Implementing Standards:
Revised Standards of Pharmacy Operation-Community Pharmacy

Part1

Rheya White, B.Sc. Pharm, R.Ph. (*they/her*)
Community Pharmacy Practice Consultant
rwhite@nlpb.ca

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Learning Objectives

At the completion of this session, participants should:

1. Understand the purpose of the Standards of Pharmacy Operation- Community Pharmacy and its place within the greater pharmacy legislative scheme.
2. Recognize changes to various standards of operation, including those that may require changes to policy, procedure, equipment and/or infrastructure.
3. Become familiar with the intentions of policy and procedure and their application within pharmacy practice and operations.

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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

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Brief History

- Previous version published 2015 with a 2017 revision
- Scheduled for review every 5 years (originally due 2020):
  - work delayed due to the workload associated with the pandemic and internal human resource constraints
- Late 2021 - Review began with:
  - review of issues identified during site visits over previous years
  - review of feedback received at NLPB office
  - jurisdictional scan of other provinces' similar standards and requirements

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Brief History

- **March 2022** – NLPB board reviewed progress on Standards of Pharmacy Operation-Community; approved a consultation plan; Task Force struck consisting of community-based practicing board members
- **April 2022** – Task Force met with staff working on the document to review draft to date and provide feedback
- **May 2022** – Feedback from Task Force integrated into document; draft finalized for broad consultation
- **June 2022** – Consultation survey developed and launched
- **July 2022** – Consultation open; results from consultation reviewed by staff and Task Force; feedback integrated into final draft
- **August 2022** – Final draft presented to the NLPB board for review and approval with suggestion for delayed implementation window

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Delayed implementation window

- Published August 2022 with a September 1st, 2023 implementation deadline
- Allow time for pharmacy professionals and owners to:
  - Familiarize themselves with updated standards. Notable changes in:
    - Security standards, including lock and leave requirements;
    - Narcotic and controlled drug (NCD) storage;
    - Document retention;
    - And more…
  - Develop any related policies and procedures
  - Upgrade facilities/equipment as needed
- Provide an opportunity to communicate these changes in greater detail.

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Revised Standards – Part 1

- Review Sections 1 and 2 of the updated SOPO-Community
  - “General” and “Supplemental” standards of operation
  - Second webinar will cover Section 3 – Pharmacy Practice
- Not intending to highlight and discuss *every* change in detail
  - Still important familiarize yourself with the original document!
- Emphasis on:
  - changes most likely to require intervention/action
  - frequently misinterpreted standards that updated for clarity
- Opportunity for questions at mid-point and end

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Revised Standards of Pharmacy Operation- Community Pharmacy

Focus Area #1:

Security, Lock and Leave, Narcotic and Controlled Drug Inventory

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General Security

- Greatly expanded detail around security/surveillance requirements
- Physical measures:
  - **Exterior doors**: metal/metal-clad; deadbolt lock; tamper-resistant door bars
    - Consider: exit only/no exterior handle, video surveillance, height markers
  - **Glass protection**: shatterproof glass or bars
    - Consider: shatter resistant films, shatter sensors (in addition to physical protection)
  - **Others as needed:** plexiglass/metal security gates and curtains
- Exterior/interior lighting:
  - Consider all areas including parking areas, entrances and exits, where cash is used or stored, and access points to staff only areas

SOPO-Community Section 1.4b

Security – Video surveillance

- High-resolution video surveillance equipment should be used
- Cameras should be visible and appropriately positioned on both the exterior and interior of the pharmacy:
  - Entrances to main premises, pharmacy and dispensary
  - Within the dispensary
  - Anywhere controlled substances are stored
- Additional considerations:
  - Eye-level cameras, particularly near storage safe
  - Height markers

SOPO-Community Section 1.4b

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Security – Video Surveillance

- Have clear and visible signage on both the exterior and interior of the pharmacy indicating that video surveillance and other security systems are in place
- Recording equipment should be kept in a locked area out of public view with recordings kept for at least 30 days.
- Relevant staff should be trained on how to use security equipment so that data is readily accessible.

Security - Access

- Restricted access to pharmacy/dispensary
  - Keys/access codes limited to minimum number of authorized people
  - Policy in place determining how access assignments are made and removed
  - Documentation in place outlining current persons with authorized access
- Monitored alarm system with motion and door sensors
  - All security equipment must be kept up to date and in working condition
  - Should test regularly; ensure motion sensors capture dispensary and areas containing controlled substances (including prescriptions awaiting pickup)
  - Ensure contact persons and phone numbers are up to date

SOPO-Community Section 1.4b

Security – Lock and Leave

- Enclosure requirements more clearly defined:
  - *"constructed in such a way to physically and securely separate the dispensary from the rest of the pharmacy during periods of closure."*
  - composed of transparent, semi-transparent, or opaque materials, or any combination thereof, and a least 5 feet high
  - Examples: folding/sliding gate, permanent wall
- **The dispensary must be monitored by an alarm system during times that the dispensary is closed but the pharmacy remains open or accessible to non-regulated staff members**. This may be:
  - A separate zone within the pharmacy's existing system or a separate system

SOPO-Community Section 2.1

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Narcotic, Controlled, BZDs and Targeted Drugs

- Pharmacists-in-charge are expected to take all reasonable steps that are necessary to protect controlled substances on the pharmacy premises against loss or theft.
- Pharmacies must employ a variety of security, inventory reconciliation, and record-keeping measures.
- Must take into consideration protection from:
  - External theft (e.g. Robbery, break-and-enter)
  - Internal theft (e.g. pilferage, diversion)

Storage and security

- Narcotics and controlled drugs, including exempted codeine products, must be stored in a **secure safe** (not cabinet) which:
  - Has a tamper-resistant locking mechanism
  - Has tamper-resistant hinges
  - Is made of steel or other durable material not prone to bending/prying
  - Is not damaged/worn
  - Is bolted to the ground
- Liquid dosage forms that require refrigeration, including prepared doses of methadone, must be stored in a locked refrigerator

SOPO-Community Section 1.8b

Example – Secure Safe

Example – Locked Cabinet

- Thin material
  - Often matches same grade used in surrounding cabinetry
  - May show signs of wear in form of dents, bends and warping
- Similar quality lock to that seen with a filing cabinet
- **No longer meet standards**

NCBT perpetual inventory

- Must maintain a **perpetual inventory** of narcotics, controlled drugs, benzodiazepines, and other targeted substances
- Must be able to generate a report for each individual NCBT that shows the sequential inventory changes by date, including:
  - dispenses/sales
  - purchases
  - cancelled prescriptions
  - any manual inventory changes (including who made them and the reason)
- If it is not possible to have a computerized perpetual inventory record, a manual record must be maintained with separate documentation for each NCBT.

SOPO-Community Section 1.8c

Monitoring for internal diversion

- Modified to permit a greater variety of methods for detecting diversion
- Pharmacists-in-charge must have policies and procedures in place to prevent and detect theft of NCBTs by pharmacy staff members. These processes **may include**:
  - Random audits of purchase invoices against the perpetual inventory record;
  - Random audits of dispenses to ensure that there is a corresponding valid prescription and that it has been dispensed accurately;
  - Technology safeguards such as automated ordering and receiving
  - Restricted ability to make manual inventory changes, requirement for the rationale for a manual inventory change to be documented
  - Regularly generating or reviewing a report that details all manual inventory changes made within a period of time (e.g., weekly or monthly).

SOPO-Community Section 1.8h

Questions?

Security, Lock and Leave,
Narcotic and Controlled Drug Inventory

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Revised Standards of Pharmacy Operation- Community Pharmacy

Focus Area #2:

Policy, procedure, staffing, quality improvement and facilities.

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Policy and procedure

- Policy and procedure manual section expanded for clarity
- Clearer definitions around what is meant by **policy** and **procedure**
- **Policies:** clear statements that guide processes, procedures, and decision-making related to pharmacy services;
- **Procedures:** how each policy will be put into action in the pharmacy.
  - who will do what;
  - what steps they need to take;
  - which forms or documents to use; and
  - how documentation is retained.

Quality Management Program

- Pharmacists-in-charge must implement an ongoing quality management program which includes:
  1. policies and procedures to comply with all legislation and standards applicable to the operation of a community pharmacy (*e.g. policy and procedure manual*);
  2. monitoring of staff performance, equipment, facilities, and adherence to these standards; and…

SOPO-Community Section 1.3

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Continuous Quality Improvement

3. A process for proactive risk assessment, medication incident and near miss reporting, and continuous quality improvement in accordance with the *MedSTEP NL* program, including:
   - The NAPRA "*Model Standards for Continuous Quality Improvement and Medication Incident Reporting*"
   - Related interpretation guides (to follow)

- MedSTEP NL program is currently under development and information will follow.
  - Task force consultation will take place in April to gather feedback on the standards, CQI program components, and inform implementation deadlines.

Staffing and supervision

- Expanded detail outlining responsibilities of the pharmacist-in-charge per the *Pharmacy Regulations*.
- The pharmacist-in-charge must*:*
  - collaborate with the pharmacy owner to ensure that the pharmacy has an adequate staffing complement to enable safe practice and quality patient care
    - Includes that required for adequate supervision
  - ensure that all pharmacy staff have the necessary education, training, experience, knowledge, and skills to carry out their assigned duties
    - *Includes verification of registration status, liability insurance and authorizations (i.e.as required for OAMT, injection, prescribing)*

SOPO-Community Section 1.2; Pharmacy Regulation Section 12

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Record storage and retention

- Patient records must be retained in a secure, but readily accessible format (either physical or electronic) for a minimum of **ten years**
  - Previously physical records were required to be retained for three years regardless of electronic copies being present
- **Patient records** include:
  - Prescriptions; including written copies of verbal prescriptions
  - Clinical documentation forms
  - Consultation records
  - Compounding records
  - Packaging documentation (e.g. compliance pack verification record)

SOPO-Community Section 1.6c

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Record storage and retention

- “That means I can destroy the physical copy immediately after scanning, right?”
- Standard processes and procedures must be in place to ensure electronic records are complete before the physical record is destroyed
- Questions to consider:
  - What processes are in place to ensure electronic records are complete?
  - How frequently are electronic records being backed up?
  - Are electronic prescription images consistently updated in the event of a verbal order modification/clarification, addition of handwritten clinical notes etc.

SOPO-Community Section 1.6c and 1.6d

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Non-sterile compounding

- The dispensary must have an appropriate area for Level A compounding in accordance with NLPB's Standards for Pharmacy Compounding of Non-Sterile Preparations. Includes, but not limited to:
  - surfaces that are completely clean and that are not reactive, additive, or absorptive (e.g. glass or stainless steel)
  - prescription balance and calibration weights (no change)
  - quality active pharmaceutical ingredients and inactive ingredients that are from recognized and reliable sources;
  - appropriate packaging materials for compounds;
  - equipment that is necessary to compound preparations of the highest quality

SOPO-Community Section 1.4d and Section 1.5a

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Reference materials

- Mostly unchanged in terms of categories
- Updated examples; reminder that these are examples
- Reference materials may be hardcopy, electronic or online,
  - *When electronic or online references are utilized, there must be policies and procedures in place to ensure that pharmacy staff are familiar with the resources that are available and that they are accessible and available to all pharmacy staff, including relief staff, where and when they need them, when the pharmacy is open for business.*

SOPO-Community Section 1.5a and Appendix C

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Prescription Delivery

- Language adjusted to allow easier application beyond local delivery, notably acceptable “paper trail” when using mail/courier.
- *For each prescription delivered, there must be a record (either physical or electronic) that includes the details necessary to confirm that the prescription was received by the patient, such as:*
  - *the name of the patient or other person to whom the prescription was delivered,*
  - *the name of the delivery person, and/or*
  - *a tracking number with documentation that dispensary staff used to confirm successful delivery to the patient.*
- The patient or agent must be properly identified by the delivery person in accordance with Section 3.8 “Prescription Release”

SOPO-Community Section 2.2

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Automated Equipment

- Policies and procedures must be in place around use of automated equipment including pre-packaging machines, including those related to:
  - determining the appropriateness of medications to be utilized in these machines;
  - how medications are added to the machines, including initial setup, replenishment, and related documentation processes (e.g., the identity of pharmacy personnel involved in each process);
  - calibration and recalibration, and maintenance of the machine (including cleaning) as per manufacturer recommendations, and appropriate documentation of such;
  - the assignment of beyond-use-dates based on established standards;
  - maintaining records of dispensing and packaging for each machine; and
  - the responsibility of the pharmacist-in-charge to review any reports related to the machines to ensure patient safety.

SOPO-Community Section 1.5b

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Conclusion

- All aspects of SOPO-Community require review but not all revisions will require intervention.
- Proactive recognition of deficiencies and development of an action plan is key.
- Reminder: The standards represent a *minimum* standard.
- When in doubt, please ask questions!

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Questions?

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