NEWFOUNDLAND & LABRADOR PHARMACY BOARD

THE APOTHECARY NEWSLETTER

FALL 2020 - nlpb.ca

IN THIS ISSUE:

- MESSAGE FROM THE REGISTRAR
- BOARD MEMBER ELECTION RESULTS
- BOARD MEETING UPDATES
- COMPLAINTS AND DISCIPLINE SUMMARY
- QUALITY ASSURANCE PROGRAM UPDATE

The official newsletter of the Newfoundland & Labrador Pharmacy Board.

Registrants are responsible for reviewing all information within this publication.

@NLPHARMACYBOARD

Welcome to the Fall 2020 edition of The Apothecary! Please read all of the content in this issue. If you have any questions or comments please email inforx@nlpb.ca

MESSAGE FROM THE REGISTRAR

Can the COVID crisis spark positive change in health care?

Without a doubt COVID-19 has taken, and continues to take, a huge toll on our health care system, and while it has been a most disruptive and unwelcome force, the pharmacy profession has risen to the challenge and, in collaboration with other health professions, has contributed to meaningful change.

Collectively our health system has responded swiftly to the pandemic. New strategies have been conceived, new policies created, new solutions developed - all implemented in a short period of time during a rapidly evolving public health crisis.

Federal and provincial regulation changes that would normally have taken years - with long decision-making processes - occurred in matter of weeks, and the adoption of technology and virtual care models triggered by necessity have changed the way patients interact with the health care system. How these and other changes are maintained will have lasting impacts on health care post-pandemic .

When the dust settles, NLPB will be taking time to reflect and review the 2020-2022 Strategic Plan through the lens of this new world we find ourselves in. Is this a window of opportunity to accelerate the changes needed in health care? How will the profession respond to the opportunity? How will the role of the regulator change? There are just so many questions.

One thing that the COVID crisis has shown is that even with all the advancements and change, **people remain the most critical element of the health care system.** As we navigate through this pandemic, please continue to look after yourselves. You are essential.

Kind regards,

Margot Liddle

Reminder

Registrants are reminded that NLPB continues to maintain a COVID-19 Guidance for Pharmacy Professionals page on our website.

This page is regularly reviewed and updated as the situation evolves throughout the pandemic.

While the NLPB office continues to be closed to the public, staff continue to work to support both registrants and the public. Please contact staff as you would regularly do so, or email inforx@nlpb.ca if you have questions.

BOARD MEMBER ELECTIONS 2020

While initially delayed due to the pandemic, board member elections took place over the summer of 2020 with the following registrants being elected to the board:

ZONE 5: Nicole MacDonald

ZONE 6: Jillian Thorne

ZONE 7: Tim Buchanan and Taggarty Norris

This fall, the Minister of Health and Community Services also reappointed Gerri Thompson and appointed Christopher Smith to the board as government-appointed public representatives.

NLPB would like to thank out-going board members Ruby Chaytor, Brittany Churchill, Chad Parsons, and Colleen Squires for their service to the NLPB and the pharmacy profession.

NLPB EXECUTIVE 2020-21

CHAIR
Gerri Thompson

VICE CHAIR
Taggarty Norris

EXECUTIVE MEMBER
Henry White

PAST CHAIR
Colleen Squires *(ex officio)*

NLPB BOARD 2020-21

ELECTED MEMBERS

Zone 1 Pharmacist
Keith Bailey

Zone 2 Pharmacist
Jason Ryan

Zone 3 Pharmacist
Jennifer Godsell

Zone 4 Pharmacist
Henry White

Zone 5 Hospital Pharmacist
Nicole MacDonald

Zone 6 Pharmacy Technician
Jillian Thorne

Zone 7 At Large Pharmacists
Tim Buchanan
Taggarty Norris

PUBLIC REPRESENTATIVES

Board Appointed
Shirlene Murphy
Mark Sheppard
Government Appointed
Christopher Smith
Gerri Thompson

DEAN, MEMORIAL UNIVERSITY SCHOOL OF PHARMACY

Shawn Bugden

Board Meetings Update 2020

This year, the NLPB board had to quickly adapt to working virtually to achieve its goals. This was key to the NLPB's success in providing support to registrants throughout 2020. In addition to the numerous practice changes posted on the COVID COVID-19 Guidance for Pharmacy Professionals page of the website, highlights from this year's meetings include the following:

February 2020

- By-law amendments were made in relation to:
  - the nomination procedures for Board elections
  - the information that is collected in relation to pharmacy ownership in the province

  For more information on these by-law changes, see the Winter 2020 issue of *The Apothecary*.
- The board approved new *Standards for the Provision of Pharmaceutical Care to Long-Term Care Facilities*. This document is complementary to existing Standards of Practice for personal care homes. The long-term care standards were approved with a delayed implementation date of July 1, 2021 to allow pharmacists-in-charge time to work through the complex issues related to delivering this service, and for NLPB to create awareness and support the implementation of the standards.

August 2020

- Revisions were made to the NLPB *Code of Ethics for Pharmacists and Pharmacy Technicians* following an internal and jurisdictional review. In this revision, a number of the "Guidelines for Application" have been either revised or relocated within the document. It is intended that these changes will fill a number of noted gaps as well as clarify sections that have been identified as confusing or ambiguous.
- The *Standards of Practice regarding the Facsimile Transmission of Prescriptions and Personal Health Information* were also revised for currency and relevancy to practice. Additionally, the following two sections were deleted:
  - The requirement that registrants confirm ALL faxed prescriptions for drugs subject to the Tamper Resistant Prescription Drug Pad Program; requiring instead that registrants use their professional judgement to authenticate and validate prescriptions as they determine is appropriate.
  - The requirement for "Signed certification that the prescription represents the original of the prescription, the addressee is the only intended recipient and there are no others, and the original prescription will be invalidated or retained so that it cannot be re-issued."

October 2020

- The *Standards for the Provision of Compliance Packages* were revised to:
  - include more detail in the "Patient Assessment" section, including clarifying what information should be discussed with the patient prior to initiating the service
  - include more detail on the package labelling requirements
  - separate the counselling expectations when the patient is picking up the packages from the earlier pre-service discussion
  - clarify the roles of pharmacists and pharmacy technicians in the service, including details regarding the clinical check vs. the final "packaging check"
- New *Guidance for the Dispensing and Administration of Buprenorphine Extended-Release Injection (Sublocade®)* was approved. This guidance document is supplementary to both the NLPB's OAMT Standards and Injection Standards.

Please visit the NLPB website to view these and other pieces of legislation, Standards of Practice, Guidelines, and Policies.

Complaints and Discipline Summary 2019-20

Failing to assess prescription for appropriateness, and problematic pharmacy workflow

A pharmacy received a prescription for metoclopramide hydrochloride, 10 ml per dose, three times per day, for three days. Although it was not noted on the prescription, the patient was a child weighing 22 pounds. The prescription was accepted by an assistant, input by one pharmacist, prepared by an assistant, and the clinical verification was performed by another pharmacist. Neither the registered or non-registered pharmacy staff members questioned or obtained the patient's weight, and the prescription was filled as it was written - for ten times the maximum dose for a patient of that weight. The prescription was also not flagged for counselling, no counselling was provided at the time of pick-up, and no reason was documented for not providing counselling. After taking the second dose of the medication, the pediatric patient fell into a paralyzed state with extrapyramidal symptoms.

The two pharmacists involved, as well as the pharmacist-in-charge, all agreed that a medication error had occurred, and that there were breakdowns at several stages in the dispensing process. The Complaints Authorization Committee ("Committee") found that there were reasonable grounds to believe that sections 3.1, 3.4, 3.5, and 3.8 of the *Standards of Pharmacy Operation – Community Pharmacy* ("SOPO-Community") were breached during the dispensing process. The medication profile was not properly updated or reviewed, in particular with the weight of the patient, and the prescription was not flagged for counselling. The two pharmacist respondents were counselled as follows:

a. Remember the importance of identifying the patient and all relevant information about them upon intake to ensure that the appropriate medication and dose is determined
b. Look at the patient as a whole and not just the prescription itself
c. Ensure that counselling happens for all new prescriptions

The Committee also found that there were reasonable grounds to believe that the pharmacist-in-charge breached sections 12(e) and (p) of the *Pharmacy Regulations, 2014* by failing to enforce and ensure compliance of the staff with the Standards. The pharmacist-in-charge was counselled to ensure that legislation and standards applicable to pharmacy professionals, as well as processes and policies established to enable and ensure compliance with the legislation and standards, are understood and followed by all staff.

LESSONS LEARNED

⇒ Lack of clear policies and procedures for safe dispensing, and breakdowns in the dispensing process can lead to significant patient harm - pharmacy professionals must be mindful of this in the busy-ness of their daily practice.

⇒ Section 3 of both Standards of Pharmacy Operation outline practice requirements and professional roles and responsibilities. A number of these professional responsibilities were not met in the medication error case described above - relevant patient information was not collected to support clinical verification of dose appropriateness and patient counselling was not provided.

⇒ Patients must be counselled on all new medications and pharmacists are expected to gauge the need for follow-up counselling on refill medications by asking questions regarding changes to dosage regimens, compliance, efficacy, and the presence of adverse effects.

⇒ All counselling must be documented. If a patient refuses counselling, this should also be documented in the patient record.

⇒ Pharmacists-in-charge (PICs) are expected to have processes in place for appropriately managing medication errors, including documentation of the error, disclosure to patients and follow-up, root-cause analysis, and implementation of error prevention measures. PICs should support safety culture within the workplace and take a systematic approach to assessing what may have led to a medication incident. Additionally, making an error can be very traumatic for a pharmacy professional. Supports should be in place to assist the professionals involved.

Complaints and Discipline Summary 2019-20

Missed PANL membership and breach of an undertaking

An allegation was filed by the Registrar when a registrant failed to renew membership with the Pharmacists' Association of NL ("PANL"), and by doing so, breached a previously signed undertaking in which she promised to "comply with all requirements for registration with the Board." The Complaints Authorization Committee ("Committee") determined that there were reasonable grounds to believe that conduct deserving of sanction had occurred, and cautioned the registrant for the conduct. In issuing the caution, the Committee advised the registrant that due to the repeat nature of the matter, if another allegation were to be filed in the future a caution would not likely be sufficient to address the matter.

Breaching an undertaking and failing to respond appropriately to NLPB communications

On December 19, 2019, a hearing of the Adjudication Tribunal of the NLPB was held in the matter of a complaint against a pharmacist registrant ("respondent"). Following the hearing, the Adjudication Tribunal issued a decision finding the respondent guilty of breaching an undertaking given to the NLPB and of failing to respond appropriately and within a reasonable period of time to written inquiries from the NLPB. On August 24, 2020, the Adjudication Tribunal reconvened to hear submissions on the appropriate sanctions.

The complaint originated when NLPB received information that the respondent had not renewed his PANL membership as required in April 2019. Two years prior, the respondent had also failed to maintain his PANL membership and had resolved the resulting complaint by signing an Undertaking stating that he would ensure that he kept up all registration requirements in the future. The NLPB wrote to the respondent in May of 2019 about the alleged breach of his Undertaking and requested a response. In the months following this initial correspondence, two subsequent written inquiries and a telephone call were made to the respondent on the matter. The respondent did not respond to any of the NLPB's inquiries until August of 2019 when the NLPB notified the respondent that the matter was moving forward in the complaints and discipline process. It was subsequently confirmed that the respondent did not renew his PANL membership until more than two months after it expired.

The Adjudication Tribunal determined that the respondent had breached his Undertaking and had not responded appropriately and within a reasonable period of time to written inquiries from the NLPB, and thus found him guilty of breaching sections 85(o) and (p) of the *NLPB By-Laws*.

The respondent had four prior infractions on his disciplinary record in the previous eight years for matters relating to compliance with NLPB administrative requirements, including completing required continuing education and maintaining his PANL membership. The Adjudication Tribunal stated the following with respect to the respondent's conduct:

> *While no patient or individual was adversely affected by the respondent's conduct, the troubling nature of his offences and the gravity associated with them relate to the lack of respect shown toward the regulatory body. The significance that such conduct has is with respect to the public image of the profession and the public confidence in the profession, and the ability of the regulator to effectively regulate in the public interest is threatened if actions such as those taken by the respondent are not the subject of a regulatory response.*

The Adjudication Tribunal stated that "undertakings are not just pieces of paper…if an undertaking is breached it is something that has to be dealt with by the regulator or it would be allowing its ability to govern to be compromised."

Since the incidents occurred, the respondent had retired from practice. The Adjudication Tribunal considered that the respondent was a mature member of the profession whose behaviour could not be accounted for by inexperience or immaturity, and the offences had occurred over a period of time during which the respondent showed no remorse or understanding that he had acted inappropriately. Although some personal stressors in the respondent's life were considered somewhat mitigating, his history with the NLPB demonstrated his lack of respect

Complaints and Discipline Summary 2019-20

towards the NLPB and an unwillingness to follow requirements over a period of time. The need to maintain public confidence in the integrity of the profession was an obvious consideration. The Adjudication Tribunal ordered the following:

a. The respondent be reprimanded;
b. The respondent pay a fine of $3,000.00
c. The respondent pay the cost of a one day hearing;
d. Prior to re-entering into the profession the respondent complete at his own cost an ethics course as prescribed by the board as well as the continuing education requirements for each year that he is out of practice and that he meet any other requirements for re-entry that may exist at the time he re-enters the profession; and
e. To assist with general deterrence a summary of the decision and the sanctions shall be published on a no-name basis in The Apothecary.

LESSONS LEARNED

⇒ Under s. 21, 3(a) of the *Pharmacy Act, 2012*, pharmacists are required to be members of PANL as a condition of their registration certificate, which means that if a pharmacist does not maintain PANL membership the validity of their registration is questionable. Therefore, NLPB is compelled to address situations where a pharmacist is found to have not met this condition of provincial legislation.

⇒ Undertakings may be used in situations where a registrant is found to have not fully met regulatory requirements; the registrant acknowledges their professional misstep and agrees to ensure it does not happen again.

⇒ An undertaking is a legal agreement between a registrant and the NLPB. Registrants should be aware that breaches of undertakings result in escalated disciplinary processes so that NLPB meets the responsibility to effectively govern the pharmacy profession.

Self-prescribing and self-dispensing

An allegation was filed by a pharmacist-in-charge that a pharmacist employee had prescribed and dispensed medications to himself. The matter was referred to the Complaints Authorization Committee ("Committee").

With respect to self-prescribing, the registrant acknowledged actions which the Committee found created reasonable grounds to believe that he had self-prescribed medications on several occasions, as well as extended prescriptions for himself, omitted completion of the required documentation at the time of his prescriptions for himself, and adapted prescriptions for himself by changing the dispense quantity prior to submitting to his insurer. The Committee found that there were reasonable grounds to believe that these actions amounted to conduct deserving of sanction based primarily on section 3 of the *Standards of Practice – Prescribing by Pharmacists* ("Prescribing Standards"), which states that "a pharmacist may not prescribe for themselves," as well as based on documentation requirements of the Prescribing Standards, sections 85(a), (e), (i), and (k) of the NLPB *By-Laws*, and sections 6.1 and 6.3 of the *Code of Ethics*.

The Committee issued a caution to the registrant. He was warned not to self-prescribe in the future and to reflect seriously on the provisions of the Prescribing Standards and the Code of Ethics, considering how his actions and decisions as a pharmacist reflect on the profession as a whole and the trust that the public places in the profession.

With respect to self-dispensing, the registrant acknowledged doing so with the intention of protecting his privacy. The Committee determined that where a legitimate prescription was in place, there were no reasonable grounds to believe that the registrant had engaged in conduct deserving of sanction by dispensing his own medication and dismissed this portion of the allegation. The Committee did, however, direct the registrant to review section 2.6 of the *Code* of Ethics and to avoid self-dispensing medication whenever possible.

Complaints and Discipline Summary 2019-20

Self-prescribing and failing to follow Tamper Resistant Drug Pad ("TRPP") Program rules

An allegation was filed by a registrant when he became aware that, on three occasions, another registrant had provided herself an interim supply of a drug that was required to be written on a TRPP. These actions were in violation of section 3 of the *NLPB Standards of Practice–Prescribing by Pharmacists* ("Prescribing Standards") and section 2.6 of the *Code of Ethics*.

The registrant acknowledged her breach of the Standards and Code of Ethics, and the matter proceeded through alternate dispute resolution. A Settlement Agreement in the matter was reached. The Registrar, the reporting registrant, and the registrant in breach agreed to the following disposition of the Allegation:

a. The registrant is reprimanded for her admitted conduct deserving of sanction.
b. The registrant will abide by the requirements of the following documents and will provide a signed undertaking confirming that she has read and understands each one:
   - *Pharmacy Act, 2012*
   - *Standards of Pharmacy Operation – Community Pharmacy*
   - *Standards of Practice–Prescribing by Pharmacists*
   - *Code of Ethics*
   - *Pharmaceutical Services Act*
   - *Pharmaceutical Services Regulations*
   - *List of Drugs Covered By The Tamper-Resistant Prescription Drug Pad Program*
c. The registrant will recomplete the *Orientation to Prescribing By Pharmacists in Newfoundland and Labrador* course.
d. The registrant will not serve as pharmacist-in-charge or a preceptor for a period of one year.
e. The registrant will pay a contribution towards the costs of the NLPB's involvement in the allegation.
f. A copy of the Settlement Agreement will be placed in the registrant's file and will be noted on any requests for a Letter Standing from the NLPB.

LESSONS LEARNED

⇒ In accordance with the NLPB Code of Ethics, pharmacy professionals are expected to avoid providing pharmacy services to themselves and immediate family members, unless the care is related to a minor condition or emergency circumstances exist.

⇒ Registrants should reflect on the appropriateness of providing care to any individual with whom they have a close relationship as the ability to make unbiased professional decisions may be compromised as this could be considered a conflict of interest.

⇒ Section 3.d) of the Prescribing Standards directly prohibits pharmacists from prescribing for themselves (this applies to all categories of prescribing, including interim supply, extension, and adaptation).

⇒ Under federal legislation, pharmacists are not permitted to prescribe controlled substances (including narcotics, controlled drugs, and targeted substances), except under a specific exemption issued by Health Canada, such as in the case of the COVID-19 pandemic. In these cases, pharmacists must follow the specific conditions of the exemption.

NLPB Quality Assurance Program - Practice Site Assessment Update

2020 has certainly been an interesting year. Not unlike other areas of practice, the events of Snowmaggedon along with the COVID-19 pandemic have created challenges with the administration of the NLPB practice site assessment (PSA) program. Early in the pandemic, NLPB halted all PSA activities so that both pharmacy professionals and NLPB staff could focus on the critical issues facing pharmacy services and patient care. Some sites were partway through the assessment process at that time and were made aware of areas where improvements were needed, but we held off on following up on action items until later in the summer, given the challenges that pharmacists-in-charge (PICs) and pharmacy staff were experiencing. Throughout the summer, the NLPB QA team consulted with pharmacy regulators in other jurisdictions about resuming QA programming and how to offer continuing supports to assist registrants in the field with meeting pharmacy practice and regulatory standards. Subsequently, QA activities resumed this fall as described below.

Community Pharmacy Assessments

The modified community pharmacy PSA process that launched in late October enables assessments to be partially completed by distance, reducing the amount of time NLPB assessors are on-site. This plan was communicated to registrants in the October issue of The PostScript. Key revisions include:

- A more extensive pre-assessment component, including PICs submitting their completed Self-Assessment Form earlier, and a pre-assessment phone call with an assessor to review the self-assessment and help prepare for the in-person visit.
- Assessors spending less time on-site - ideally no more than 2 hours - during which they will focus primarily on assessing physical elements and documentation that cannot be adequately assessed electronically.
- While on-site, assessors will follow Public Health guidance as well as the pharmacy's policy for COVID-19 risk mitigation, including having both the assessor and pharmacy staff wear face masks.
- Following the assessment, assessors will arrange a time to discuss the overall findings and areas for improvement with the PIC by telephone, email, or video conference.

Despite this year's challenges, NLPB is pleased to say that we have completed 22 practice site assessments in 2020, to date.

In the interests of "*Lessons Learned*", we have identified the following common area of practice where improvement is generally needed:

- **Implementation of Compounding Standards:**
  - ⇒ Many community pharmacies have still not met the implementation deadlines for Phase One of compounding standards implementation, which were required to be completed by December 31, 2019. For clarification, the Phase One deadline was not extended by NLPB as a result of COVID as this deadline should have already been met. Phase Two and Three deadlines were extended by one year; however, pharmacy professionals are expected to meet standards as soon as possible.
  - ⇒ NLPB is particularly concerned that some community pharmacies continue to compound preparations without completing risk assessments and implementing associated risk mitigation plans. This results in continued risk to pharmacy personnel as they may be exposed to products that pose health hazards without adequate protection, and also may present continued risks to patients if they are receiving compounded products that do not meet quality standards.

NLPB Quality Assurance Program - Practice Site Assessment Update

⇒ **Bottom line**: If pharmacy professionals cannot provide a rationale for their compounding activities that is supported by references and addresses quality and safety concerns, they must cease compounding until such expectations are met.

- **Use of Required References**
  ⇒ Most PICs declare that they have all of the required references to support practice, but when assessors confirm references on site, the PIC is unable to locate them. This raises concerns that they may not be readily available to pharmacy staff and utilized by pharmacists to support clinical decision-making.
- **Opioid Agonist Maintenance Treatment (OAMT)**
  ⇒ NLPB has specific concerns about pharmacists' familiarity with required clinical references for OAMT, based on the questions received during practice site assessments and by NLPB office. Pharmacy professionals involved in OAMT should ensure they are up-to-date with current practice guidelines for this rapidly evolving area of practice, and should complete additional education to address any identified knowledge gaps.
- **Security and Accountability of Narcotics and Controlled Drugs**
  ⇒ Despite previous NLPB communications, assessors continue to detect issues with timely and consistent completion of physical inventory counts and reconciliation, and completion of required audits of purchases and sales. PICs are responsible under federal legislation to protect controlled substances from loss or theft. It is concerning when PICs are not meeting inventory monitoring requirements as it may present risk of diversion.
- **Documentation of Vaccinations**
  ⇒ Assessors have identified that many pharmacists are unfamiliar with how to properly document administration of vaccinations in the provincial electronic health record via the Pharmacy Network. The NL Centre of Health Information and/or the pharmacy's software vendor should be consulted to ensure that this necessary information is being successfully transmitted.

Hospital Pharmacy Assessments

In comparison to the community program, the PSA program for hospital pharmacies is in the early phase of implementation. Baseline assessments have been completed for all hospital pharmacies in the province. The primary goals of these initial assessments were to introduce QA program objectives to hospital pharmacy teams and Regional Health Authority senior management, and to work with the teams to identify areas where NLPB standards may not be fully met and set improvement priorities.

NLPB has not yet resumed the on-site portion of the hospital PSA program. However, since early fall, the Practice Site Assessor (Hospital) has been holding regular virtual meetings with representatives from each hospital pharmacy in the province. Currently, the focus of these meetings is implementation of the sterile and non-sterile compounding standards, and monitoring of associated complex site renovations. At this time, NLPB plans to continue to provide virtual support for hospital pharmacies into 2021.

Concluding Remarks

The NLPB QA team looks forward to engaging with pharmacy colleagues in the field to a greater capacity as soon it is safe to do so. Thank you to all registrants who have participated in QA programming this year - your commitment to quality and safety is appreciated.

NEWFOUNDLAND & LABRADOR PHARMACY BOARD

NLPB Office Contact Information

Address	**Phone / Fax**
Suite 201 145 Kelsey Drive St. John's, NL A1B 0L2	Phone: 709-753-5877 Toll-Free: 877-453-5877 Fax: 709-753-8615
General Information	inforx@nlpb.ca
Sonya Doran Office Administrator *(Leave Replacement)*	sdoran@nlpb.ca
Meghan Handrigan *(on Leave)* Office Administrator	mhandrigan@nlpb.ca
Melanie Healey Associate Registrar – Professional Practice	mhealey@nlpb.ca
Gayle Johnson Complaints and Quality Assurance Coordinator	gjohnson@nlpb.ca
Amanda Martin *(on Leave)* Communications Specialist	amartin@nlpb.ca
Aileen O'Keefe Registration and Licensing Administrator	aokeefe@nlpb.ca
Noelle Patten Associate Registrar – Quality Assurance	npatten@nlpb.ca
Natalie Payne *(on Leave)* Legal Counsel	npayne@nlpb.ca
Margot Priddle Registrar	mpriddle@nlpb.ca
Russell White Practice Consultant / Practice Site Assessor	rwhite@nlpb.ca

@NLPHARMACYBOARD