17	Documentation of the identity of any registrant who prepared a prescription product or performed a final check must be readily available and retained for at least three years after the date on which the prescription product was last dispensed.

PODSA Bylaws 23.1(1)	All records required to be kept under the bylaws of the college or other legislation that regulates the practice of pharmacy shall be readable, complete and filed systematically by a registrant in a manner that is secure, auditable and allows for easy retrieval.
PODSA Bylaws 23.1(2)	Notwithstanding subsection (1), a prescription record that is valid must be retrievable immediately
PODSA Bylaws 23.1(4)	With respect to prescriptions for drugs included in the controlled prescription program, the original prescription form must be retained, regardless of whether or not such prescription form has also been stored electronically.
PODSA Bylaws 23.1(5)	Prescriptions stored electronically must accurately reflect the original prescription, including the colour composition of that prescription.
HPA Bylaws s.69(2)	In addition to correcting personal information in a record in accordance with section 70, a registrant who discovers an error or omission in such a record must amend the record to correct the error or omission and that amendment must reflect the original record entry, the identity of the registrant amending the record, the date of the amendment and the reasons for the amendment.

After Hours Services

Legislation	Requirement(s)
PODSA Bylaws s.30(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. b) arranging for a full pharmacist to be available for consultation on an on-call basis.

Pharmacy Manager's Responsibilities

Legislation	Requirement(s)
PODSA s.11	Subject to this Act and the bylaws, a pharmacist named in a pharmacy license as manager must personally manage and be responsible for the operation of the pharmacy.
PODSA s.4.1(2)	A direct owner and a manager must display a pharmacy licence in the pharmacy in a place conspicuous to the public.
PODSA Bylaws s.18(2)(a) to (p), (s) to (x) and (z) to (bb)	A manager must do all of the following: a) personally manage and be responsible for the daily operation of the pharmacy; b) ensure compliance with all legislation, bylaws, policies and procedures applicable to the operation of a pharmacy; c) establish policies and procedures (i) to specify the duties to be performed by registrants and support persons, (ii) for inventory management, product selection, and proper destruction of non-usable drugs and devices, (iii) for pharmacy security, (iv) for emergency preparedness, and (v) for drug recall of pharmacy inventory; d) ensure all policies and procedures are in writing and regularly maintained; e) ensure that pharmacy staff are trained in policies and procedures; f) ensure that all steps in the drug recall procedure are documented, if the procedure is initiated; g) ensure that all individuals working in the pharmacy who present themselves as registrants have been granted and maintain registration with the College, in accordance with the policies approved by the board; h) notify the registrar of any appointments, resignations or terminations of registrants employed at the pharmacy as those changes occur; i) cooperate with inspectors acting under section 17 of the Act or section 28 or 29 of the Health Professions Act; j) ensure that (i) registrant and support persons staff levels are commensurate with workload volumes and patient care requirements are met at all times in accordance with the bylaws, Code of Ethics and standards of practice, and (ii) meeting quotas, targets or similar measures do not compromise patient safety or compliance with the bylaws, Code of Ethics or standards of practice; k) ensure that all records related to the purchase and receipt of controlled drug substances are signed by a full pharmacist; l) ensure safe and secure storage of all Schedule I, II, and III drugs and controlled drug substances for all aspects of pharmacy practice, in accordance with the policies approved by the board;

	m) ensure that pharmacy records containing personal information about patients are secure from unauthorized access, use, disclosure, modification and destruction; n) ensure that each individual working in the pharmacy presents themselves to the public in a manner that clearly identifies their registration class; o) ensure that registrants identify themselves in a manner that clearly differentiates them from other individuals working in the pharmacy who are not registrants; p) immediately notify the registrar in writing of ceasing to be the pharmacy's manager; s) ensure that narcotic reconciliation is performed in accordance with the policies approved by the board; t) notify the registrar of any incident of loss of narcotic and controlled drug substances within 24 hours; u) 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; v) ensure the pharmacy contains the reference material and equipment in accordance with the policies approved by the board; w) require anyone 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 personal health information; x) retain the undertakings referred to in subsection (w) in the pharmacy for 3 years after employment or any contract for services has ended; z) ensure that no incentive is provided to a patient or patient's representative for the purpose of inducing the patient or patient's representative to (i) deliver a prescription to a particular registrant or pharmacy for dispensing of a drug or device specified in the prescription, or (ii) obtain any other pharmacy service from a particular registrant or pharmacy; aa) notify the registrar of persistent non-compliance by a direct owner and indirect owner(s) with their obligations under the bylaws to the Act; bb) notify the registrar of any change of telephone number, fax number, electronic mail address or any other information previously provided to the registrar.
HPA Bylaws Schedule F Part 2 s.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, d) eliminates or reduces the need to maintain ward stock.

PODSA Bylaws s.29(1)	A hospital pharmacy's manager must establish and maintain written quality management policies and procedures that a) ensure pharmacy staff, equipment, and facilities comply with all legislation, bylaws and policies applicable to the operation of a hospital pharmacy, b) include a process to monitor compliance with the quality management policies and procedures, c) include a process for reporting, documenting and following up on known, alleged and suspected errors, incidents and discrepancies, d) document periodic audits of the drug distribution process, e) include a process to review patient-oriented recommendations, f) include a process that reviews a full pharmacist's documentation notes in the hospital's medical records, g) include a process to evaluate drug use, and h) regularly update policies and procedures for drug use control and patient-oriented pharmacy services in collaboration with the medical and nursing staff and appropriate committees.
PODSA Bylaws s.29(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.
PODSA Bylaws s.23.2(1)	A pharmacy manager must ensure that a policy is in place that: (a) describes the pharmacy's records filing system, the records format and the method and system for storing records, (b) is compliant with the sections 23.1, 23.2 and 23.3 requirements; and (c) is readily accessible to and understood by pharmacy staff.
PODSA Bylaws s.23.2(2)	With respect to electronic records, the policy must include a description of the process for the preservation, storage and backing up of records that is compliant with section 23.3 requirements.
PODSA Bylaws s.23.3(3)	A pharmacy manager must ensure that electronic records are preserved and backed up at least once daily and that such electronically preserved and backed up records are stored: (a) in a location resistant to environment perils including but not limited to fires and floods; (b) so that they are secure from unauthorized access, use, modification, destruction and disclosure; and, (c) in a manner that would enable the backed up records, once restored, to be compliant with section 23.1(1) requirements.

Owner/Director Responsibilities

Reference	Requirement(s)
PODSA Bylaws s.18(7)	A direct owner, directors and officers must do all of the following: a) ensure compliance with subsections (2)(c)(i), (c)(iii), (c)(iv), (c)(v), (i), (j), (l), (y) and (z); b) ensure that the requirements to hold a pharmacy licence under the Act are met at all times; and c) notify the registrar of any change of name, address, telephone number, electronic mail address or any other information previously provided to the registrar.
PODSA Bylaws s.23(3)	Registrants, support persons, managers, direct owners, and indirect 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.
PODSA Bylaws s.17(5)(d)	If there is a change in layout of the pharmacy, the direct owner must submit the following: a diagram to demonstrate the changes in layout in accordance with section 6(2)(c) for a hospital pharmacy.

Bulk/Batch Drug Repackaging♦

Legislation	Requirement(s)
HPA Bylaws Schedule F Part 2 s.9(1)	A registrant must supervise all bulk/batch drug repackaging.
HPA Bylaws Schedule F Part 2 s.9(2)	Bulk/batch drug repackaging records must be kept for three years after the repackaging date.
HPA Bylaws Schedule F Part 2 s.9(6)	A label must be affixed to the finished bulk/batch repackaged 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.

Residential Care♦

Legislation	Requirement(s)
HPA Bylaws Schedule F Part 2 s.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.

Non-Sterile Compounded Preparations♦

Reference	Requirement(s)
Policy on Manufacturing and Compounding Drug Products in Canada s5.1(a)	Healthcare professionals who provide compounding related services and products to patients/clients must be able to demonstrate that a patient-healthcare professional relationship exists.
PPP-3 POLICY STATEMENT (1)	All hospital pharmacies and hospital pharmacy satellites must be equipped with, current references relevant to the services provided (Compounding).
PODSA Bylaws s.19(2)	A registrant 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.
Health Canada Policy on Manufacturing and Compounding Drug Products in Canada (2009) s.5.1(n)	The expiration date of the compounded product is based on known stability data. If stability data is not available, the expiration date should be short, usually limited to the duration of the prescription or use.

Health Canada Policy on Manufacturing and Compounding Drug Products in Canada s5.1(c)	It is expected that healthcare professionals who compound products will have appropriate risk management processes in place to manage risks associated with the compounded product and the workplace (facilities, safety etc.), in line with the standards set by their provincial/territorial regulatory bodies (for example but not limited to the toxicology, pharmacology, therapeutic value, stability, adverse reactions, labelling requirements etc. of the compounded product).
Health Canada Policy on Manufacturing and Compounding Drug Products in Canada s5.1(d)	A pharmacy may prepare drugs in very limited quantities, in anticipation of a prescription. For the purpose of this Policy, preparation involves compounding or repackaging of multiple units, not for immediate use, in a single process, by the same operator in accordance with a standardized batch preparation procedure.
Health Canada Policy on Manufacturing and Compounding Drug Products in Canada s5.1(e)	Compounding should only be done if there is a therapeutic need or lack of product availability and should not be done solely for economic reasons for the healthcare professionals.
Health Canada Policy on Manufacturing and Compounding Drug Products in Canada s5.1(h)	Drugs should not be compounded in order to be sold to third parties who will in turn sell/deliver to patients outside of their defined patient-healthcare professional relationship (see definition of "sell"). Pharmacists that do not provide specific compounding services may contract this activity to another pharmacist who provides this type of specific compounding service.
Health Canada Policy on Manufacturing and Compounding Drug Products in Canada s5.1(j)	Product should be produced from an authorized drug or Active Pharmaceutical Ingredient (API) used in an authorized drug for use in Canada or listed in a recognized Pharmacopoeia (USP, PhEur, PhF, PhI, BP, CF, NF, Codex - Schedule B Food and Drugs Act.)
HPA Bylaws Schedule F Part 2 s.12(2)(h)	A list of all current drug orders (including compound formulations) 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.

Sterile Compounding♦

Legislation	Requirement(s)
PODSA Bylaws s.18(9)	A direct owner, manager, directors, and officers must ensure compliance with the National Association of Pharmacy Regulatory Authorities standards as approved by the board from time to time, applicable to the operation of a pharmacy.
PPP-64	The Board of the College of Pharmacists of BC adopts the following NAPRA standards for compounding of sterile preparations for registrants: • Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations; and, • Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations. Refer to the **Sterile Compounding Review Form** for requirements.

Ambulatory/Outpatient Services♦

Legislation	Requirement(s)
HPA Bylaws Schedule F Part 2 s.4(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.
HPA Bylaws Schedule F Part 1 s.6(1)	A registrant must ensure that a prescription is authentic.
HPA Bylaws Schedule F Part 1 s.6(2)	A prescription must include the following information: (a) the date of the prescription; (b) the name of the patient; (c) the name of the drug or ingredients and strength if applicable; (d) the quantity of the drug; (e) the dosage instructions including the frequency, interval or maximum daily dose; (f) refill authorization if applicable, including number of refills and interval between refills; (g) in the case of a written prescription, the name and signature of the practitioner; (h) in the case of a written record of a verbal prescription, i. the name of the practitioner and the identification number from the practitioner's regulatory college; and ii. the name, college identification number and signature or initial of the registrant who received the verbal prescription.

HPA Bylaws Schedule F Part 1 s.6(7)	A registrant must make a written record of a verbal prescription containing the applicable information in section 6(2).
HPA Bylaws Schedule F Part 1 s.10(5)	A registrant must not dispense a prescription more than two years from the prescribing date and must not dispense a prescription for a benzodiazepine or other targeted substance more than one year from the prescribing date. Despite subsection (5), a registrant may dispense a prescription for a benzodiazepine or other targeted substance up to two years from the prescribing date, if permitted by a section 56 exemption to the Controlled Drugs and Substances Act.
HPA Bylaws Schedule F Part 1 s.6(8)	A registrant must not dispense a prescription issued for more than one patient.
HPA Bylaws Schedule F Part 1 s.11(1)	A patient record must be established and maintained for each patient for whom a Schedule I drug is dispensed.
PODSA Bylaws s. 35(1)	A registrant must enter the prescription information and record it in PharmaNet at the time of dispensing and keep the patient record current.
HPA Bylaws Schedule F Part 1 s.6(4)	At the time of dispensing, a prescription must include the following additional information: (a) the address of the patient; (b) the identification number from the practitioner's regulatory college; (c) the prescription number; (d) the date on which the prescription was dispensed; (e) the manufacturer's drug identification number or the brand name of the product dispensed; (f) the quantity dispensed; (g) written confirmation of the registrant who (i) verified the patient identification, (ii) verified the patient allergy information, (iii) reviewed the personal health information stored in the PharmaNet database in accordance with section 11(4), (iv) performed the consultation, (v) performed the final check including when dispensing a balance owing, and (vi) identified and addressed a drug therapy problem, if any.

PODSA Bylaws s.19(6)	Drugs included in the controlled prescription program (CPP) must not be sold or dispensed unless (a) the registrant has received the prescription on the prescription form approved by both the 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.
HPA Bylaws Schedule F Part 1 s.7(3)	A registrant must not dispense a prescription authorization received by facsimile transmission for a drug referred to on the Controlled Prescription Drug List, except in a public health emergency declared by the provincial health officer. In a public health emergency, the pharmacy must receive a completed copy of the Controlled Prescription Program form transmitted by facsimile prior to dispensing the medication.
PODSA Bylaws s.19(6.1)	Despite subsection (6), a registrant may dispense drugs included in the controlled prescription program upon receipt of a verbal prescription from a practitioner if doing so is permitted under a section 56 exemption to the Controlled Drugs and Substances Act. The pharmacy must receive the original prescription form, or a copy of the completed form transmitted by facsimile, from the practitioner as soon as reasonably possible.
PODSA Bylaws 23.1 (4)	With respect to prescriptions for drugs included in the controlled prescription program, the original prescription form or a paper copy of the completed form transmitted by facsimile must be retained, regardless of whether or not such prescription form has also been stored electronically.
Narcotic Control Regulations s.37	A pharmacist must not use an order or prescription to dispense a narcotic after the quantity of the narcotic specified in the order or prescription has been dispensed. The narcotic prescription must specify the total quantity to be dispensed, the part fill quantities and the interval between the part fills.
HPA Bylaws Schedule F Part 1 s.9(1)	All drugs dispensed pursuant to a prescription or a full pharmacist-initiated adaptation, must be labeled.
HPA Bylaws Schedule F Part 1 s.9(2)	The label for all prescription drugs must include (a) the name, address and telephone number of the pharmacy, (b) the prescription number and dispensing date, (c) the full name of the patient, (d) the name of the practitioner, (e) the quantity and strength of the drug, (f) the practitioner's directions for use, and (g) any other information required by good pharmacy practice.

HPA Bylaws Schedule F Part 1 s.9(3)	For a single-entity product, the label must include (a) the generic name, and (b) at least one of (i) the brand name, (ii) the manufacturer's name, or (iii) the drug identification number (DIN).
HPA Bylaws Schedule F Part 1 s.9(4)	For a multiple-entity product, the label must include (a) the brand name, or (b) all active ingredients and at least one of (i) the manufacturer's name or (ii) the drug identification number (DIN).
HPA Bylaws Schedule F Part 1 s.9(5)	For a compounded preparation, the label must include all active ingredients.
HPA Bylaws Schedule F Part 1 s.9(7)	All required label information must be in English, but may contain directions for use in the patient's language following the English directions.
HPA Bylaws Schedule F Part 1 s.10(4)	All 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 (e) the drugs are prescribed for medical assistance in dying.
HPA Bylaws Schedule F Part 1 s.12(1)	A full pharmacist must consult with the patient or patient's representative at the time of dispensing a new or refill prescription in person or, where not practical to do so, by telephone.
PODSA Bylaws s.35(4)	A registrant must reverse information in PharmaNet, 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.