Newfoundland and Labrador Pharmacy Board

The Apothecary

Fall 2017

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.
The Apothecary is now circulated electronically and is available in hard copy format only upon specific request.

Holiday Hours for NLPB Office

Please note that, in recognition of the Christmas and New Year holiday season, the Board office will be closed from Monday, December 25th through to Monday, January 1st, reopening on Tuesday, January 2, 2018.

If you need assistance during this time, please email inforx@nlpb.ca.

➡ ***SAVE THE DATE*** ⬅

NLPB Symposium 2018

Join us for the 3rd Annual NLPB Symposium, scheduled for **Saturday, May 12, 2018** at the Comfort Inn, St. John's Airport (comfortinnstjohns.com).
Look for more information about the schedule of events and registration in your inbox in the coming months.

Why is Professional Liability Insurance so Important?

During an audit conducted in 2017, the Board identified a number of registrants who inadvertently missed the renewal deadline for their professional liability insurance policies. When balancing a demanding workplace with family commitments, it can be easy to miss what seems like a minor administrative deadline. Unfortunately, professional liability insurance is one administrative deadline that cannot be missed.

The Legal Requirements

Sections 14-17 of the *Pharmacy Act, 2012* and sections 8-9 of the *Pharmacy Regulations, 2014* require all registrants – pharmacists, pharmacy technicians, interns, and students – to maintain a professional liability insurance policy. This policy must be "in a form and amount satisfactory to the board." The Board's specific requirements can be found in the document, *Professional Liability Insurance Requirements for Registration*, available on the Authorization & Registration Information For Registrants page of the NLPB website. Section 94(c) of the Board's Bylaws also includes "practicing pharmacy while not covered by a policy of professional liability insurance acceptable to the board" in the definition of Professional Misconduct.

The Practical Concerns

Having sufficient professional liability insurance coverage is essential to protect both you and your patients. Even the most skilled and diligent practitioners make mistakes from time to time. Consider a hectic day in the pharmacy where there are many distractions and it is difficult to focus, or a question you casually answer for a friend at a party without knowing that person's full medication history. Fortunately, most mistakes are caught before medications go out the door and do not result in harm. But once in a while, the worst case scenario happens and a medication error occurs or patient counselling goes wrong.

When a patient is harmed by a mistake made or advice given by his or her practitioner, that patient may be entitled to damages (a financial award from the practitioner) to compensate for medical expenses incurred as a result of the mistake or lost wages if the patient loses work. In some circumstances, these damage awards can be significant, particularly if a patient requires significant medical care for a long period of time, or is unable to return to work in his or her previous career. The patient may also be entitled to additional damages for pain and suffering, which are generally granted by a court to the patient suffering as a result of the mistake. If a patient dies after a medication error, his or her family may also be entitled to cost recovery for expenses and damages.

Having an active professional liability insurance policy helps ensure that your patient will get the support and resources he or she needs to prevent any further undue suffering after a mistake has occurred. It is your professional liability insurance that pays the damages awarded to the patient, and generally also pays for a lawyer to handle any court matters. You will likely have only minimal involvement in the legal and financial processes, which greatly reduces the stress on both you and your employer.

However, if you do not have an active professional liability insurance policy when such a mistake occurs, you may be held personally liable for any financial damages that result from the mistake. This means that you may be personally responsible for paying your patient's related medical bills for the rest of his or her life, compensating for his or her lost wages, and paying for lawyers to handle the court matters. If you don't have the finances in your bank account to pay these bills, you may lose your investments, vehicles, or even

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your home. In addition, the pharmacy you work for may also be held liable for damages that result from your mistake. In the worst case, your injured patient may suffer even further if you do not have appropriate insurance and you or your pharmacy cannot cover the cost of the damages they are entitled to.

What Can I Do To Make Sure This Doesn't Happen To Me or My Patients?

- Set a recurring reminder in your calendar for one month before your policy expires to make sure you remember to renew on time.
- Do not rely solely on reminders from your insurer or the Board – we all know e-mails sometimes get lost, missed, or sent to junk mail. While reminders are a helpful trigger, ensuring your policy is up to date is your responsibility and relying on another organization to remind you might not be enough to protect you or your patients.
- Ask your administrative support person to put it in his or her calendar (but again, don't rely 100% on someone else to remind you).
- Add professional liability insurance status to your Staff Meeting standing agenda and check in with your whole staff on a regular basis to make sure no one misses their policy renewal date.
- If you do miss your renewal date, contact your insurer immediately upon discovering the lapse and make sure that they back-date your renewal to the day your policy expired.

Self-Declarations - Are Yours Accurate and Up-to-Date?

As part of the annual registration renewal process, all registrants are required to respond to a number of self-declarations. Self-declarations are a way for the Board to monitor registrant compliance with the legislation and standards without requiring registrants to submit evidence of compliance every year. In order to balance the efficiency of self-declarations with accountability, the Board conducts compliance audits of self-declarations.

Self-declarations are required by all registrants, as well as those in the role of pharmacist-in-charge, and those with additional authorizations. It is important to remember that when you make a self-declaration, you are not only declaring that it is correct at the time of renewal, but also that it will remain correct throughout the year. For example, when you declare your CPR training is up to date, you are not only declaring that it is current on the date of renewal, but also that you will maintain it throughout the up-coming year.

This year the Board is aware of several registrants who have lapsed in various self-declarations including maintaining professional liability insurance, maintaining PANL membership, having current CPR and First Aid training, hours worked at the pharmacy as pharmacist-in-charge, and others. Providing false information in the self-declaration process or lapsing in maintenance throughout the year can result in allegations of professional misconduct or temporary loss of the certificate to practice pharmacy or engage in expanded scopes of practice.

In order to ensure that your self-declarations are accurate and up to date, remember the following:

- Each registrant is required to complete his or her own self-declarations. This activity cannot be passed on to another individual such as a co-worker or assistant.
- Track the expiry dates of your policies, memberships, and certificates.
- Set reminders of expiry dates that will jog your memory well in advance.
- Review your self-declarations throughout the year to ensure they are still valid.

Drug Information Resources for Opioid Dependence Treatment

It's been almost a year since buprenorphine-naloxone (Suboxone®) became an open benefit under the NL Prescription Drug Program (NLPDP), with the goal of increasing access to treatment options available to those affected by opioid use disorder. Currently, while 370 NL pharmacists (of a total of 741) participate in opioid dependence treatment (ODT) services, only 57 community pharmacies offer this service to the public (about 25% of pharmacies in the province). Furthermore, these numbers can be misleading as they do not reflect the number of pharmacies that are currently accepting new patients. In light of the opioid crisis, there is an increasing demand for pharmacies to offer ODT services. Pharmacists play a key role in provision of addiction services that goes beyond the dispensing of medication; pharmacists interact with patients on a daily basis and are often key supports to patients throughout their recovery. The purpose of this article is to share some of the resources available to assist pharmacists in helping patients with opioid use disorder.

Recognizing inappropriate or inadequate pain treatment

In 2017, a new **Canadian Guideline for Opioids for Chronic Non-Cancer Pain** was developed at the National Pain Centre at McMaster University. This guideline is useful for assessing patients' opioid use as well as for forming recommendations on dose optimization, rotation, tapering and special patient populations.

Assessing symptoms of opioid withdrawal

Pharmacists are familiar with providing drug information when counselling patients about opioid prescriptions; however, it can be difficult for pharmacists to assess pain and opioid withdrawal when following up with patients. A **study of a pharmacist-physician team model in Alberta** illustrates the impact pharmacists can have in the assessment and management of pain (Slipp and Burnham, 2017).

To assess the control of pain related to treatment with opioids, pharmacists can start by asking patients to rank their pain level from 0 to 10. In addition, a tool called **SAFER-OPIOIDS** (Murphy et al., 2013) provides a more comprehensive assessment of opioid use that may be helpful when completing patient assessments.

A useful tool to assess withdrawal is the **Clinical Opiate Withdrawal Scale (COWS)**. This tool is often used to assess withdrawal from opioids during buprenorphine-naloxone induction, but it can be useful to quickly assess and review opioid withdrawal symptoms under other circumstances as well, such as when following up with patients who are tapering to lower doses of opioids.

Methadone vs. buprenorphine-naloxone

Patients may have questions about the differences between methadone and buprenorphine, such as, which is more effective or which is easier to discontinue. An **article** by Srivastava et al. (2017) may be helpful in answering these questions as it provides an overview of treatment options for specific patient populations. In addition, Table 2 in **A Guideline for the Clinical Management of Opioid Use Disorder** (BC Centre for Substance Use, 2017) provides a concise summary of the advantages and disadvantages of both methadone and buprenorphine-naloxone.

Buprenorphine-naloxone administration

Buprenorphine-naloxone administration can be time-consuming, especially for higher doses, because it can take the buccal tablets up to 10 minutes to dissolve. The purpose of witnessed dosing is to ensure that patients are getting the full benefit of the medication as well as to prevent diversion. However, the extent of diversion and use of illicit buprenorphine is not fully characterized (Yokell et al., 2011) and data on the benefits of supervised dosing versus unsupervised is also mixed (Saulle et al., 2017).

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The **Buprenorphine/Naloxone for Opioid Dependence: Clinical Practice Guideline** (CAMH, 2012) provides guidance for administration of sublingual buprenorphine-naloxone, including:

- For patients with dry mouth, give some water to moisten mouth prior to administering tablets.
- For sublingual tablets that are supplied by the manufacturer in blister packages, remove the tablet from foil, but do not touch the tablet (skin contact to be avoided).
- For higher doses, tablets may be cut into half or quarters to reduce dissolution time, and then placed in clear plastic dispensing cup. Do not grind or crush tablets as they may coalesce into a single mass with a reduced surface area thereby reducing dissolution.
- Ask patient to place contents of cup under the tongue, and not to suck on tablets while they are dissolving.
- Suggest that patients keep their head tilted slightly forward to reduce saliva collecting at the throat and being swallowed.
- After approximately 1 minute, ask patient to show oral cavity for dissolution. A chalky residue may remain even after drug has been sufficiently absorbed.
- Advise patient to refrain from drinking fluids and eating for approximately 5 minutes to allow for sublingual absorption to be maximized.

Off-label use of buprenorphine-naloxone

The official approved use for buprenorphine-naloxone is to treat opioid dependence. The transdermal formulation of single entity buprenorphine is indicated to treat pain, but there is less literature for the sublingual form that is combined with naloxone. **Buprenorphine for Chronic Pain: A Review of the Clinical Effectiveness** (CADTH, 2017) provides a focused summary of the clinical effectiveness of buprenorphine for chronic pain, which may help with assessing the appropriateness of buprenorphine-naloxone prescriptions. An **article** by Chen, Chen, & Mao (2014) also discusses the role of buprenorphine-naloxone in pain management.

In addition, you may see buprenorphine-naloxone used for withdrawal management as well as for rotation and tapering of opioids. For further reading, see this **Cochrane Review**.

Both these off-label uses are also discussed in the new McMaster chronic non-cancer pain guidelines.

Learning opportunities

To build on knowledge about opioid use disorder and opioid agonist maintenance treatments, pharmacists may be interested in:

- The BC Centre on Substance Use (BCCSU) **Online Addition Medicine Diploma Program**
- Training programs provided by the manufacturer of Suboxone®; a 6-hr self-guided program and a 1-hr video review are available at **www.suboxonetrainingprogram.ca**
- The **Opioid Dependence Treatment Core Course**
- **Buprenorphine-Assisted Treatment of Opioid Dependence: An Online Course for Front-Line Clinicians**

There is an abundance of information available about this important pharmacy practice topic. This article is not intended to be fully comprehensive. If you have further questions about this or any other clinical issue, feel free to contact the Drug Information Centre at the School of Pharmacy - a free service for all your medication and treatment related questions.

Submitted by: Mike Chong, Memorial University Drug Information Centre
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Full reference list available upon request

PostScript Recap

Throughout the year, the NLPB publishes a number of important pharmacy practice-related articles in both The Apothecary and the monthly e-newsletter, The PostScript. Below are a few particularly relevant articles that were published in The PostScript over the past year. Please visit the **NLPB Newsletters** page of the NLPB website to view all past issues in their entirety. For answers to more Pharmacy Practice questions like this one, see the **Frequently-Asked Questions About Pharmacy Practice** page of the website.

Is an Electronic Signature on a Prescription Acceptable?

No, not at the moment. The Board supports the concept of e-prescribing, but at this time, requirements for securing patient confidentiality, verifying authenticity, and preventing diversion have not been defined.

A prescription generated via a prescriber's computer system or PDA and physically given to a patient for eventual processing at a pharmacy must comply with the federal regulations regarding prescriptions and must include a valid signature. Rubber stamps, pre-signed forms, signature images or other forms of signatures that are not distinct for each transaction do not fulfill federal requirements. A pharmacist considering a prescription with one of these forms of signature cannot confirm that this is the one and only copy of the order (as identical copies of the order could have been produced by photocopy). To ensure that the prescription document presented by the patient is the original copy of the order written by the prescriber, the signature must be original.

A prescription generated via a prescriber's computer system or PDA and faxed directly to a pharmacy for processing must comply with the NLPB Standards of Practice – Facsimile Transmission of Prescriptions and Personal Health Information. As with above, electronic "digitalized" signatures are not permitted since they are not distinct for each transaction. When prescriptions are transmitted by fax directly between a prescriber and a pharmacy, the prescription must still be manually signed prior to transmitting the prescription.

At this time, prescription authorization via email has not been approved by Health Canada.

Ethical Decision-Making: Putting Patients' Interests First

Recently, the NLPB has been alerted to several instances where pharmacists have acted inappropriately when faced with a prescription where the quantity prescribed was less than the full package size of the product. We have heard of situations where the pharmacist has refused to fill the prescription, falsely indicated to the patient that the product was back-ordered, contacted the original prescriber to revise the prescription, or adapted the prescription so that the quantity dispensed matched the package size.

Pharmacists are reminded that, as health care professionals, first and foremost, they are expected to place the health and well-being of their patients at the centre of their professional practice. Making clinical decisions or advising practitioners or patients based on business interests or financial benefit is a

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direct violation of the Code of Ethics. Additionally, the Standards of Practice – Prescribing by Pharmacists specifically states:

- Prescribing decisions must be based on clinical suitability, cost-effectiveness and what is in the best interests of the patient. Prescribing decisions based on biased information or financial advantage may be regarded as constituting conduct deserving of sanction. (section 5.1 b) iv));
- A pharmacist may change the quantity of medication prescribed as long as doing so will not result in the patient receiving drug therapy for longer than the prescriber intended. (section 5.6 a) ii)); and
- The pharmacist must be reasonably satisfied that the original prescriber would not object to the adaptation (section 5.6 b) ii)).

Finally, in any situation where a prescription is adapted, pharmacists are also expected to:

- obtain informed consent from the patient;
- send notification describing the action taken to the original prescriber within one week; and
- provide a copy of the documentation to the patient for their records.

The Sale of Exempted Codeine Products in Community Pharmacies

In light of recent questions and discussions during practice site assessments, registrants are reminded that as per Section 3.1 of the *Standard of Practice for the Sale of Exempted Codeine Products in Community Pharmacies*, only a pharmacist may authorize the sale of an exempted-codeine product (ECP). Prior to authorizing the sale of an ECP, the pharmacist must personally consult with the patient to determine the appropriateness of the request. It is important that the patient assessment includes obtaining a complete medication history and checking the patient's Pharmacy Network profile. Patient assessments related to an ECP request cannot be delegated to any other member of the pharmacy team.

After assessing the patient, the onus is on the pharmacist to refuse the sale of an ECP, and refer the patient to another health care provider, if it is determined that:

- the condition or symptom(s) are chronic or serious in nature;
- the ECP will inadequately treat the medical or dental reason for use; or
- continued use of ECPs is not in the best interests of the patient.

If the sale of an ECP is authorized by the pharmacist, it must be fully documented in the patient's medication profile, and the electronic health record via the Pharmacy Network, in accordance with section 3.5 of the *Standards of Pharmacy Operation-Community Pharmacy*. It is critical that provision of an ECP to a patient is recorded accurately in the electronic health record using the patient's MCP number so that other health professionals involved in the patient's care can make informed decisions about the care they are providing.

Finally, while section 3.8 of the *Standards of Pharmacy Operation-Community Pharmacy* requires pharmacists to provide education and counselling to patients only on the original filling of a prescription, due to the issues associated with the inappropriate use of ECPs, pharmacists are expected to consult with and counsel patients on each and every sale of an ECP.

Professional Practice Webinars

Since June, the NLPB has delivered three webinars on several Professional Practice topics:

⇒ June 13, 2017 – Standards 101 – Security & Accountability of Narcotics & Controlled Drugs

⇒ August 8, 2017 – Current Issues – Buprenorphine-Naloxone for the Treatment of Opioid Dependence

⇒ October 10, 2017 – Frequently-Asked Questions – Professional Development Standards and Online Portal

Please visit the **Professional Practice Webinars** page of the NLPB website to view recordings of these webinars.

We have received very positive feedback on the webinars and intend to continue to deliver them in 2018, starting on January 16th and continuing on either the second or third Tuesday of every other month going forward. On the day of the webinar, we will go live from 9:00 to 10:00 am. If you are not able to join us for the live session, a recording of the event will be posted to the website shortly thereafter. We continue to welcome any feedback you may have on these or any other NLPB communications.

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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