

# Implementing Standards: Revised Standards of Pharmacy Operation- Community Pharmacy Part 2

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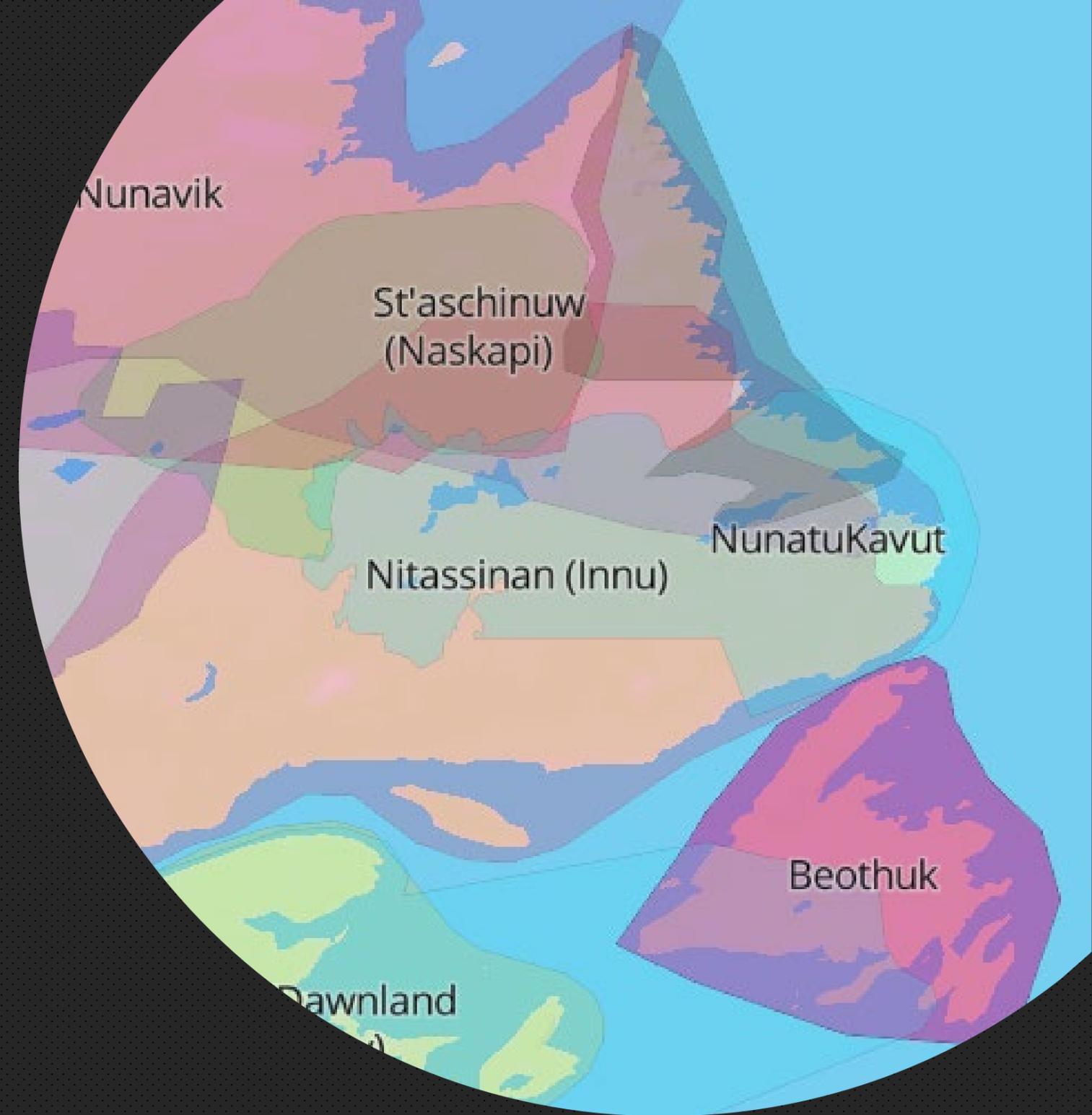
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We respectfully acknowledge the land on which we gather as the ancestral homelands of the Beothuk, whose culture has now been erased forever.

We also acknowledge the island of Ktaqmkuk (Newfoundland) as the unceded, traditional territory of the Beothuk and the Mi'kmaq. And we acknowledge Labrador as the traditional and ancestral homelands of the Innu of Nitassinan, the Inuit of Nunatsiavut, and the Inuit of NunatuKavut.

We recognize all First Peoples who were here before us, those who live with us now, and the seven generations to come.

As we open our hearts and minds to the past, we commit ourselves to working in a spirit of truth and reconciliation to make a better future for all.



# Learning Objectives

At the completion of this session, participants should be able to:

1. Recognize the roles and responsibilities of pharmacists, RPTs, and other members of the pharmacy team.
2. Discuss what is meant by a “therapeutic” and “technical” check.
3. Understand the level of documentation required when maintaining a patient’s medication profile and health record.
4. Recognize requirements surrounding the cold-chain for temperature sensitive medications.

# What are the “Standards of Pharmacy Operation”?

- One component of the legislative scheme that governs the practice of pharmacy, and the operation of pharmacies in NL.
  - Pharmacy Act, 2012
  - Pharmacy Regulations, 2014
  - NLPB Bylaws
  - NLPB Code of Ethics
  - all NLPB Standards of Practice, Guidelines and Practice Policies
- Describe the *minimum* acceptable standards applicable to operating a licensed pharmacy in Newfoundland and Labrador
- Are intended to promote consistency in the provision of pharmacy services in the province

# Standards of Pharmacy Operation - Community

- Updated standards published in August 2022 with a September 1<sup>st</sup>, 2023 implementation deadline
- Allow time for pharmacy professionals and owners to:
  - Familiarize themselves with updated standards.
  - Develop any related policies and procedures
  - Upgrade facilities/equipment as needed
- Provide an opportunity to communicate these changes in greater detail.

# Revised Standards – Part 2

- Last time: Reviewed Sections 1 and 2 of the updated SOPO-Community
  - “General” and “Supplemental” standards of operation
- Today: Review Section 3 - “Pharmacy Practice”
  - Less focus on “change”, more on “application”
  - Areas most likely to require intervention/action
  - Clarify frequently misinterpreted standards
- Not intending to highlight and discuss every standard in detail
  - Still important to familiarize yourself with the original document!
- Opportunity for questions at end

# Pharmacy Practice Overview

Recognize and practice within roles and responsibilities

Create,  
maintain and  
access  
patient  
profiles

Record,  
prepare and  
verify  
medications  
being  
dispensed

Transfer  
prescriptions

Counsel on  
non-  
prescription  
medications

Communicate  
within the  
circle of care

Protect cold-  
chain  
medications

# Roles and responsibilities

- Standards now refer directly to the [NAPRA Model Standards of Practice for Pharmacists and Pharmacy Technicians in Canada](#)
  - Outline professional practice standards for pharmacists and registered pharmacy technicians.
  - Describe the minimum expectations for the delivery of quality pharmacy care.
- Watch for “**Roles and Responsibilities Reminders!**” (**RRRs**)
- Pharmacy assistants:
  - May participate in administrative or technical functions
  - Must be directly supervised by a pharmacist or pharmacy technician
  - Appropriate procedures, checks, and controls must be in place

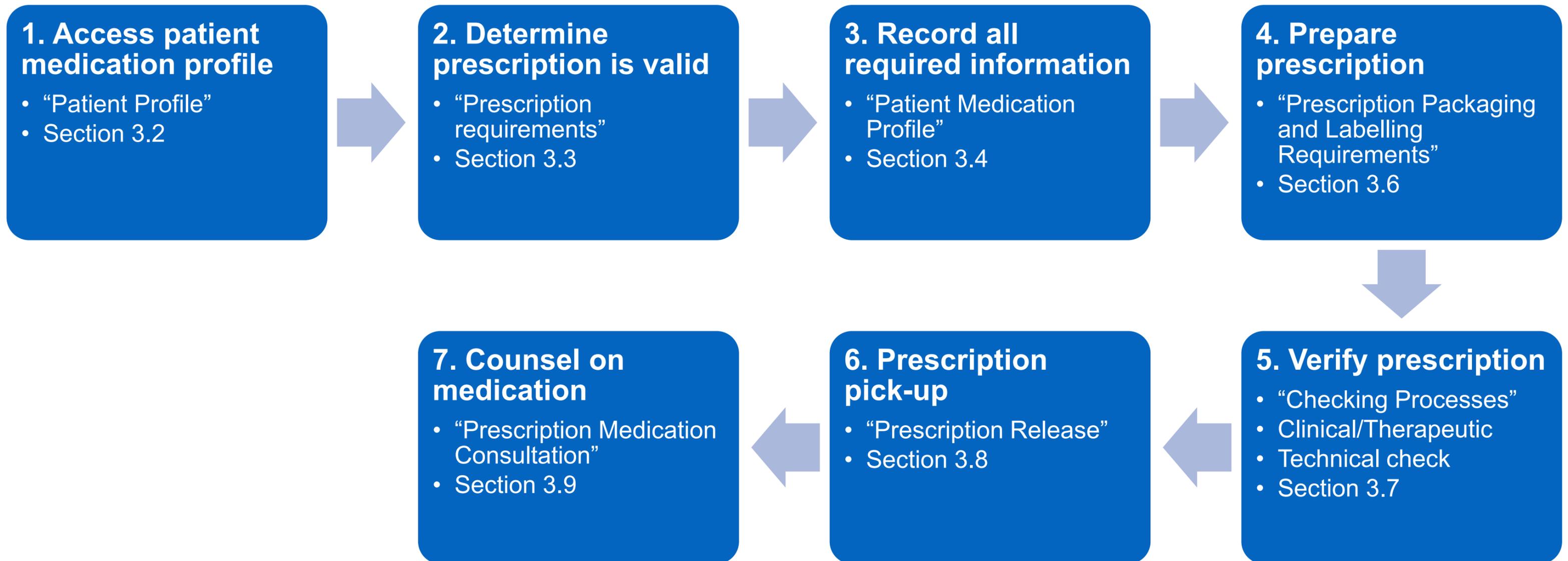
# Pharmacy students and interns

- “Pharmacy student” and “Pharmacy intern” are titles that require registration with NLPB.
- Registration confers upon the individual the ability to perform certain tasks within the scope of practice of a pharmacist with delegation and appropriate supervision.
- Practical placements may only be completed by students who are registered with the board.
- Must identify oneself using these titles when interacting with the public and members of the pharmacy profession.

## Focus Area:

*Patient profiles and prescription workflow*

# Applying standards to practice



# 1. Patient Profile

- A patient profile must be prepared and maintained for each patient to whom:
  - a prescription is dispensed;
  - an inhalation or injection is administered; or
  - another pharmacist-administered assessment or activity is performed (e.g. pharmacist prescribing, sale of exempted codeine)
- 2022 update has removed “*when a Schedule II medication is provided*” from this list. May still choose to do so!
- Minimal changes to what information must be maintained in patients’ profiles
  - Some “requirements” have been moved to “suggested”

# 2. Prescription Requirements

- Standards outline the requirements for a prescription to be considered valid.
- Minimal changes overall with no notable changes in:
  - Information required (patient name, name of medication, strength, quantity etc)
  - Verbal prescription requirements
  - Prescription transfer requirements
  - One year expiration from written date
- **RRR:** *“At this time, pharmacy technicians may not accept verbal prescriptions for narcotics, controlled drugs, benzodiazepines, or targeted substances.”*

# Note on logged prescriptions

- Prescriptions being logged for dispensing at a later time:
  - must be accurately entered into the patient's medication profile, as if it were to be dispensed that day
  - must have a pharmacist assess the therapeutic appropriateness of the drug therapy (i.e. complete a "Clinical check")
  - must include the identity of any staff members involved in entering the prescription into the patient profile
- When filling a logged prescription for the first time:
  - Must be handled as if it were a new prescription with regards to assessing validity, accuracy and therapeutic appropriateness.

# Prescription Requirements - FAQ

## Can we accept prescriptions by email?

- Language updated to accommodate electronic means for receiving Rxs
- Any method used must take into consideration responsibilities to PHIA and ability to ensure origin and authenticity:
  - Consider: *Who has access to the email address? How is the account secured? Is it accessible outside the pharmacy including on mobile devices?*
- Pharmacies, as well as clinics sending Rxs, should conduct a privacy impact assessment and are encouraged to consult with the “Office of the Information and Privacy Commissioner NL” before changing how PHI is collected, retained and/or communicated.

# 3. Patient medication profile

- Standards describe what must be recorded each time a prescription medication is dispensed.
  - May also record schedule 2 sales, add OTC meds to profile, non-Rx counselling.
- Information to be recorded has not changed (*Rx number, date, dose form, med, strength, etc*)
- Worth reviewing - Records must contain:
  - Interactions that were detected, how they were addressed, and who addressed them. (*Is this consistent? How are these retrieved? Is documentation meaningful?*)
  - The identity of all staff members involved in the dispensing process (i.e. “*who did what*”). Recorded to a “hardcopy”; either manual, electronic, or combination.

# 4. Packaging and Labeling

- No major changes, but some items worth reviewing!
- Compliance pack/blister pack labels:
  - Commonly noted as having additional compliance pack label requirements but missing base label requirements during site visits
  - Most commonly missing prescriber name; number of refills or total remaining quantity
- Small packaging: “Where a drug container size is too small to accommodate a full label [...] a trimmed label must be affixed to the small container”:
  - First and last name; name of drug; prescription number; date of dispense
  - Complete label affixed to a larger container, intended for storage

# 5. Checking Processes

- Before **any** dispensed medication is released to a patient (new or refill) it must receive **a clinical/therapeutic check** as well as a **technical check**.
- **Therapeutic checks** must be completed by a pharmacist
  - Focus is on appropriateness of drug therapy.
  - Screening for contraindications, allergies, therapeutic duplication, adherence concerns, and more...
- **Technical checks** may be completed by a pharmacist or an RPT
  - Focus is on accuracy of patient medication record and label versus prescription
  - Ensure packaging is appropriate and contains any appropriate aux labels

# 5. Checking Processes

- During both processes the following must be made available in print or displayed:
  - The original prescription or a scanned image
  - A printout or visual representation of the information being recorded to the patient medication profile (Section 3.4)
- **Note:** While the technical check requires the prescription to be prepared, there is no set place in the workflow for when the clinical check may occur.
  - Where does the placement of the clinical check best fit your workflow?
  - How might the presence of an RPT on your team alter this?

# 5. Checking Processes

- Both checks must be recorded for every medication dispensed to indicate they were completed.
- Consider how these are being recorded/retained across all workflows:
  - Compliance pack prescriptions
  - LTC/PCH prescriptions
  - Prescriptions packaged using automated packaging machines (e.g. PacMed, BlistAssyst)
  - Compounded prescriptions

# 6. Prescription Release

- Patient identification:
  - A minimum of two patient identifiers should be utilized (*Address; Date of Birth; MCP number; Photo ID*)
  - Agents picking up for a patient must provide similar patient identifiers in addition to identifying themselves
- Agents and Informed Consent:
  - Informed consent must be received before releasing prescriptions or disclosing personal health information to another person
  - Should be documented to the patient profile with understanding that it may be changed or revoked by the patient in the future

# Prescription Release

- Documentation of prescription release is required
  - Date and time of Rx release, who released it and who it was released to
- Rx release must be reported to the pharmacy network as close to the pick-up time as possible
  - Ensures the data integrity of the patient's personal health information and to enable drug utilization reviews to be performed accurately
- Pick up when lock and leave enclosure is in place:
  - must be a record (either physical or electronic) that includes the name of the patient (or agent) and the name of the staff member who released the prescription.
  - retrieved and reviewed by dispensary staff when the dispensary reopens, and confirmation of prescription pick-up must be appropriately recorded, per above

# 7. Prescription Medication Counselling

- Pharmacists shall promote the safe and effective use of medication by educating and counselling patients about their drug therapy on the original filling of each prescription, while also giving the patient the opportunity to ask questions.
- Should assess need for counselling on subsequent fillings and document as provided.
- All patient counselling must be documented and include at a minimum:
  - Name of the pharmacist who provided the counselling, and when.
- If the patient refuses to participate in patient counselling, the pharmacist should document the refusal in the patient record.

# 7. Prescription Medication Counselling

- How you do it is up to you but should be consistent across all pharmacists (defined through policy and procedure)
- Different methods are available with some benefiting specific pharmacies over others:
  - Electronic documentation (e.g. Prescription counselling module in software)
  - Directly on the manual paper hardcopy, if using.
    - Visibility of patient health information?
    - Organization of records?
  - Separate written documentation (e.g. to a privacy label or other tag attached to rx bags)

## Focus Area:

*Other areas of pharmacy practice*

# Protecting the cold chain

- **What constitutes a suitable fridge?**
  - A “Purpose-Built” Refrigerator (pharmacy or vaccine refrigerators) – a specialized refrigerator that responds to fluctuations in temperature
  - A “Modified” Frost-Free Domestic Refrigerator - A typical household refrigerator that has had the following modifications:
    - Crisper removed
    - Large water bottles have been placed in the crisper area, in the door and against the walls of the unit
    - Freezer packs or ice cube trays are kept in the freezer section of the unit, if present
- **Remember:** Prescriptions available for pick-up when the dispensary is closed must be stored in a manner that meets these requirements.

# Protecting the cold chain

- **What constitutes continuous temperature monitoring?**
  - Using a thermometer that provides continuous monitoring (i.e., a digital data logger). Should be possible to review a history of recorded temperatures for trends.
  - a “Min/Max” thermometer that provides current temperature and the min/max range observed since the last time the thermometer was reset. Recorded and reset twice a day.
  - On its own, connection to an alarm/security system is not sufficient monitoring.
- **What processes are in place to prevent medications being left out at room temperature during receiving, packaging and verification activities?**
- **Is manufacturer guidance followed regarding maintenance and capacity?**

# Transfer prescriptions

- General process and requirements have not changed
  - Pharmacist or RPT makes request for transfer
  - Pharmacist or RPT transfers the prescription in a timely manner; transfer-out information recorded; remaining refills deactivated
  - Requesting pharmacy receives the transfer, information is verified for completeness and records to PMP
- **RRR:** At this time, pharmacy technicians may not participate in prescription transfers for benzodiazepines or targeted substances.

# Transfer prescriptions

- Please ensure use of the Pharmacy Network in transfer process.
  - Reduces the likelihood of transcription errors
  - Avoids duplicate records within the provincial electronic health record
- Requires both teams to follow the process as designed
  - When transferring a prescription out, a transfer message is sent to the Pharmacy Network.
  - This must indicate which pharmacy the prescription is going to so the other may create a local copy
  - Reassigns the prescription to the new pharmacy location as opposed to creating a second record

# Questions?