Newfoundland and Labrador Pharmacy Board

The Apothecary

Fall 2018

The Apothecary is the newsletter of the Newfoundland & Labrador Pharmacy Board.
It contains information on a wide variety of topics intended to enhance the practice of all pharmacists in the province of Newfoundland & Labrador.
All registrants are responsible for reviewing any and all information contained within including documents which are made available on the NLPB website via links throughout the newsletter.

New Non-Sterile Compounding Standards Approved in Principle - Implementation Information Coming Soon

Earlier this year, the National Association of Pharmacy Regulatory Authorities (NAPRA) released new Model Standards for Pharmacy Compounding of Non-Sterile Preparations with an accompanying Guidance Document. At their meeting in February 2018, the NLPB Board adopted these Standards "in principle" and struck a committee to give direction to the Board on an implementation plan. This committee has been formed and is currently working on the plan. In the meantime, it is important for registrants to understand that these standards are coming, and to begin considering how they will be implemented in NL pharmacies.

What Do These Standards Replace?

These standards replace the former Guidelines to Pharmacy Compounding, approved by the Board in January 2007.

Why Are These Standards Important?

These standards were developed with the intention of increasing patient safety. The documents are designed to provide pharmacists and pharmacy technicians who compound non-sterile preparations with the standards and tools necessary to evaluate their practice, develop service-related procedures, and implement appropriate quality controls for both patients and compounding personnel.

Who Do These Standards Apply To?

The standards apply to ALL pharmacies that perform any type of non-sterile compounding in any quantity (whether once in a while or every day). Health Canada considers compounding to be:

> *"The combining or mixing together of two or more ingredients (of which at least one is a drug or pharmacologically active component) to create a final product in an appropriate form for dosing. It can involve raw materials or the alteration of the form and strength of commercially available products. It can include reformulation to allow for a novel drug delivery. Compounding does not include mixing, reconstituting, or any other manipulation that is performed in accordance with the directions for use on an approved drug's labelling material."*

Remember, in accordance with Health Canada's Policy on Manufacturing and Compounding Drug Products in Canada, pharmacists and pharmacy technicians should ensure they are not compounding a product for which there is already a

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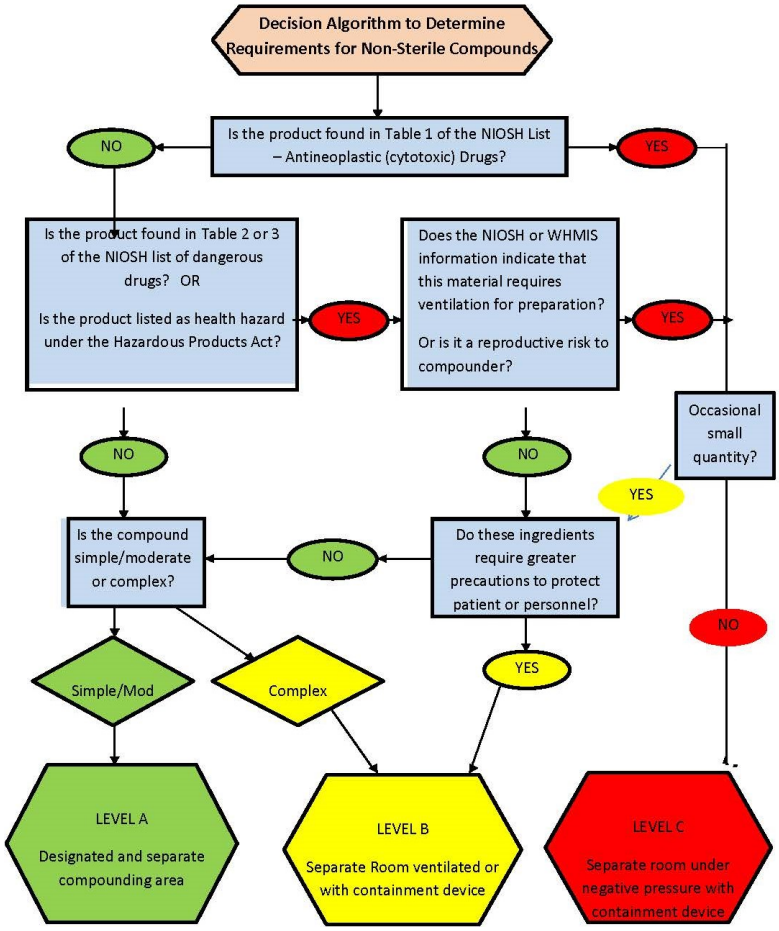
commercially-produced equivalent. To confirm this, before compounding, registrants should check the Health Canada Drug Product Database and contact manufacturers, if necessary.

What Should You Be Doing To Prepare For Implementation?

Even though the final implementation timeline has not been decided, NLPB expects that registrants prepare to implement the standards now; there is no need to wait until the implementation deadline is announced to begin getting your pharmacy ready. Proactive preparation for the standards could include:

- Review and become familiar with the Standards and Guidance documents.
- Use the "Decision Algorithm for Risk Assessment" from the guidance document, shown below, to undertake a risk assessment for each compounding product used in your pharmacy. This will help you to identify the appropriate level of precaution required to minimize contamination and provide adequate protection for personnel.
- Identify gaps between the Standards and your current practice, processes, and compounding environment. The Guidance document can then be used to help you start to work on closing those gaps. For example, review your current policies and procedures, Master Formulation Records, and Safety Data Sheets. Additionally, inventory all compounds that are prepared in the pharmacy and decide whether or not you will continue to compound these products in your pharmacy.
- Look for resources (e.g. education) that are relevant to any gaps in their knowledge or processes.



September 2018 Board Meeting Recap

2019 Budget

Each year, the Board is tasked with creating a balanced budget that includes sufficient resources to support the Board's Strategic Goals and Objectives, and to ensure that the Board meets its regulatory responsibilities as a patients-first regulator. As with all decisions of the Board, much thought and analysis goes into this process, including professional subject matter expertise (such as accounting and legal advice).

The Budget for 2019 includes an increase in the Annual Registration Fees for pharmacists and pharmacy technicians, as well as in the Annual Licensing Fee for pharmacies.

These fee increases are necessary at this time to support several key initiatives such as the further development of the Board's Quality Assurance (QA) Program, including fully operationalizing the QA program in hospital pharmacies, as well as the implementation of a medication safety standard that includes a national error reporting component. Additionally, the public's expectations of pharmacy has and will continue to increase as we move forward with expanding and fully realizing the scope of practice of pharmacists. Finally, during the past number of years, the NLPB has been defending the Board's position and decisions in several civil litigations in the Supreme Court.

As self-regulated health care professionals, pharmacists and pharmacy technicians can expect increases in registration fees throughout your career to support the mandate of your regulator. The NLPB is not a "member"-driven organization. The Board has a duty to regulate pharmacy practice in the public interest and to ensure its programs are fully funded in order to meet its legislated responsibilities.

New Interpretation Guide – Professional Development Requirements for Pharmacists and Pharmacy Technicians

What was formerly the *Standards of Practice - Professional Development for Pharmacists and Pharmacy Technicians* has been converted to an *Interpretation Guide - Professional Development Requirements for Pharmacists and Pharmacy Technicians*. This alignment is intended to clarify the fact that professional development is a registration requirement and a Quality Assurance expectation, rather than an area of practice. While the overall requirements for professional development remain unchanged, the new document:

- is reorganized with legislative requirements and high level concepts defined upfront, followed by a description of what constitutes the Learning Portfolio, and, finally, an overview of the annual audit process;
- includes a section introducing the concept of "Intentional Learning" to support the expectations of the Code of Ethics and the Quality Assurance program goal of continuing competence and quality improvement; and
- contains expanded detail in some sections, while extraneous information was eliminated from others.

The new document is now posted on the Professional Development page of the NLPB website.

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Revised Standards for the Provision of Pharmaceutical Care to Personal Care Homes

Revised *Standards for the Provision of Pharmaceutical Care to Personal Care Homes* were approved by the board at their September meeting. The document is now posted on the Standards, Guidelines, Policies and Positions page of the NLPB website and will come into force on January 1, 2019.

Key points in the Standards include:

- A Policy and Procedure Manual specific to personal care home service must be developed, regularly reviewed and revised, as needed.
- Both Medication Storage and Medication Safety audits must be completed at the personal care home at least once every 6 months.
- Any medication that is not packaged in a unit-dose or multi-dose package must be labelled with FULL instructions for use, as appropriate, including frequency, route of administration, interval and/or maximum daily dose, indication, and specific site of application, if applicable.
- Medication Administration Records (MARs) must be prepared for residents on a monthly basis and delivered to the personal care home for review at least 4 days before the start of the next cycle.
- Staff at the home must be provided with sufficient education, including appropriate printed information, to ensure that they have an understanding of the medications that they are administering to patients.
- A pharmacist must conduct a comprehensive Medication Review for each resident at least annually.

These Standards, along with several other recent and upcoming changes were discussed during the October 15, 2018 Professional Practice Webinar. An archived copy of this, and other NLPB webinars, can be found on the Professional Practice Webinars page of the NLPB website.

New NLPB Online Learning Portal Goes Live

In September of this year, the NLPB launched its own Online Learning Portal. At launch time, this portal included two Standards of Practice Orientation Programs:

- An Orientation to Prescribing by Pharmacists in Newfoundland and Labrador
- An Orientation to the Standards for the Safe and Effective Provision of Opioid Agonist Maintenance Treatment

In the near future, this portal will also include the Pharmacist-in-Charge Orientation Program and the Professional Practice Webinar archives.

To access the portal, visit the NLPB Homepage and click on the Online Learning Portal banner. If you have not already done so, you will be required to create an account. Once your account has been created and approved, click on "Available Courses" to select a program.

Once the program is completed, print your certificate of completion and follow the usual processes to document your learning in your learning portfolio and apply for authorization following the usual processes, if required.

If you have questions about the NLPB Online Learning Portal, please email learn@nlpb.ca.

Complaints & Discipline Learnings

Registrants are advised to review and consider the following recent decision published in the Spring 2018 issue of the Ontario College of Pharmacy publication, *Pharmacy Connection*.

"Close-Up on Complaints" explores incidents reported to the College that have occurred in the provision of patient care and which present learning opportunities. Ideally, pharmacists and pharmacy technicians will be able to identify areas of potential concern within their own practice, and plan and implement measures to help avoid similar incidents from occurring in the future.

A FUNDAMENTAL DUTY TO PUT THE PATIENT'S WELLBEING FIRST

SUMMARY OF THE INCIDENT

This incident occurred when a husband attended the pharmacy on a statutory holiday to fill a hydromorphone 2mg prescription for his wife from a Quebec physician. The patient required the prescription to manage the pain of a broken tibial plateau until she was able to see another doctor at their local hospital. The pharmacist indicated to the patient that he could not dispense the prescription because the prescriber did not write down the patient's health card number on the prescription; he referenced that per Ontario's Narcotic Monitoring System, prescribers are required to record the patient's identification number, such as their health card, on any prescription for a monitored drug.

The patient returned to the hospital and, following a five hour wait, received a new prescription which was dispensed the following day.

WHY DID THIS HAPPEN?

This incident illustrates a lack of compassion for the patient, and an adherence to rules over the wellbeing of the patient.

The pharmacist insisted on rigid observance of the rules and regulations. He did not exhibit empathy for the patient nor did he seem to understand how he could use his professional judgment and discretion to make a decision that would have put the patient's interest first by providing quicker treatment.

COMPLAINT OUTCOME

The College's Inquiries, Complaints & Reports Committee oversees investigations of each complaint the College receives. A committee panel considers a pharmacy professional's conduct, competence and capacity by assessing the facts of each case, reviewing submissions from both the complainant and the professional, and evaluating the available records and documents related to the case.

In this case, the panel noted that the patient was required to wait a significant amount of time, until the next day, for pain relief. While pharmacy professionals must adhere to dispensing rules overall, particularly with respect to narcotic prescriptions, there are accommodations that can be made for particular situations. The pharmacist may not have been able to dispense the entirety of the prescription until certain aspects were verified with the prescriber. However, the panel notes that there are more options besides dispensing in full and not dispensing – for example, he could have dispensed a few tablets to provide pain relief while waiting for verification.

The panel emphasized that pharmacists must first and foremost consider the patient and their wellbeing. There was no reason to believe that the prescription was fraudulent and the pharmacist had information to support the authenticity of the prescription, including the availability of the patient who was in a vehicle outside of the pharmacy. The health card number could have been confirmed verbally or by fax with the physician or the clinic. While the prescription was

ORAL CAUTIONS

An oral caution is issued as a remedial measure for serious matters where a referral to the Discipline Committee would not be appropriate. Oral cautions require the pharmacy professional to meet with the ICRC in person for a face-to-face discussion about their practice and the changes they will make that will help avoid a similar incident from occurring in the future.

REMEDIAL TRAINING (SCERPS)

A SCERP is ordered when a serious care or conduct concern requiring a pharmacist or pharmacy technician to upgrade his or her skills has been identified. The ICRC orders SCERPs when they believe that remediation is necessary.

For all complaints filed after April 1, 2015, the College posts a summary of the oral caution and/or SCERP and its date on the "Find a Pharmacy or Pharmacy Professional" tool.

not written exactly as required by Ontario regulations, the pharmacist could have used his judgment and discretion in how the prescription was confirmed and how identifiers were used, recognizing that the physician was from another province.

Furthermore, the panel felt that the pharmacist displayed no compassion for his patient and, in his communication with the patient and response to the investigation, sought only to protect himself.

Due to the seriousness of the incident and the lack of appropriate patient care provided, the panel ordered that the pharmacist appear in person to receive an oral caution, and that he complete remedial training — a specified continuing education or remediation program (SCERP) – related to ethics.

LEARNINGS FOR PHARMACY PROFESSIONALS

The Code of Ethics clearly articulates the ethical principles and standards which guide the practice of pharmacists and pharmacy technicians in fulfilling the College's mandate to serve and protect the public by putting patients first. The first foundational principle is that pharmacy professionals must actively and positively serve and benefit the patient and society. Specifically, Standard 1.1 states that "members ensure that their primary focus at all times is the well-being and best interests of the patient." This means that pharmacy professionals must maintain the patient's best interests as the core of all activities. They should not place their own interests – or self-preservation – above the patient. Furthermore, pharmacy professionals must be diligent in their efforts to do no harm and, whenever possible, prevent harm, such as unnecessary pain and suffering, from occurring.

Patients seek care because they believe and trust that pharmacy professionals will apply their knowledge, skills and abilities to make them better. Standard 1.2 of the Code of Ethics states that "members utilize their knowledge, skills and judgment to actively make decisions that provide patient-centred care and optimize health outcomes for patients." Pharmacists should, when appropriate, look beyond black and white decision making to ensure they are properly assessing and acting on the big picture – incorporating what they know about the patient, the situation, the medication and any other key factors. When making a decision, documentation is critical, including making a note on the rationale for the decision and how it supports the best possible health outcome for the patient.

CODE OF ETHICS MODULES

- Principle of Beneficence
- Principle of Non-Maleficence

The Standards of Practice are clear that pharmacists must demonstrate a caring, empathetic and professional attitude. They should seek to understand the patient's perspective and communicate with compassion, recognizing that many individuals seeking healthcare are in pain, frightened or vulnerable. A lack of compassion, and tactful communication, can end up making the situation worse.

CONCLUSION

With Ontario's current opioid crisis, there is a significant focus on narcotics and how pharmacies manage and dispense them. Pharmacy professionals must be diligent in how they assess narcotic prescriptions, manage narcotic inventory and dispense narcotics, including respecting laws and regulations. However, due diligence and caution should not interfere with the fundamental duty that a pharmacist or pharmacy technician has as a healthcare professional to put patients and their wellbeing first and foremost. Pharmacists must use their professional judgment to make appropriate decisions in the best interests of their patients.

Professional Practice Webinars

The next Professional Practice webinar is tentatively scheduled for December 11, 2018

⇒ **Topic - To Be Determined**

We aim to have a webinar either the second or third Tuesday of every other month, going live from 9:30 to 10:30 am. Invitations to each webinar go out via email 2-3 weeks before the scheduled date.

If you are not able to join us for the live session, a recording of the event an a copy of the slides are usually posted to the Professional Practice Webinars page of the NLPB website within a week following the event.

Please visit the NLPB website to view recordings of past webinars or to check the dates of upcoming webinars.

Forgot Your Password?

From the login screen, under **Forgot Your Log In/ Password**, enter the email address associated with your profile and click **Retrieve.**

You will receive an email within a few minutes with your user name and password.

Looking for a Receipt?

Did you know you can view and print your invoices and receipts at any time?
Under **My Profile**, click **Renewal/Other Invoices** to see a list of invoices.
Click the invoice number you want to view. You can print it right from your browser by clicking on the printer icon.

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