

Pharmacy Quality Assurance Self-Assessment

(Community and Hospital Outpatient Pharmacy)

Date:

Contact information							
Pharmacy:			CPh	CPhM license #:		Licence posted	
Address:		City:					Postal code:
Phone #1:		Fax a	Fax #1:			E-mail add	Iress:
Phone #2:		Fax a	#2:			Website:	
Pharmacy information	1						
Last inspection date:		Phar	macare	#:		Computer system:	
Please list component Hospital Services, Personal							Leave, Central-Fill, Secondary
Pharmacy hours							
Store hours: Mon-Fri:	Sat:	Sun:		:	Holidays:		
Dispensary hours (i.e. Mon-Fri:	lock an Sat:	d leav	/e):	Sun	:	Holida	nys:
Pharmacy staff							
Pharmacy manager:						Manager's l	licence #:
Staff pharmacists:	Licence number	Full time	Part time	Posted	Pharmacy	y technicians	: Students & interns:
Other persons:							

Note: This form is being used for new pharmacy openings, existing pharmacy self-assessments and for inspections. In the case of a new pharmacy application, provision must be made to comply with these standards in the operation of the pharmacy immediately upon opening. The pre-opening inspection will include a discussion with the inspector on the processes in place ensuring the pharmacy will be compliant prior to opening.



College of Pharmacists of Manitoba 200 Tache Avenue, Winnipeg, Manitoba R2H 1A7

200 Tache Avenue, Winnipeg, Manitoba R2H 1A7 Phone (204) 233-1411 | Fax: (204) 237-3468 E-mail: info@cphm.ca | Website: www.cphm.ca

In cases of a new pharmacy or relocation or renovation of your pharmacy application:

A floor plan has been submitted to the College with the Pharmacy Licence	> / / N I
application.	Y / N

Please complete the assessment by circling the most accurate response based on the following rating scale:

1	We are confident in our compliance	
2	We are not sure if we are compliant	
3 We need help to be compliant		
N/A	Not applicable at this pharmacy	

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Facility

1. <u>Dispensary Equipment</u>

CPhM Standard of Practice #8: Extemporaneous Compounding

A member must ensure that extemporaneous compounding is done in a manner that ensures the preparation is safe and of an appropriate consistency and quality.

1 2 3	The dispensary sink is sanitary, supplied with hot and cold running water, is easily accessible to the prescription preparation area ¹ , is not accessible to the public, and has a provincial plumbing code acceptable drain.		
1 2 3	The dispensary refrigerator is clean, in good working condition (no excess frost build-up), dedicated to the storage of pharmaceuticals, maintains an appropriate temperature for the products stored within, and is regularly monitored for temperature. ¹		
1 2 3	An electronic balance, or a prescription balance and weights, is available with precision, reproducibility and accuracy in mass determination. The weighing apparatus has minimum and maximum weighable mass specifications as suited to the compounds prepared at this site. ¹		
1 2 3	Compounding and dispensing equipment includes: metric graduates (10 ml, 100 ml); mortar and pestle (250 ml); ointment slab or pad; spatulas; counting tray(s); computer or printing system for labelling prescriptions; and reference weights to conduct routine quality assurance testing.		
1 2 3	A DPIN connection is installed and tested, or is in use. ²		

2. Premises & Management

			A pharmacist is on duty whenever the pharmacy is open. ³
1	2	3	The pharmacy hours meet the needs of the community, hospital or institution served by the pharmacy. ⁴

¹ Pharmacy Facilities Practice Direction

² Drug Distribution and Storage Practice Direction

³ *The Pharmaceutical Act*, Part 7: Pharmacies

⁴ The Pharmaceutical Regulation 34(2), 35(2), 36(2), 39(2)

1 2 3	The College is notified of the employment of pharmacy managers, pharmacists (including part-time), pharmacy students and interns, including any changes in employment within 7 days of the change. ³
1 2 3	The pharmacy is readily accessible by telephone, facsimile and in person.
	The pharmacy has internet access for the purposes of:1
1 2 3	 □ Email (a subscription to the MedEffect™ Canada is recommended) □ Electronic fan-out □ Information research
1 2 3	The hours of operation and call back information are posted at the principle entrance.1
1 2 3	The entire premise is clean, well ventilated and sufficiently lit. ¹
1 2 3	The dispensary is 150 sq. ft. in addition to the patient counselling area. ¹
1 2 3	The prescription preparation area in the dispensary provides at least 12 sq. ft. of free working counter space. ¹
1 2 3	The dispensary shelves, front store shelves and floors are clear of dust, dirt and clutter. ¹
1 2 3	A metal or plastic waste container is readily available in the dispensary. ¹
1 2 3	The dispensary is accessible to authorised personnel only (e.g. a swing gate is installed to restrict public access). ¹
1 2 3	A patient counselling area is available that affords confidential counselling, is free of clutter, and contains no items for sale apart from articles needed for counselling. ¹
	The following signs are posted in view of the public:1
1 2 3	 Accepting Drugs for Return to Inventory Proof of Identity It's Your Right to Know Updated Personal Health Information
	Note: These signs can be found on the College website <u>here</u> .
1 2 3	The dispensary contains no products inappropriate to the practice of pharmacy. ¹
1 2 3	All NAPRA Schedule 3 products are displayed immediately adjacent to the dispensary, ⁵ are given priority over unscheduled drugs in their proximity to

⁵ The Pharmaceutical Regulation, Part 10: Restrictions on the Dispensing and Sale of Drugs

	the dispensary, and any patient viewing them can be seen from the dispensary.
1 2 3	NAPRA Schedule 1 and 2 products are stored out of the reach of the public. ⁶
1 2 3	Exempted codeine products are stored out of public view. ⁶

Advertising (Including Pharmacy Website)

1 2 3	Advertisements that display prescription prices do not use vague pricing terms such as "low", "lower", "lowest", "discount", "extra saving", or similar such descriptions. ⁷
1 2 3	Advertisements for professional services provided by the pharmacist do not claim superiority over other pharmacies or pharmacists. ⁷
1 2 3	All advertisements about the pharmacy are factual and clear.8
1 2 3	Advertisements do not use qualifying words such as "professional", "trusted", "prompt", "accurate", "licensed", or other words of similar intent.8
1 2 3	Advertisements do not claim exclusivity of any aspect of the practice of pharmacy. ⁸
1 2 3	Advertisements do not use the word "specialist" or a word with similar meaning unless the pharmacist is qualified as a specialist under the Manitoba <i>Pharmaceutical Act</i> .8
1 2 3	The pharmacy does not advertise a drug that is covered under the Controlled Drugs and Substances Act.8
1 2 3	Advertisements for pharmacy services that are required under provincial or federal legislation (such as patient counselling), include the statement "as required by law in all Manitoba pharmacies".8
1 2 3	Dispensing fees are only advertised when the total price of the drug is included in the same advertisement.8

 ⁶ The Pharmaceutical Regulation, Part 1: Definitions
 ⁷ Advertising in Manitoba Pharmacies Practice Direction
 ⁸ The Pharmaceutical Regulations, Part 17: Advertising

Pharmacy Library (minimum requirements) 4.

1	2	3	The online CPhM Manual ¹ , legislation and supporting documents, which can be found at: http://cphm.ca/sitsafe/legislation?nav=practice		
1	2	3	The Manitoba Drug Benefits and Interchangeability Formulary is readily available for reference (hardcopy or electronic).9		
1	2	3	Reference materials for drugs, interactions, nutraceuticals, herbs and food. ¹		
			Other reference material consistent with the standards of practice, practice guidelines and this pharmacy's area practice, such as:1		
1	2	3	☐ Geriatric ☐ Pediatric ☐ Medical dictionary ☐ Policy & Procedure Manual		
	2		The Policy and Procedures Manual contains the minimum requirements as outlined by Council ¹ in the guideline document <u>Minimum Pharmacy</u> <u>Policy and Procedures Manual Content.</u>		
1	2	3	The Policy and Procedures Manual is updated as circumstances in the pharmacy change (e.g. change of ownership, change of manager etc.) or at a minimum of every three years and dated to indicate the time of the last review and/or revision. 10		
1	2	3	The Policy and Procedures Manual contains an entry to indicate the pharmacy's policy for provision of services to a residential care home, if applicable.		
1	2	3	Staff is familiar with the pharmacy's Policy and Procedure Manual. 10		

5. Lock & Leave Enclosure (if applicable)

1 2 3	One copy of the lock and leave permit containing the hours of operation is posted at the principle entrance and visible from the exterior of the premises. ¹¹
1 2 3	A second copy of the lock and leave permit containing the hours of operation is posted in the vicinity of the lock and leave enclosure in public view. ¹¹

 ⁹ The Pharmaceutical Act, Part 9: Interchangeable Pharmaceutical Products
 ¹⁰ Minimum Pharmacy Policy and Procedures Manual Content
 ¹¹ Lock and Leave Component Practice Direction

1 2 3	The lock and leave enclosure is inaccessible to staff and the public when a pharmacist is not on duty. This includes all prescription records, all prepared prescriptions and NAPRA Schedule 1, 2 and 3 products. ¹¹
1 2 3	Pharmacist services are available for at least 25 hours per week over four days of the week, unless otherwise approved by Council. 11
1 2 3	The wall separating the lock and leave enclosure from the remainder of the premises extends from floor to ceiling or is 10 feet high and provides complete security during periods of closure. ¹¹

6. **Pharmacy Security**

1 2 3	The pharmacy provides secure drug storage against loss, theft, and diversion by installing: Alarm system ¹² Motion detector ¹²
	☐ Cameras ¹² ☐ Barred windows and doors
	There is strict control on the number of keys available to access the:
1 2 3	 □ Pharmacy □ Dispensary □ Lock & leave enclosure □ Narcotics
1 2 3	Dispensary/pharmacy alarm system codes and safe combinations are restricted to authorized personnel.
1 2 3	The use of advertisements in the pharmacy windows is limited to leave an open view into the pharmacy. ¹²
1 2 3	Computer terminals and records containing personal information are situated to ensure confidentiality of information and are accessible to authorized personnel only. ¹
1 2 3	The pharmacy back door (where applicable) is locked at all times when not in use. ¹²
1 2 3	Staff and suppliers having access to personal health information, including information management contractors, have signed a pledge of confidentiality.

¹² Procedures in the Event of a Robbery or Burglary

7. Prescription Records

1 2 3	Prescription records are stored electronically or in written form and are readily accessible for audit if requested by the College. 13
1 2 3	Prescription records that are not stored on the pharmacy premises are stored in a secure location that has been approved by the Registrar. ¹³
1 2 3	Destruction of records, prescriptions, and other notes containing sensitive information is done by either: 14 Physical destruction using a shredder or complete incineration, or Erasure or destruction of electronic records in such a manner that the information cannot be reconstructed.
1 2 3	The following records are maintained for at least 5 years and are readily accessible: 13 Prescription records Drug labels Patient profiles Counselling records Drug acquisition and sales records Prescriptions, or copies of them if they were refused to be filled Drug administration records Test interpretation records Test ordering and results records Prescribing records.
1 2 3	The sale of pharmaceuticals to other pharmacies occurs only for emergency supply on an individual patient basis. In the case of wholesale quantities of drugs, the pharmacy is compliant with the relevant establishment licensing requirements of Health Canada.
1 2 3	All dispensed prescriptions have a record with the following information: 13 Name and address of the patient Name and address of the prescriber Name of the drug Number of refills Manufacturer of the drug Strength and quantity of the drug Directions for use Date the drug is dispensed or refilled Total price charged Pharmacist's initials or signature

¹³ The Pharmaceutical Regulation, Part 9: Prescriptions and Records¹⁴ Records and Information Practice Direction

Faxed Prescriptions

1 2 3	The dispensary fax machine is only accessible to dispensary personnel. ¹
1 2 3	Faxed prescriptions do not include medication requiring an M3P prescription unless the prescription is for methadone or buprenorphine/naloxone for opioid maintenance and the daily dosage is clearly indicated on the facsimile in addition to the M3P form. ¹⁵
1 2 3	Faxed prescriptions are only accepted if they are sent from a machine authorized by the prescriber. ¹⁵
	Faxed prescriptions are only accepted if they are legible, include all required prescription information, and have a signed certification that: ¹⁵
1 2 3	 The prescription represents the original of the prescription drug order, The addressee is the only intended recipient, and The original prescription will be invalidated, securely filed and not transmitted elsewhere at another time.
1 2 3	Faxed prescriptions are filed and stored for at least 5 years and are accessible for validation upon request by the College. 15

Refill Recording System

	The pharmacy utilizes a prescription refill recording system compliant with one of the following options: 16
1 2 3	 Option 1: Recording and initialling refills on the original prescription. Option 2: Recording and initialling refills in a hardcopy logbook. Option 3: Recording refills using a computer-generated transaction system
1 2 3	The refill recording system applies to all prescriptions, including benzodiazepines and other targeted substances, but not narcotic or controlled medications. ¹⁶
1 2 3	Refills for targeted substances are not filled after 1 year from the date the prescription was written. ¹⁶
1 2 3	The logbook refill recording system (option 2 above) is retained for five years beyond the last refill date (if applicable). 16

¹⁵ Facsimile Transmission of Prescriptions Joint Statement¹⁶ Refill History Recording System Practice Direction

10. Prescription Labels

Prescription label information is complete and includes: 13 Patient's name		
Prescription number Pharmacy name, address and telephone number Name of the drug as follows: If a single entity drug, its generic name followed by the name of the manufacturer If a multiple entity drug, its trade name The strength and quantity of the drug Name or initials of the person preparing the drug for dispensing Name or initials of the person performing the final check of the product The date the drug is dispensed Name of practitioner Directions for use Total price charged The number of refills, part-fills or doses remaining. Plantage of the person performing the final check of the product The date the drug is dispensed Name of practitioner Directions for use Total price charged The number of refills, part-fills or doses remaining. Plantage of the person performing the drug for dispensing the drug for dispensing the drug for dispension of the drug, including shape, colour, size, form, and any other identifiable markings. Labels for compliance packaged medications are placed directly on the package. Auxiliary labels are placed on the appropriate vials or compliance packages to indicate the package is not child resistant.		Prescription label information is complete and includes: ¹³
packaged medication contain a clear description of the drug, including shape, colour, size, form, and any other identifiable markings. ² Labels for compliance packaged medications are placed directly on the package. ² Auxiliary labels are placed on the appropriate vials or compliance packages to indicate the package is not child resistant. ²	1 2 3	 □ Prescription number □ Pharmacy name, address and telephone number □ Name of the drug as follows: ○ If a single entity drug, its generic name followed by the name of the manufacturer ○ If a multiple entity drug, its trade name □ The strength and quantity of the drug □ Name or initials of the person preparing the drug for dispensing □ Name or initials of the person performing the final check of the product □ The date the drug is dispensed □ Name of practitioner □ Directions for use □ Total price charged
package. ² 1 2 3 Auxiliary labels are placed on the appropriate vials or compliance packages to indicate the package is not child resistant. ²		packaged medication contain a clear description of the drug, including
packages to indicate the package is not child resistant.2	_	
1 2 3 Drug labels are retained for a minimum of 5 years. ¹³		
	1 2 3	Drug labels are retained for a minimum of 5 years. ¹³

Please affix a prescription label here featuring a **multiple ingredient** product

(Obliterate patient's name.)

Please affix prescription label here featuring a **single ingredient** product

(Obliterate patient's name.)

Please affix **compliance package label** here featuring a **multiple ingredient** product.

(Obliterate patient's name.)

Please affix **compliance package label here** featuring a **single ingredient** product.

(Obliterate patient's name)

Narcotic and Controlled Drugs Record Keeping 11.

1 2 3	Narcotic and controlled prescriptions are filed separately from prescriptions for medications on Health Canada's Prescription Drug List and other medications. ¹⁷
1 2 3	Narcotic part fill prescriptions are accepted only when the prescriber indicates in writing the total quantity of drug to be dispensed, the quantity of each fill, and the specific interval. ^{13, 18}
1 2 3	M3P prescriptions with part fills are entered into DPIN indicating the actual quantity supplied with the first fill and with each subsequent fill. 19
1 2 3	The documentation of narcotic part fills refers back to the original prescription number or transaction number, not the previous part fill
1 2 3	All subsequent part fills of narcotics are cross-referenced to the original prescription authorization. ¹⁷
1 2 3	Narcotic, controlled drug and targeted substances acquisition and sales records (original invoices or "green pages equivalent") are dated and retained in a readily retrievable chronological manner for a period of 5 years. ¹³
1 2 3	A narcotic and controlled drug perpetual inventory record system (logbook or computer record) is maintained for all drugs that require an M3P prescription. ²⁰
1 2 3	Physical inventory counts are preformed and documented at a minimum of every 3 months. ²⁰
1 2 3	Discrepancies in perpetual and physical inventory counts are recorded by the pharmacy manager on an incident report form. ²⁰
1 2 3	The pharmacy manager takes necessary steps to identify the cause of a discrepancy or shortage and the responsible staff. The manager subsequently takes corrective actions. ²⁰
1 2 3	The resolution to the discrepancy is recorded in the incident report form and significant shortages or diversions are reported to Health Canada and the College. ²⁰
1 2 3	The pharmacy manager maintains an inventory of expired or returned narcotics, and performs a physical count at least every 3 months. ²⁰ The inventory records of expired and returned narcotics and controlled drugs includes the date of entry and quantity of the drug. ²⁰

Narcotic Control Regulations to the Controlled Drugs and Substances Act
 Outline of Prescription Drug Regulations: M3P

Manitoba Prescribing Practices Program Pharmacist Questions and Answers
 Narcotic and Controlled Drug Accountability Guidelines

Drug Distribution and Storage

NAPRA Professional Competencies for Canadian Pharmacists at Entry to Practice. Competency #3: Product Distribution

Pharmacists ensure accurate product distribution that is safe and appropriate for the patient.

CPhM Standard of Practice #6: Drug Distribution and Storage

A member must comply with the conditions of sale for all prescription and nonprescription drugs, in accordance with applicable legislation, to ensure the safety and quality of drugs being distributed.

12. Storage, Disposal & Deliveries

1 2 3	Outdated drugs are removed from the areas of sale (i.e. quarantined) promptly to avoid any possibility of accidental resale. ^{2, 5}
1 2 3	Narcotics and controlled drugs are stored in a secure safe that is out of public view.
1 2 3	Medications prepared pursuant to prescriptions are stored in the dispensary and inaccessible to the public. ⁶
1 2 3	All products regulated by the <i>Controlled Drugs and Substances Act</i> (e.g. narcotic, controlled, and targeted substances etc.) are delivered to the dispensary directly, or where applicable, to the receiving area and subsequently delivered to the dispensary. ²
1 2 3	Policies and procedures are in place to ensure the security of all medications during the time from delivery to the time the medication is stored safely and properly by dispensary staff. ²
1 2 3	The pharmacy has a policy and procedure for ensuring the integrity of temperature sensitive drugs during transport, storage and handling. ²
1 2 3	Temperature sensitive drugs are appropriately maintained between the time of dispensing and administration. ²
1 2 3	All courier or postal services that the pharmacy uses for delivery offer a signed proof of delivery/registered mail (or equivalent) for narcotic, controlled and targeted substances. ²
1 2 3	Delivery/shipping receipt information is retained for 60 days. ²

1	2	3	All medications for delivery are properly stored, and if not received by the patient, the medication is returned to the pharmacy within 24 hours. ²
1	2	3	For pharmacies that provide services to Residential Care Homes (not PCH), all medication must be individualized for each patient and authorized in advance by either the physician or pharmacist.
1 🗆	2	3	Rubbing alcohol and stomach bitters are sold only from behind the dispensary counter. ²¹
1 🗆	2 _	3	Liquids for internal use are kept separate from those for external use in the pharmacy.
1 🗆	2	3	Distilled water is stored separately from other diluents in the pharmacy.
1	2	3	All expired drugs and devices are kept separately from other inventory until they are destroyed or returned to the supplier. ²
1		3	All medication disposed of in such a manner as to ensure patient confidentiality in compliance with the <i>Personal health Information Act and Regulations</i> . ²
Destruction and return of narcotic and controlled drugs:			
Des	stru	ction	and return of narcotic and controlled drugs:
1		3	Destruction of narcotic and controlled drugs at the pharmacy takes place in the presence of at least two health care professionals.
1	2	3 3	Destruction of narcotic and controlled drugs at the pharmacy takes place
1 1	2 🗀	3 3	Destruction of narcotic and controlled drugs at the pharmacy takes place in the presence of at least two health care professionals. Destruction of the drugs is done in such a way as to ensure the substance is altered or denatured to such an extent that its consumption
1 1	2 🗀	3 3	Destruction of narcotic and controlled drugs at the pharmacy takes place in the presence of at least two health care professionals. Destruction of the drugs is done in such a way as to ensure the substance is altered or denatured to such an extent that its consumption has been rendered impossible or improbable. The following information is recorded when drugs are destroyed at the
1 1	2 2 0	3 3	Destruction of narcotic and controlled drugs at the pharmacy takes place in the presence of at least two health care professionals. Destruction of the drugs is done in such a way as to ensure the substance is altered or denatured to such an extent that its consumption has been rendered impossible or improbable. The following information is recorded when drugs are destroyed at the pharmacy: Name, strength and quantity of the drug Date of destruction Name of the two health care professionals witnessing the

Non-Potable Intoxicating Substances, Stomach Bitters and Rubbing Alcohol Regulation
 The Controlled Drugs and Substances Act, section 56
 Section 56 Class Exemption for Pharmacists and Persons in Charge of a Hospital for the Sale or Provision of Narcotics and Controlled Drugs to Licensed Dealers for Destruction

	The following information is recorded by the pharmacy when drugs are returned to a licensed dealer for destruction: ²³
1 2 3	 Name, strength and quantity of the drug Name and address of the licensed dealer to whom the narcotic and/or controlled drugs were provided The name of the pharmacist requesting the destruction A copy of the authorization to return the narcotic or controlled drug.
1 2 3	All destruction and return for destruction records are maintained for a period of 5 years. ²⁰

13. Compliance Packaging

1 2 3	Compliance packaged medication is not returned and repackaged more than once for the same patient when lot numbers and expiry dates were not tracked or the pharmacy used a heat seal method of packaging. ²
1 2 3	Medication is only repackaged for the same patient if the pharmacy tracked the lot number and expiry date and a cold seal system was used. ²
1 2 3	Compliance packaged medication is never returned to the pharmacy and repackaged for a different patient. ²
1 2 3	The pharmacy informs patients and caregivers that compliance packaging is not child resistant. ²
1 2 3	Proper hygiene procedures are followed when preparing compliance packaging, such as handwashing with hypoallergenic soap and the use of rubber or latex-free gloves. ²
1 2 3	Policies are in place to prevent the possibility of cross contamination for patients with known drug allergies, such as the use of rubber or latex-free protective gloves. ²

14. <u>Drug Programs Information Network (DPIN):</u>

1 2 3	The "Days Supply" field is filled in and calculated using professional judgement or calculated using the maximum dose resulting in a lower number of days supply. ²
1 2 3	When accessing a patient profile in DPIN without subsequently dispensing a prescription on the same day, the pharmacist: ² Confirms the identity of the person requesting access and their authority to do so, Clarifies the inquiry with respect to patient care, Documents the name of the person and reason for inquiry, and Retains this information for a period of 5 years.
	Note: There is no need for special documentation when the DPIN profile is accessed during the dispensing of prescriptions for the patient.
1 2 3	Where critical patient care codes MY and MZ appear, the pharmacist intervenes and documents the intervention(s) on DPIN and the patient's record in the pharmacy. ²
1 2 3	If a DPIN review or other information reveals an intervention is critical to patient care or results in a change in the prescription, the pharmacist documents the action in DPIN and the patient's pharmacy record. ²
1 2 3	If a pharmacist becomes aware of an individual that is receiving a drug that is excessive or inconsistent with good medical care, the pharmacist makes all reasonable attempts to consult with the prescriber(s).
	If the prescriber cannot be contacted, the identity of the patient and circumstances is forwarded in writing to the registrar at the College. ²
1 2 3	Prescriptions prepared but not picked up by the patient are electronically reversed in the patient's record and the DPIN system prior to the 28 day deadline required by Manitoba Health.

Patient Care

NAPRA Professional Competencies for Canadian Pharmacists at Entry to Practice #2: Patient Care

Pharmacists, in partnership with the patient and in collaboration with other health professionals, meet the patient's health and drug-related needs to achieve the patient's health goals.

15. Patient Counselling

CPhM Standard of Practice #1: Patient Counselling

Each time a drug is dispensed pursuant to a prescription, a member must provide the patient with sufficient information to enable the patient to safely and effectively manage his or her drug therapy.

	The pharmacy has a patient medication profile system to assist in counselling and the monitoring of patient adherence with their treatment plan. The system is able to record: ²⁴
1 2 3	 □ Name, address, telephone number, date of birth (age), gender □ PHIN (for Manitoba residents) □ Clinical information (allergies, disease states, interventions etc.) □ Medication histories and current medications □ Use of relevant medical devices □ Non-prescription drug use, herbal and homeopathic drug use
	 Non-medical use of tobacco, drugs and alcohol Laboratory results Non-safety vial requests
1 2 3	A licensed pharmacist, academic registrant, intern or student (under the direct supervision of a licensed pharmacist) provide patient counselling on the release of all new prescriptions. ²⁵
	A licensed pharmacist, academic registrant or intern exercises professional judgement as to the content of the dialogue on repeat and refill prescriptions. Possible topics for discussion include: ²⁵
1 2 3	 □ Changes in dosage regimes □ Compliance and efficacy □ Presence of adverse effects

²⁴ Patient Profiles Practice Direction

²⁵ Patient Counselling Practice Direction

	Patient counselling for new prescriptions contains at a minimum: ²⁵
1 2 3	 Confirmation of the patient's identity Confirmation of the identify and strength of the medication being dispensed (show & tell) Confirmation of the prescribed dosage regime Directions for use (including frequency, duration and route of therapy) Importance of compliance and what to do if a dose is missed Common side effects and what to do if present Food and drug interactions Activities to avoid Special storage requirements Prescription refill information How to monitor response to therapy Information regarding expected therapeutic outcomes When to seek medical attention Other information unique to the specific drug or patient
1 2 3	For patients with language or communication difficulties, the pharmacist uses any reasonable means to provide the counselling information listed above. ²⁵
1 2 3	The pharmacist evaluates the patient's understanding of the counselling through appropriate questioning or follow-up.
1 2 3	If a medication, a health care item or a medical device is delivered off premises, the pharmacist makes reasonable attempts to contact the patient directly to provide counselling. ²⁵
1 2 3	When direct verbal communication is not possible in advance of dispensing, written information is provided with the dispensed medication. ²⁵
1 2 3	In addition to counselling, printed drug information is supplied with all new and repeat prescriptions unless the materials are not available or it is not in the patient's best interests. ²⁵
1 2 3	Patient counselling occurs in a confidential manner. ²⁵
	Prior to recommending a NAPRA Schedule 2 or 3 drug, the pharmacist gathers specific information, such as: ^{26, 27}
1 2 3	 History of complaint as well as length of present symptoms Condition or symptom(s) to be treated Current and relevant information regarding disease state(s), allergies and/or sensitivities Current medications and therapies previously tried.

Sale of Schedule 2 DrugsSale of Schedule 3 Drugs

	Counselling of NAPRA Schedule 2 and 3 products includes: ^{26, 27}
1 2 3	 Directions for proper use and length of therapy Common adverse effects Expected response or outcome Non-drug treatments, if any Follow-up with the licensed pharmacist if there is no improvement or symptoms worsen
1 2 3	A pharmacist, academic registrant or intern is available and accessible at all times for patients who wish to self-select a NAPRA Schedule III drug. ²⁵

16. **Drug Information**

1 2 3	Only a pharmacist, academic registrant, intern or student (under the direct supervision of a licensed pharmacist) may handle drug information requests.
	The pharmacist uses professional expertise and judgement in processing drug information requests, including:
1 2 3	 Obtaining all necessary background information Interpreting the drug information request Conducting a thorough literature search Evaluating the literature in an accurate, unbiased manner Formulating a relevant and informative response Communicating the response in a verbal/written form
1 2 3	Pharmacists contribute to drug literature by reporting adverse drug reactions and medication incidents.
1 2 3	Pharmacist are aware of more extensive sources of information and procedures necessary to access them.
1 2 3	Drug information services are available during regular hours of operation and where an "on call" service exists, the information is available after hours.

17. Documentation

1 2 3	Pharmacist decisions for Part 2 EDS made by a pharmacist, and the reasons for the decision, are documented in the patient's record and/or on the prescription.
	There is ongoing documentation of interventions recorded in the patient's profile that include:
1 2 3	 Actual and potential drug interactions and adverse effects Compliance & drug discontinuation Changes to dosage regimen or quantity Counselling refusals Pharmacist's reasons for refusing to fill/refill a prescription Counselling on deliveries Provision of a lesser or greater quantity than specified by the physician, by package size restrictions, or upon patient requests
1 2 3	"Verbal Order", "V/O", "Phoned", "Copy", "Continued Care", "Partial Fill" or similar designations referring to how the authority to supply a prescription was obtained if not written or faxed are documented on the original prescription, new prescription or the new transaction hardcopy.
1 2 3	"Deferred", "Unfilled", "Logged", or similar designation when prescription information is pre-entered into the pharmacy computer and the prescription is not filled is documented on the original prescription, new prescription or the new transaction hardcopy.
1 2 3	"Prescriptions not filled", "NF", "ward stock", or similar designation when a prescription is provided from the OTC stock or from ward stock is documented on the original prescription, new prescription or the new transaction hardcopy.
1 2 3	Reference to an original prescription number is documented on a new hardcopy when an old prescription number is updated.
1 2 3	The refusal to fill a prescription is documented on the prescription and in DPIN as <i>Drug Utilization only</i> .
1 2 3	Pharmacists document that they have taken reasonable steps to ensure patient safety by checking the appropriate boxes on M3P forms and signing the form when the prescription is filled.
1 2 3	Permission from the patient or caregiver for using non-child resistant packaging is documented and kept on the patient's file. ²

Legal and Ethical

18. Code of Ethics

1 2 3	Pharmacists keep informed about new pharmaceutical knowledge, clinical literature and guidelines through a commitment to lifelong learning. ²⁸
1 2 3	Pharmacists consult with other healthcare professionals to ensure optimal patient care. ²⁸
1 2 3	Pharmacists respect the autonomy of a minor who is able to make decisions about his or her health and healthcare and is able to consent to care. ²⁸
1 2 3	Pharmacists leave the treatment of themselves and their immediate families to other health professionals, except for minor conditions or emergency circumstances. ²⁸
1 2 3	Pharmacists do not delegate responsibilities requiring professional judgement except to another pharmacist.
1 2 3	If a pharmacist objects to providing a pharmacy product or service to a patient for moral and ethical reasons, the pharmacist explains the basis of their objection to the pharmacy manager and respects the patient's right to receive pharmacy products and services. ²⁸
1 2 3	Pharmacists are involved in the education of pharmacy students, interns, residents and pharmacy technicians. ²⁸

19. <u>Medication Incidents and Discrepancies or Near Misses</u>

CPhM Standard of Practice #9: Incidents and discrepancies

A member must expeditiously address, document and report incidents, discrepancies and adverse events in dispensing drugs and in providing patient care.

(Medication Incidents and Near Miss Event Practice Direction)

1 2 3	The pharmacy has policies and procedures for addressing, reporting, investigating, documenting, disclosing and learning from medication incidents and near miss events. (3.1.1)
1 2 3	The pharmacy meets and follows the requirements of the College's standardized continuous quality improvement (CQI)program-Safety IQ. (3.1.3)

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²⁸ Explanatory Document: Applying the Code of Ethics in Pharmacy Practice

1	2	3	The pharmacy uses a medication incident reporting platform that satisfies College platform criteria and can export incident and near miss data anonymously to the National Incident Data Repository (NIDR) housed by ISMP Canada (3.2.4.1)
			What is the online incident reporting platform used in your pharmacy?
1	2	3 _	All pharmacy staff are trained in the elements of the Safety IQ program and the pharmacy's incident reporting platform or program. (3.1.4)
			Describe the process for training new employees on Safety IQ and the pharmacy's incident reporting platform or program:
			Does your pharmacy have a CQI coordinator in addition to the pharmacy manager?
1	2	3	Medication incidents, CQI improvement plans and formal CQI meetings are documented and accessible for regulatory review. (3.2.6.1)
Dis	cov	ery a	and Disclosure
1		3	Medication incidents are given priority over any other non-emergency tasks and duties. (3.2.1)
1	2	3	Upon discovery of an incident the pharmacist determines if the patient has experienced or is at risk of experiencing harm and protects the patient's health and safety by providing care for the patient to the best of their ability (3.2.1.1/3.2.1.2)
1	2	3	The pharmacist ensures the patient receives the correct medication in a timely manner and takes reasonable steps to ensure the incorrect medication is quarantined and/or returned to the pharmacy. (3.2.1.3/3.2.1.4)
1	2	3	The pharmacy manager and the patient's prescriber are notified about all medication incidents (3.2.1.5/3.2.1.6)

1 2 3	Disclosure of the medication incident to the patient includes an acknowledgment of the incident, an apology, information on potential consequences from the incident and a description of known facts. (3.2.2.1-3.2.2.4)
1 2 3	Throughout the response to the incident the patient is listened to and treated with empathy and respect.
	Reflecting on the steps taken by the pharmacy manager and staff pharmacists in the management of a medication incident that has reached the patient. Are any changes required to be compliant with the Medication Incidents and Near-Miss Events Practice Direction? Why or why not?
	Does your policy and procedure manual sufficiently outline the steps taken in response to a medication incident?
1 2 3	Conversations with pharmacy staff involved, the patient and prescriber are documented. (3.2.6.2)
	Describe where the pharmacy staff and manager document these communications:
1 2 3	The patient is informed regarding the pharmacy process for reporting and investigating the incident and implementing changes in processes to prevent recurrence. (3.2.2.5/3.2.3.3)
Reporting	

1 2 3	Medication incidents are promptly reported by pharmacy staff member(s) to a medication incident reporting platform which will export the de-identified report details to a national medication incident database. (3.2.4.1)
	Number of incidents reported into online reporting platform in last 3 months:
	Number of near miss events reported into online reporting platform in last 3 months:
	Date of last incident or near miss report:
	Describe the process for incident/near miss reporting (eg. Who is reporting, timeframe for reporting, etc.)
	Give one or more example(s) of change(s) made to pharmacy processes as a result of a medication incident or near miss. How effective was each change?
	Has your pharmacy developed any novel approaches to reporting, communicating or analyzing incidents and near misses? If so, please share your experience.

1 2 3	The pharmacy manager ensures that all staff member(s) involved in the incident are made aware of the incident and provided access to support if needed. (3.2.3.2) Describe how incident or near miss events are communicated to staff in your pharmacy:
1 2 3	Near misses that are recurrent or could potentially cause harm if not corrected are also reported to identify trends and preventive recommendations. (3.2.4.2)
Investigati	on and Analysis
1 2 3	CQI improvement (action) plans to minimize recurrence of a medication incident or near miss are developed and documented. This includes changes to processes or procedures, implementation date(s) and a monitoring plan for effectiveness. (3.2.5.2/3.2.6.3)
	Describe where action plans are documented:
	Describe how your pharmacy reviews incidents/near misses and develops action plans to prevent recurrence:
	How are action plans monitored for progress and effectiveness?

1 2	_	A pharmacy-specific safety self-assessment (SSA) is completed during the first year of the Safety IQ program or pharmacy opening, and then every three years. (3.2.5.3)
		Date of completion of last safety self-assessment:
		What safety self-assessment did you complete? (Pharmapod, ISMP Canada, etc)
		Describe an action plan developed as a result of your SSA:
Chara	1	
Share		
1 2	_	Findings and changes to be implemented are shared with pharmacy staff and changes reflected in the policies and procedures manual if deemed necessary (3.2.3.4)
1 2		Patients are informed of the action plan implemented to prevent further incidents. (3.2.3.3)
1 2	_	A formal Continuous Quality Improvement meeting be conducted with pharmacy staff at a minimum annually with informal huddles occurring as medication incidents occur and as deemed necessary. (3.2.5.4)
1 2	3	CQI meetings with staff including date, staff in attendance and agenda items discussed are documented. (3.2.6.5)
		Describe how CQI meetings are conducted and documented:

Feedback	
	What areas of Safety IQ is your pharmacy managing well?
	What areas of Safety IQ does your pharmacy need support or resources?

Expanded Scope of Practice

20. Pharmacist Prescribing

CPhM Standard of Practice #4: Prescribing and Dispensing Drugs

A member who prescribes a drug must provide a written prescription to the patient to advise the patient that he or she may choose to have the prescription dispensed at another pharmacy or by the prescribing member.

1 2 3	Pharmacists only prescribe a medication when it is in the patient's best interest and after considering the risks and benefits to the patient and other relevant factors specific to the situation. ²⁹
1 2 3	Pharmacists do not prescribe a medication unless the intended use: ²⁹ Is an indication approved by Health Canada; Is considered to be best practice or accepted clinical practice in peer-reviewed clinical literature; or Is part of an approved research protocol.
1 2 3	Pharmacists only prescribe drugs or medical devices where they have the necessary knowledge, skill, and judgment about the condition for which the drug/device is prescribed. ²⁹
1 2 3	Pharmacists only prescribe a drug or medical device for a patient whom they have seen and assessed in person. ²⁹

²⁹ Prescribing Practice Direction

	Pharmacists who issue a prescription conduct a patient assessment which includes, but is not limited to, the following: ²⁹
1 2 3	 Demographic information Signs and symptoms Laboratory or other test results Medical history Allergies Current medications Extent and results of previous treatment Pregnancy and lactation status (if applicable) Patient preferences
1 2 3	Pharmacists issue a prescription only after presenting the patient with the therapeutic alternatives and providing the patient with adequate information so that the patient can make an informed decision. ²⁹
1 2 3	A licensed pharmacist who issues a prescription must make and retain for 5 years a prescription record containing the following information: ²⁹ Name and address of the patient Patient's date of birth Name of the drug/device prescribed Strength, if applicable, and quantity of the medication Directions for use Number of refills Name of the licensed pharmacist issuing the prescription
	□ Date the prescription was written □ Treatment goal, diagnosis or clinical indication □ Rationale for the prescribing decision □ Follow up plan □ Other health professionals notified
1 2 3	Prescriptions for exempted codeine preparations written by a pharmacist do not exceed 100 tablets or 250 mL to be dispensed initially, and no more than 200 tablets or 500 mL if part fills are indicated. ³⁰

21. **Prescription Adaptation**

1 2 3	Adaptation of a prescription is based on an existing prescription provided by a practitioner. ³¹
1 2 3	Adaptation is limited to: ³¹

³⁰ Exempted Codeine Preparations Practice Direction³¹ Adaptation of a Prescription Practice Direction

	Dosage strength,Dosage interval, and/orFormulation
	Pharmacists only adapt a prescription when they are knowledgeable of the patient, the condition being treated and the drug therapy, and if one or more of the following applies: ³¹
1 2 3	 The prescription is not commercially available or is temporarily unavailable from the supplier; Information is missing from the prescription and sufficient information about the drug therapy can be obtained from the patient, patient record, or other sources; Adaptation will facilitate patient adherence to the prescribed regimen; or Adaptation will enable the patient to benefit from approved and existing third-party drug coverage.
1 2 3	Adaptations for prescription drugs covered under the <i>Controlled Drugs</i> and <i>Substances Act</i> do not exceed total amount of milligrams prescribed. ³¹
	Pharmacists document and maintains a record of all information related to the adaptation of a prescription, including: ³¹
1 2 3	 A new prescription record signed by the licensed pharmacist; A clear reference on the new prescription indicating the location of the original prescription; The patient's informed consent; Patient name and, when available, PHIN; Pharmacist's name and signature or initials; Original prescription information; Rationale for the decision to adapt the prescription; Description of the adaptation; and Follow-up plan.
1 2 3	The pharmacist promptly notifies the original prescriber of the adaptation in addition to the information listed above. ³¹

22. Administration of Drugs Including Vaccines

CPhM Standard of Practice #5: Administration of Drugs

A member who administers a drug to a patient must:

- a) Do so only with the patient's authorization;
- b) Have policies and procedures in place respecting the administration of drugs and be prepared to immediately respond in emergencies, like anaphylaxis; and

Only administer a drug if the pharmacy has facilities that are appropriate for the c) administration.

	All pharmacists that administer drugs, including vaccines, using an advanced method of administration hold a current certification for one of the following advanced methods: ³²		
1 2 3	 Intradermal, subcutaneous, or intramuscular injection; Intravenously through an established central or peripheral venous access device; or Rectally. 		
1 2 3	Pharmacists that administer drugs and vaccines by injection possess current certification in CPR Level C (or HCP) and Emergency or Standard First Aid from a Workplace Safety and Health Branch approved in-person training program. ³³		
1 2 3	The pharmacy's policy and procedure manual includes a section on the administration of drugs, including vaccines, and emergency response protocols. ^{34, 36}		
	Pharmacists ensure that the patient or the patient's agent is informed of the following information prior to obtaining consent for administering an immunization: ³⁵		
1 2 3	 The expected benefits and risks of the immunization; Any information that a reasonable person in the same circumstances would require in order to make a decision about the immunization; and The importance of immediately consulting with the pharmacist or another healthcare professional if a reportable event occurs. 		
1 2 3	Pharmacists collaborate with the patient or the patient's agent and receive informed written consent prior to administering a drug or vaccine. 32, 35, 36		
1 2 3	Pharmacists review the relevant and applicable immunization guidelines, such as those set out by Manitoba Health and the National Advisory Committee on Immunization (NACI) prior to administering immunizations. ³⁶		
1 2 3	Pharmacists report the details of immunizations (which may include personal health information) to the Manitoba Immunization Monitoring System. ^{32, 36}		

The Pharmaceutical Regulations, Part 14: Administration of Drugs by Members
 Application for Certification of Authorization to Administer Drugs and Vaccines by Injection

³⁴ The Pharmaceutical Regulations, Part 7: Standards of Practice

³⁵ The Public Health Act, Part 4: Disease Control, Division 4: Immunization

³⁶ Administration of Drugs Including Vaccines Practice Direction

1 2 3	The pharmacy maintains a readily accessible supply of epinephrine syringes ("pens") for emergency use, a copy of the pharmacy's emergency anaphylaxis management protocol and other emergency response items deemed essential by the pharmacist such as diphenhydramine, cold compresses and non-latex gloves. ³⁶				
1 2 3	Pharmacists do not administer an injection to a person under five years of age. ³⁶				
1 2 3	Pharmacist do not administer a vaccine to a person under seven years of age. ³⁶				
1 2 3	Pharmacists do not administer a drug, including a vaccine, to a family member unless there is no other alternative. ³⁶				
1 2 3	The pharmacy maintains a clean, safe, private, and comfortable environment where injections are administered. ³⁶				
1 2 3	Pharmacists perform a basic assessment of the patient prior to administration of a drug or vaccine, including: ³⁶ Medical history; Current medical conditions; Condition of the administration site; and Past reactions to immunizations or other medications administered by injection.				
1 2 3	Before administering of a drug or vaccine, the pharmacist counsels the patient on the following information: ³⁶ Name of the drug; Indication for the drug; Expected benefits and risks; Expected reaction; Common and rare side effects; Rationale for the 15-30 minute wait following the administration; and Importance of immediately consulting with the pharmacist if a reportable event occurs.				
1 2 3	Patients are monitored for adverse reactions for a period of 15-30 minutes following administration of a drug or vaccine. ³⁶				
1 2 3	Drug administration records are maintained in the pharmacy for all patients who receive a drug or vaccine from a pharmacist. Drug administration records include the following information: ³² □ Patient's name and address; □ Name of the drug and total dose administered;				

	 For an advanced method, or vaccination by any method, the manufacturer's name, lot number and expiry date of the drug; For an advanced method, the route of administration and the location on the body where the drug was administered; Name of the pharmacist administering the drug or vaccine; Date and time of administration; Any adverse events; Price charged to the patient.
1 2 3	Pharmacists handle all bodily fluids and tissues as if they were infectious, regardless of the patient's diagnosis. ³⁶
1 2 3	Procedures are in place in the pharmacy to prevent needle stick injuries and actions to take if a pharmacist suffers a needle stick injury. ³⁷
1 2 3	Pharmacists report reportable events within 7 days of becoming aware of the event. 35, 36

Additional Resources

NAPRA Model Standards of Practice for Pharmacists and Pharmacy Technicians in Canada

NAPRA Supplemental Standards of Practice for Schedule II and III Drugs

NAPRA Supplemental Competencies on Injection

NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations

NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations

NAPRA Model Compounding Competencies for Pharmacists and Pharmacy Technicians in

Canada

NAPRA Model Standards for Continuous Quality Improvement and Medication Incident Reporting

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³⁷ Needle Stick Injury Guidelines

Notes for discussion or comment:				