NEWFOUNDLAND & LABRADOR
PHARMACY BOARD

Practice Check-in:
FAQs & Lessons Learned in Community Pharmacy

March 19, 2024

The Plan

- Review areas of community pharmacy operations and practice that often require adjustments upon review:
  - Documentation
  - Lock and leave/security
  - Non-sterile compounding
  - More
- Share insight on some of the more frequently asked questions in recent months
  - NCD prescriptions/transfers from out of province
  - Prescribing by pharmacists
  - RPT roles and responsibilities
- Time for questions at the end

Lessons from practice site visits

Overview of the site visit process

- Roughly two hours on-site or online with a focus on reviewing the various standards of operation and practice
- Requires completion and submission of the community pharmacy self-assessment, a useful tool for reviewing adherence to standards
- Focus has shifted towards best practices and methods
  - Less about “is this being done?” and more about “how?”
  - Continuous quality improvement.
  - What’s working for you and your team/patients and what’s not?
  - Even if meeting the standards, is there another approach that may work better?
- I will be nice to you!
- You can even ask for one…

Clear documentation of prescription checks

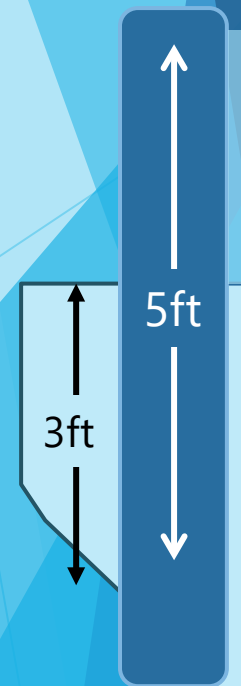
- Each prescription dispensed is required to undergo a:
  - **Therapeutic check**: *Before any dispensed medication is released to a patient, a pharmacist must review the patient's local and provincial electronic health record profiles, and take appropriate action, where applicable, with respect to… (Section 3.7b)*
  - **Packaging check**: *Before any dispensed medication is released to a patient, a pharmacist or pharmacy technician must check the prepared medication and label against the original prescription to ensure that it has been filled correctly… (Section 3.7c)*
- Processes must be in place to ensure both checks occur, with documentation, before any prescription is released
- It must be clear from the hard copy (manual or electronic) who completed each of the checks!

Clear documentation of prescription checks

- Therapeutic check documentation commonly missed when:
  - A manual hardcopy is in use, and
  - An RPT is completing the packaging check;
  - Stated that a pharmacist reviews every prescription but not documented
- **Remember**: self-regulation exists with a focus to protect the public.
  - Would a member of the public feel protected knowing there isn't a record demonstrating a pharmacist checked their prescription?
- Common solutions:
  - Start recording the identity of who provided the clinical check to the manual paper hard copy
  - Add an electronic "Clinical Verification" or "Pharmacist Verification" step to the prescription workflow that occurs before the paper hard copy is generated
  - "Less good" option: Make it impossible for anyone but a pharmacist to input a new prescription or process a refill/first fill request. Define clinical check as occurring here in policy.

Lock and leave requirements

- Lock and leave requirements were updated in the Aug 2022 update of *SOPO-Community*
- Most common non-adherence is lack of separate security zone for dispensary
  - Must be possible to arm/disarm the dispensary independent of other areas
  - Often not required to install a separate panel
  - Only registrant staff may have access to keys and codes to the dispensary
  - Other staff may have access to keys/codes for other areas
- **Barrier**: must be constructed in such a way as to completely separate the dispensary physically and securely from the rest of the pharmacy and be at least 5ft high
  - Ask yourself: What's the highest step/ledge available? Are there counters and shelves that require the barrier to be higher?
  - If you can stand on a 3ft high counter and easily hop over the remaining 2ft high gate, that's not a 5ft barrier!



Assorted security considerations

- **Security Cameras:**
  - Exterior: Consider doors/windows, exterior walls shared by the dispensary
  - Location of narcotic/controlled drug safe, especially if in area off the main dispensary
- Motion sensor testing: Crawl around!
- Ensure security user lists and emergency call processes are up to date:
  - Do you have an active connection?
  - Who will get called if there is an event?
- Entry points, namely counselling rooms attached to dispensary
  - Should be designed to deter entry
  - Consider doors that lock automatically to the outside for full doors such as those belonging to attached counselling rooms.

Non-sterile compounding policies

- Policies and procedures must be in place regarding cleaning and maintenance of non-sterile compounding area/equipment.
- Policies should define *how* the area/room and equipment should be cleaned, and when.
- In some cases more than one cleaning protocol may exist (e.g. after each use versus a weekly/monthly “deep clean”)
- The completion of this cleaning should be documented to a log
  - Does not need to be a unique log
  - May be part of a maintenance log used for other pharmacy operation activities (e.g. combine cleaning log with scale and compounding equipment calibration documentation)
- **Reminder**: carpet remains unsanitary and unacceptable in the compounding area

Non-sterile compounding policies

- Policies and procedures must be in place regarding training or competency evaluation
- **Section 5.2.1:** "All personnel involved in compounding must possess expertise commensurate with their responsibilities."
  - *"before they undertake non-sterile compounding, they must have received the proper orientation, training and a skills assessment concerning their work and the type of compounding to be done."*
- *"What if we only mix creams?"*
  - You still need to demonstrate that the compounder knows what they're doing
  - There are technical and sanitary practices at play (e.g. taring the scale, hygienic best practices when transferring product)
  - It's fair to assume an "entry to practice" skill level for any registered pharmacy professional but checklist can include understanding site-specific policies and procedures

Checklist 1 Skills assessment checklist for compounding process

Name: Position: Date:

Compounding steps	Compliant	Non-compliant
1. Consider whether the compounded preparation prescribed is appropriate and safe for the patient, based on the therapeutic intention (pharmacist).		
2. Determine whether a valid formula exists; if not, develop a Master Formula, in consultation with experts and/or reliable resources. Ensure that the Master Formula includes instructions for special handling considerations.		
3. Calculate and verify the quantities of each ingredient required on the compounding record (pharmacist/pharmacist or pharmacist/pharmacy technician).		
4. Ensure that personnel responsible for compounding are wearing the appropriate personal protective equipment (cap, mask, gloves) and a clean laboratory coat or disposable gown.		
5. For preparations that contain hazardous products, ensure that personnel wear the appropriate personal protective equipment: cap, safety goggles, two pairs of gloves, an N95 mask and face protection, a gown and shoe covers, depending on the substance used.		
6. Ensure that only one preparation is being compounded at a time.		
7. Gather the ingredients and necessary equipment. Ensure that the equipment is ready for use (clean and in good repair).		
8. Measure each ingredient using appropriate equipment in accordance with the compounding record.		
9. Use an independent check to confirm each ingredient and its quantity with the compounding record, before the preparation is compounded.		
10. Ensure that compounding of the preparation is in line with the Master Formulation Record and the prescription, as well as with good practice and pharmacy science (compounding pharmacist/pharmacy technician).		
11. Verify that the labelling complies with requirements of the provincial/ territorial pharmacy regulatory authority:		
a. All active ingredients and the concentration of each ingredient are identified on the label.		
b. The beyond-use date is marked on the label.		
c. The storage information has been added.		
12. Approve, through an independent check, the appearance of the final preparation (clarity, odour, colour, consistency, pH, etc.) and sign the compounding record.		
13. Ensure that the area and equipment are cleaned immediately after use, according to manufacturer's directions or standards, and dried.		
14. Ensure that the products, ingredients and equipment are put away immediately after use for proper storage.		

NCD auditing for internal diversion

- Updated *SOPO-Community* removed defined monitoring processes for internal diversion, however still must be addressed through internal P&P (*SOPO-Community Section 1.8h*)
- Previously prescribed a process of randomly auditing 10% of purchases and sales monthly.
  - The old methods still work!
- Other processes may be acceptable as well:
  - Auditing for internal diversion of purchases: Need to ensure what is received to the perpetual inventory matches the invoice in case there is a discrepancy particularly in scenarios where received inventory may be altered.
  - Auditing for internal diversion of sales: Looking to confirm that prescription sales have a valid prescription attached and that it was input correctly.
- PiCs are responsible to make sure it gets done but can (and should) pass around the responsibility

NCD Reporting – What is a loss?

- Unexplained losses of NCDs must be reported to Health Canada within 10 days with a copy sent to NLPB.
  - Based on the "copies being sent to NLPB", a lot of these are not getting sent in
- Often a misunderstanding as to what Health Canada considers a loss, so….
  - They made a table! (https://www.canada.ca/en/health-canada/services/publications/healthy-living/loss-theft-controlled-substances-precursors/types-incidents.html). Or search "CS-GD-005".
- **"Miscount":** Error made in counting during inventory reconciliation or during dispensing
  - Not reportable: You check the hard copy for a 20 tab Rx and see "30 tabs, double counted, Dave"
  - However: *"If the error is only assumed, then it is reportable as Loss Unexplained"*
- **"Manufacturer's shortage":** The content of a sealed bottle is less than expected after counting

NCD Reporting – What is a loss?

- "Manufacturer's shortage": The content of a sealed bottle is less than expected after counting.
  - Reportable if outside of Health Canada's "Limits of Variability"

TABLE

	Column I	Column II
Item	Labelled Number of Dosage Units Per Package	Permitted Variation from the Labelled Number
1	50 or less	0
2	More than 50, but less than 101	1
3	101 or more	the greater of one unit or 0.75% of the labelled number, rounded up to the next whole number

Pickup documentation

- Relates to *SOPO-Community Section 3.8 – "Prescription release"*
- Stage 1: Is it being done?
  - Are prescription releases being documented per *3.8d - Documentation*:
  - *There must be an auditable record confirming prescription release that includes the date and time the prescription was released and the name of the person to whom it was released.*
  - *Prescription pick-up information must be communicated to the Pharmacy Network at the time the medication is released so that patient medication profiles within the electronic health record are accurate with respect to dispensing history*
- Stage 2: Is it being done accurately/appropriately?
  - Particularly, is the "name of the person to whom it was released" part, correct?
  - Are you obtaining and documenting informed consent?

Counselling documentation

- Is it occurring as required, in a consistent, retrievable manner?
  - Electronic
  - Separate written document
  - To the paper hard copy
- Are all pharmacists following the same process?
- Is there a process to ensure all rxs requiring counselling are flagged for counselling?
  - All new prescriptions
- How are counselling refusals being received and documented?
  - Be mindful of questions such as *"Do you have any questions for the pharmacist?"* in lieu of *"The pharmacist wishes to speak with you on this medication"*

Counselling documentation

- Remember: It's the pharmacist's responsibility to offer counselling.
  - Documentation of refusal means the pharmacist accepted the refusal.
  - Pharmacist should know what was offered/refused; use consistent messaging
- **Scenario**:
  - Pharmacist flags prescription for counselling on pickup as medication appears to be new for the patient.
  - Assistant asks patient on pick-up: *"Is this new for you?"*
  - Patient, who isn't expecting a change: *"No"*
  - Later: Patient calls back asking what this new medication is and why they didn't get what they were expecting

MedSTEP NL

- Please ensure you are reviewing the implementation plan
- **December 31st, 2023:** Review Standards and Resources
  - The PiC as well as pharmacy staff members (including pharmacists, pharmacy technicians, and pharmacy assistants), review and understand NLPB's Standards of Practice for Continuous Quality Improvement (CQI) and Medication Incident Reporting (MIR)
  - PIC starts to develop a pharmacy policies and procedures manual for MedSTEP NL.
- **March 31st, 2024:** Choose a reporting platform and set up an agreement with the National Institute Data Repository (NIDR)!
  - That's 12 days from now!
- **June 30th, 2024**: Train staff new policies and processes
- **July 1st, 2024**: Implementation completion
  - Pharmacy starts reporting medication incidents and near-miss events per standards

MedSTEP NL

CHOOSE A REPORTING PLATFORM TO EXPORT DATA TO THE NATIONAL INCIDENT DATA REPOSITORY (NIDR)	MARCH 31, 2024
PIC reviews and understands MedSTEP NL criteria for a MIR platform.	
PIC either: › subscribes to a MIR platform that meets MedSTEP NL criteria; or › ensures existing or in-house MIR platform meets MedSTEP NL criteria.	
PIC signs and submits a data-sharing agreement with NIDR.	
PIC obtains a Medication Safety Self-Assessment tool included in the chosen reporting platform or from another source.	
PIC completes the pharmacy policies and procedures manual for MedSTEP NL.	
Pharmacy staff, including pharmacists, pharmacy technicians, and pharmacy assistants, review and understand the policies and procedures for MedSTEP NL.	

Compliment sandwich

- There's a lot going well!
- Notably, prescribing/clinical activities:
  - Uptake, diversity in activities
  - Documentation of prescribing
  - Documentation of not prescribing
- Efforts to allow space for focused work:
  - Seeing many pharmacies ensure flex space is available for focused work such as compliance packaging
- Injections services
  - Seeing many best practices implemented to ensure safety across high volumes
  - Methods for ensuring common vaccines are not accidentally interchanged (namely COVID-19 and influenza)
  - Processes to ensure patient is asked their identity and what they are receiving prior to injection

Frequently asked questions

Practice questions

- A new method for documenting practice questions received to NLPB's office was introduced in March 2023
- To date we have logged ~300 questions:
  - ~72% from pharmacists
  - ~7% from RPTs
  - ~7% from members of the public
  - ~10% from "other sources" – jurisdictional scans, corporate policy makers etc
- Common categories:
  - Standards of Pharmacy Operation for Community Pharmacy: 25%
  - Prescribing: 12.5%
  - NCD/TRPP legislation: 12.5%

Out of province NCD prescriptions

- *"Can I take this out of province prescription/transfer for a NCD on the TRPP schedule written by a _____?"*
- Health Canada's Class 56(1) exemption in combination to changes to the NL Governments Pharmaceutical Services act has opened up many options for receiving NCD prescriptions, including those from out of province prescribers.
- These changes permit:
  - Transfers, including those between provinces and those on the TRPP schedule
  - Verbal orders for NCDs including those on the TRPP schedule
  - Extensions/interim supplies by pharmacists, per the associated standards
- Remaining scenarios where a TRPP is still required:
  - New prescriptions faxed directly to the pharmacy
  - New prescriptions given to the patient
  - *If appropriate it may be possible to receive a verbal order in these scenarios

Pharmacist prescribing

- *"Whose name goes on the prescription?"*
  - Regardless of the category of prescribing, the pharmacists name goes on the prescription.
- *"But that might make it look like I'm initiating therapy when it's inappropriate for me to do so?"*
  - Yes. This is one reason you document prescribing activities.
  - You can refer to your documentation that would indicate the original prescriber and prescription.
- *"Are pharmacists able to prescribe for the RSV vaccine?"*
  - Not at this time.
  - The current list of approved preventable diseases is present in *Appendix B* of the *SOPP for the Administration of Drug Therapy by Inhalation or Injection*
  - This is tied to NAPRA drug schedules and *NL Gov's Authorization to Prescribe Regulations* (Schedule B) under the *Pharmacy Act*

Pharmacist prescribing

- *"Is this specific, detailed clinical scenario appropriate for therapeutic substitution?"*
  - Can help you run it through the "Limitations" and "Appropriateness" sections of the standards, however…
  - Someone outside the circle of care, without the clinical knowledge in the area you have, cannot tell you whether you have the information/competency to prescribe in the situation.
- *"But what if something goes wrong?"*
  - Clinical decision making includes balancing anticipated risks with benefits to the patient; one of many reasons we document our clinical decision making.
  - If you don't feel confident, that may be a sign you shouldn't do it
- *"But what if someone doesn't like my decision?"*
  - Talk to them. Other clinicians may challenge your decision making. This is one of many reasons you document your reasoning and evaluate your competency to make the decision.
  - Consider the other side when making your decision and feel free to respond to it in your documentation.

Evolving role of the RPT - Injection services

- Can RPT's provide injection services independent of pharmacist staff?
  - No, "*in situations where a pharmacy technician administers drug therapy, a pharmacist must be present in the pharmacy or other place where the administration is taking place to provide appropriate oversight and/or clinical support*"
- Does this pharmacist need to be authorized to inject?
  - Yes. Per the standards the injection administration is being delegated by the pharmacist
  - You can't delegate an activity you aren't authorized to do yourself
- As a reminder: RPTs must be authorized to inject.
  - CPR/First aid
  - Injection training

Evolving role of the RPT

- Prescription Monitoring Act/Therapeutic check components:
  - While a review of a patients EHR can include technical checks (i.e. how many days has it been since X was dispensed); ultimately clinical decisions are being performed
  - Don't trust DUR to "dur" it for you…
- OAT witnessed dosing and take home dose provision:
  - At their March 2024 meeting, the NLPB board approved new *Standards for the Provision of Opioid Agonist Therapy Medications.*
  - Sections specific to the technical aspects have been broadened to allow for a pharmacist to delegate the actual witnessing of the self-administration of a witnessed dose (Section 6.7 b) or the provision of take-home doses to the patient (Section 6.8 b)
  - Authorization requirements/processes are changing for registrants and pharmacies
    - e.g. the requirement for pharmacists to become "authorized" prior to participating in the provision of OAT has been eliminated

Naloxone

- What do I need to document when purchasing/selling/freely distributing naloxone?
  - Technically, nothing. Though you're free to record purchases and sales if you wish to.
- Who can give out naloxone in the pharmacy?
  - Technically any team member can give out naloxone kits to a member of the public who requests one.
  - However, an opportunity to ask questions/receive training must be provided
  - Training may come from someone other than a pharmacist who has training in the area however clinical questions must be handled by a pharmacist
- If I can get naloxone kits for free can I give them out for free?
  - Yes

In closing…

- Ways to know things:
  - Read the Postscript
  - Read the Apothecary
  - Attend webinars/view old webinars
  - Check the FAQ section on the website
- If you have a question:
  - Please leave a detailed voicemail!
  - Even better, send an email: practicequestions@nlpb.ca
- Feel free to share responses!

QUESTIONS?