NEWFOUNDLAND & LABRADOR PHARMACY BOARD

THE APOTHECARY NEWSLETTER

SPRING 2022 - nlpb.ca

IN THIS ISSUE:

The official newsletter of the Newfoundland & Labrador Pharmacy Board.

Registrants are responsible for reviewing all information within this publication.

@NLPHARMACYBOARD

Welcome to the Spring 2022 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.

COMPOUNDING STANDARDS — THE JOURNEY TO IMPLEMENTATION

Implementation of Sterile and Non-sterile Compounding Standards — A Walk Down Memory Lane...

FEBRUARY 2017

NLPB adopts NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations and Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations.

FALL 2017

NLPB conducts a pilot of the practice site assessment program for hospital pharmacies, revealing significant gaps between the requirements of the new compounding standards and current practices and infrastructure. NLPB initiates discussions with the pharmacy management and senior executives within the Regional Health Authorities (RHAs) and the Department of Health and Community Services (DHCS) about the need to implement the new standards in the interest of patient safety.

FEBRUARY 2018

NLPB adopts NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations and Guidance Document for Pharmacy Compounding of Non-Sterile Preparations, in principle.

SPRING 2018

NLPB strikes two task forces — one for non-sterile compounding and one for sterile compounding — to inform the development of implementation schedules for the standards.

FEBRUARY 2019

NLPB approves the Implementation Schedule for Non-Sterile Compounding Standards and Implementation Schedule for Sterile Compounding Standards.

2019

Registrants assess their pharmacy's gaps and start action planning as they approach the Phase 1 deadline at the end of the year.

JUNE 2020

Phase 2 and 3 Compounding standards deadlines are extended by 1 year in recognition of additional constraints on the health care system as a result of the COVID-19 pandemic.

DECEMBER 31, 2021

End of Phase 2. All pharmacies are expected to fully meet Level A non-sterile compounding standards. Pharmacies providing Level B, Level C, and sterile compounding standards have most "people and process" elements of the standards in place and are completing or have completed facility upgrades.

Celebrating Completion of Phase 2

December 31, 2021 marked the end of Phase 2 of compounding standards implementation. Pharmacy owners, managers, pharmacists-in-charge, and pharmacy professionals have made significant progress with improving the quality and safety of compounding practice by updating policies and procedures, improving the training of compounding personnel, and upgrading their infrastructure. Many community and hospital pharmacies have invested heavily to be able to safely provide compounding services. Throughout these past three years, NLPB practice consultants and assessors have received many inquiries from pharmacy professionals and have been regularly assessing pharmacy renovations. NLPB would like to thank registrants for their commitment to quality improvement and patient safety.

Phase 3: Approaching the Finish Line

DECEMBER 31, 2022

The final deadline to meet ALL Level B and C non-sterile and sterile compounding standards.

As the implementation plan progresses through Phase 3, many pharmacies engaging in complex compounding are nearing the completion of significant facility upgrades and are in the process of implementing a quality assurance program that verifies the quality of their compounding practice and the integrity of their facilities. Specifically, most hospital pharmacies have faced complex renovations that were necessary to meet facility requirements for sterile compounding, a higher risk practice that is primarily carried out by hospital pharmacies in this province. Significant resources have been invested by the provincial government through the Regional Health Authorities (RHAs) and pharmacy teams have been dedicated to bringing the sterile compounding standards to life.

Once renovations are completed, pharmacy teams must schedule and prepare for the final certification and NLPB site assessment. NLPB's Practice Site Assessor (Hospital), Ken Walsh, who teams would have been in contact with throughout the process, will provide a list of required documents and arrange an on-site or virtual assessment of the newly constructed or renovated space. Ken has been a hospital pharmacist for many years and completed his Certification for Sterile Compounding for Inspectors through Critical Point.

As many hospital pharmacies are approaching the facility certification and assessment process, Ken has some helpful tips for achieving a successful outcome:

- Contact the certification company well in advance to arrange a certification date for the compounding facility and equipment.
- When the certification is scheduled, contact NLPB at the earliest opportunity, at least 30 days in advance, to schedule your assessment.
- Complete the relevant NLPB self-assessment form to ensure all requirements are met.
- Submit the pre-assessment documentation requested by the assessor — including an up-to-date self-assessment, clearly labelled photos, and certification documents — as soon as possible.
- Ensure the relevant staff are scheduled to participate in the preparation, certification, and assessment processes.

CROSSING THE FINISH LINE - JAMES PATON MEMORIAL HOSPITAL PHARMACY

James Paton Memorial Hospital Pharmacy became the first hospital pharmacy to complete its construction of new sterile compounding facilities and the related certification and assessments processes in March 2022. John Bautista, Central Health's Compounding Supervisor, regards the accomplishment with both pride and relief. With so many moving parts, the project was a team effort, with project manager, Lindsey Lewis; sterile compounding technicians, Wendy Fudge, Robyn Jennings, and Julie Woolfrey; and housekeeping staff, led by manager Dana Fudge, all playing a vital role. When asked what factors he felt led to their success, John replied, "working with team members who respected each other and who really accepted responsibility and did what needed to be done, without hesitation."

The project team was diversely skilled to ensure all bases were covered. The project manager was a vital link between pharmacy and the various contractors and sub-contractors working on the facility, and was able to reconcile the pharmacy requirements with the physical construction to ensure all standards were being met. John was able to use his Lean Healthcare Green Belt as an asset on the project as it enabled him to visualize the workflow area and helped him design the physical layout of the facility. The housekeeping staff had an important role in meeting the standards, as they were responsible for making the area safe for staff and, by extension, safe for patients.

The project received a lot of support from management, with Pharmacy Manager, Evelena Verge, and Director of Pharmacy, George Skeard, helping to provide solutions to various challenges encountered during the life of the project. In addition, John was able to reach out to his counterparts from the other RHAs in the province to gain knowledge from their collective experiences.

John and his team have been in constant contact with NLPB's Practice Site Assessor (Hospital), Ken Walsh, since the beginning of the project. "He was, and continues to be, very timely in answering my questions, and has really worked with us, providing potential solutions to any problems we meet along the way," said John of working with Ken, "he appreciates the enormity of this project, and that has been beneficial indeed."

In preparing for the final certification and NLPB assessment of the renovation, John and his team took the time to write a revised and detailed gap analysis based on what is required by NLPB. It allowed the team to reflect on what they had collectively created and how far they had come since their initial gap analysis in 2019. To prepare for the arrival of the certifiers, the housekeeping staff began a thorough cleaning of the area as soon as the contractors had finished their work. Once the housekeeping staff were finished, the pharmacy technicians took time out of their busy work day to intensively clean the hoods. When preparing for the NLPB site assessment, John and his team took many photos, as the public health restrictions at the time due to the COVID-19 pandemic prevented an on-site assessment. In addition to the list of requirements provided by NLPB, when taking pictures, John tried to anticipate any small details that may need to be assessed, such as signage, ceilings, air vents, and the locations of alcohol-based hand rub dispensors.

As many hospital pharmacy teams are working diligently towards this achievement, John would offer this advice, "Engage stakeholders, such as housekeeping, early and regularly. Consult your peers and reach out to NLPB if you run into problems. And pictures, lots of pictures."

Having worked closely with the team during the duration of this project, NLPB's Practice Site Assessor (Hospital), Ken Walsh, would like to commend Central Health's pharmacy team for their work towards reaching compliance with the facility requirements of the sterile compounding standards.

BOARD MEMBERS

BOARD UPDATES

The NLPB Board of Directors met on March 11 for their first board meeting of 2022. The next meeting of the board will take place in August 2022, along with a strategic planning session to re-evaluate the 2020-2022 Strategic Plan. The Annual General meeting will take place on May 13, 2022.

EXECUTIVE COMMITTEE

CHAIR
Taggarty Norris

VICE CHAIR
Henry White

EXECUTIVE MEMBER
Jason Ryan

PAST CHAIR
Gerri Thompson

PUBLIC REPRESENTATIVES

BOARD-APPOINTED
Shirlene Murphy
Mark Sheppard

GOVERNMENT-APPOINTED
Gerri Thompson

NON-VOTING

REGISTRAR
Margot Priddle

ELECTED MEMBERS

ZONE 1 PHARMACIST
Amy Randell

ZONE 2 PHARMACIST
Jason Ryan

ZONE 3 PHARMACIST
Jennifer Godsell

ZONE 4 PHARMACIST
Henry White

ZONE 5 HOSPITAL PHARMACIST
Nicole Kennedy

ZONE 6 PHARMACY TECHNICIAN
Jillian Thorne

ZONE 7 AT-LARGE PHARMACISTS
Timothy Buchanan
Taggarty Norris

DEAN, MEMORIAL UNIVERSITY SCHOOL OF PHARMACY

Shawn Bugden

BOARD MEETING UPDATE

Prior to the March 11 meeting of the board, the board decided to postpone the planned strategic planning session for March, due to the additional strain pharmacy professionals experienced during the COVID-19 outbreak earlier this year, making meaningful registrant engagement difficult. The strategic planning session has been rescheduled for August 2022, with registrant engagement planned prior to the session.

Point of Care Testing Guidelines

At this meeting, NLPB board members approved the *Guidance for Point of Care Testing in Community Pharmacy* document. The guidelines detail both operational and pharmacist expectations when providing point of care testing services and are intended to guide pharmacy practice in the absence of defined legislation or standards of practice. Registrants should only depart from a guideline if they can demonstrate that, by doing so, they did not detract from the safety, effectiveness, or appropriateness of patient care. These guidelines should be reviewed by all registrants. The guidelines are available on the Standards, Guidelines, Policies & Positions page under the Pharmacy Practice section of the NLPB website or by clicking this link: https://nlpb.ca/media/Guidelines-POCT-March2022.pdf

Professional Development Accreditation

Following a jurisdictional scan conducted by staff and discussion of the issue at a previous meeting of the board, the board formally acknowledged that professional development accreditation is not an appropriate business line for a regulatory body. Therefore, the board decided that NLPB will cease accreditation services by November 30, 2023, with the understanding that NLPB will support initiation of accreditation services by another organization who is interested to the extent possible. Additional information regarding this matter will be communicated in the coming months.

Quality Assurance Committee

Following a recent call for expressions of interest for registrants to fill open positions for hospital pharmacists and pharmacy technicians on the Quality Assurance Committee, the board appointed four applicants, Brittany Churchill, Cassandra Osmond, Paula Chaplin, and Sheilagh Hanley to the committee for a three-year term. In addition, current committee members Karen Mercer, Kelda Newport, Susan Gladney-Martin, and Andrew Sweetapple were re-appointed to sit on the committee for a further three-year term.

Continuous Quality Improvement Program

NLPB committed to the development and implementation of medication safety standards (including incident reporting processes) in the 2020-2022 Strategic Plan. The project was placed on hold in 2019 to allow for the completion of the *National Association of Pharmacy Regulatory Authorities (NAPRA) Model Standards for Continuous Quality Improvement and Medication Incident Reporting*. NLPB staff members sat on the task force responsible for the development of these standards, which were published in July 2021. During the most recent meeting of the board, these standards were adopted in principle, for the purpose of developing an accompanying interpretation guide and continuous quality improvement (CQI) program for community pharmacies. It was noted that CQI programs implemented by some other Canadian provinces have included common elements which may be implemented in NLPB's future program, such as the reporting of medication incidents, data analysis, proactive risk management, open communication about medication incidents and lessons learned, and documentation and evaluation of medication incidents.

In order to begin development on a plan to launch the program, the board approved a name for the CQI program — MedSTEP NL (Medication Safety Through Error Prevention).

Also during this meeting, a task force was struck to provide feedback on the development of an interpretation guide, advise on CQI program components, and recommend implementation deadlines. Several members of the board have joined the task force, with plans to put out a call for additional volunteers in the coming months.

RESPONSIBILITIES OF A PHARMACIST-IN-CHARGE — MANAGING LEAVE

Whether staff are taking a short vacation, an extended leave of absence, or leaving their position with the pharmacy, pharmacists-in-charge have a duty to ensure the pharmacy is taken care of while staff members are away. Recently, NLPB has encountered several instances when this duty has not been upheld. A pharmacist-in-charge's failure to comply with their responsibilities and obligations as set out in the *Pharmacy Act, 2012* and *Pharmacy Regulations, 2014*, may result in disciplinary action. To avoid such instances and to ensure public safety, pharmacists-in-charge are encouraged, when possible, to have policies and procedures in place to ensure staff leave does not negatively affect pharmacy operations or patient care.

Replacing the Pharmacist-in-charge

A pharmacy cannot operate for an extended period of time without a designated pharmacist-in-charge on site. Pharmacists-in-charge who will be away for more than 45 days or will be permanently leaving their position with the pharmacy are responsible to ensure another pharmacist is designated as a pharmacist-in-charge. In these instances, it is not only the pharmacist-in-charge's responsibility to notify the pharmacy owners, but they are also required to notify NLPB. When possible, notice should be given to NLPB 30 days prior to the pharmacist-in-charge taking extended leave or leaving their position with the pharmacy, otherwise the application will be subject to an additional fee. Although the pharmacist-in-charge may not be the person responsible for hiring their replacement, they do have a responsibility to ensure that the pharmacy does not operate without a designated pharmacist-in-charge.

The timeline to replace a pharmacist-in-charge can vary depending on the candidate selected. At one end of the spectrum, if the candidate is a current registrant with NLPB and has already been authorized to be designated a pharmacist-in-charge, then the processing time is minimal upon NLPB receiving the completed Application to Change Pharmacist-in-Charge. On the other end of the spectrum, if the candidate is currently practicing in another Canadian province and is not registered with NLPB, then the timeline can take up to 8 weeks to allow for obtaining required documents, processing of applications, and successful completion of both the NLPB registration exam and pharmacist-in-charge education program. In addition, documents which must be obtained from third-parties, such as a certificate of conduct or letter of standing, are subject to the third-parties' processing times. Explore all of your options for designating a new pharmacist-in-charge by reviewing Chart A: Process for PIC Replacement on page 8.

In the case of extended leave of more than 45 days, if no suitable candidate is found before the pharmacist-in-charge leaves, then they must apply to NLPB for a temporary closure by completing and submitting the Request for Temporary Closure form.

In the case of a pharmacist-in-charge permanently leaving their position with the pharmacy, if no suitable candidate can be found before they leave, they are required to contact NLPB to discuss the process for closing the pharmacy. If the pharmacy owner is able to hire an eligible pharmacist-in-charge in the future, they can apply for a new pharmacy licence.

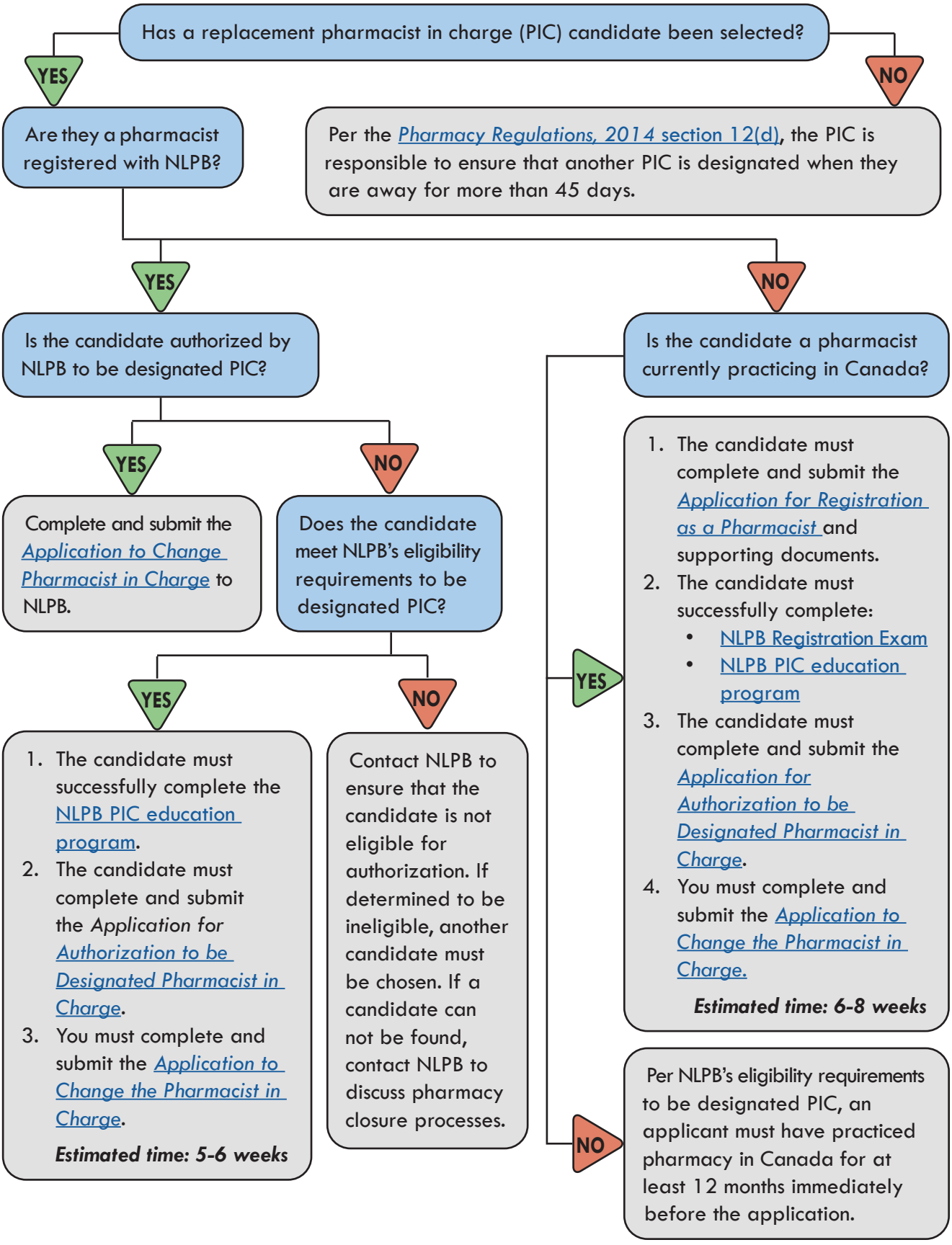
HIRING FROM ANOTHER PROVINCE

The registration process for a pharmacist practicing within another Canadian province includes obtaining:

- Certificate of conduct issued within the past six months;
- Letter of Standing from all pharmacy regulatory authorities with which they are currently, or were formerly, registered;
- Verification from their employer(s) that they have practiced as a pharmacist for a minimum of 420 hours in the previous two calendar years;
- Successful completion of the NLPB Registration Exam;
- Proof of professional liability insurance; and
- Proof of membershp with PANL.

RESPONSIBILITIES OF A PHARMACIST-IN-CHARGE — MANAGING LEAVE

CHART A: Process for PIC Replacement



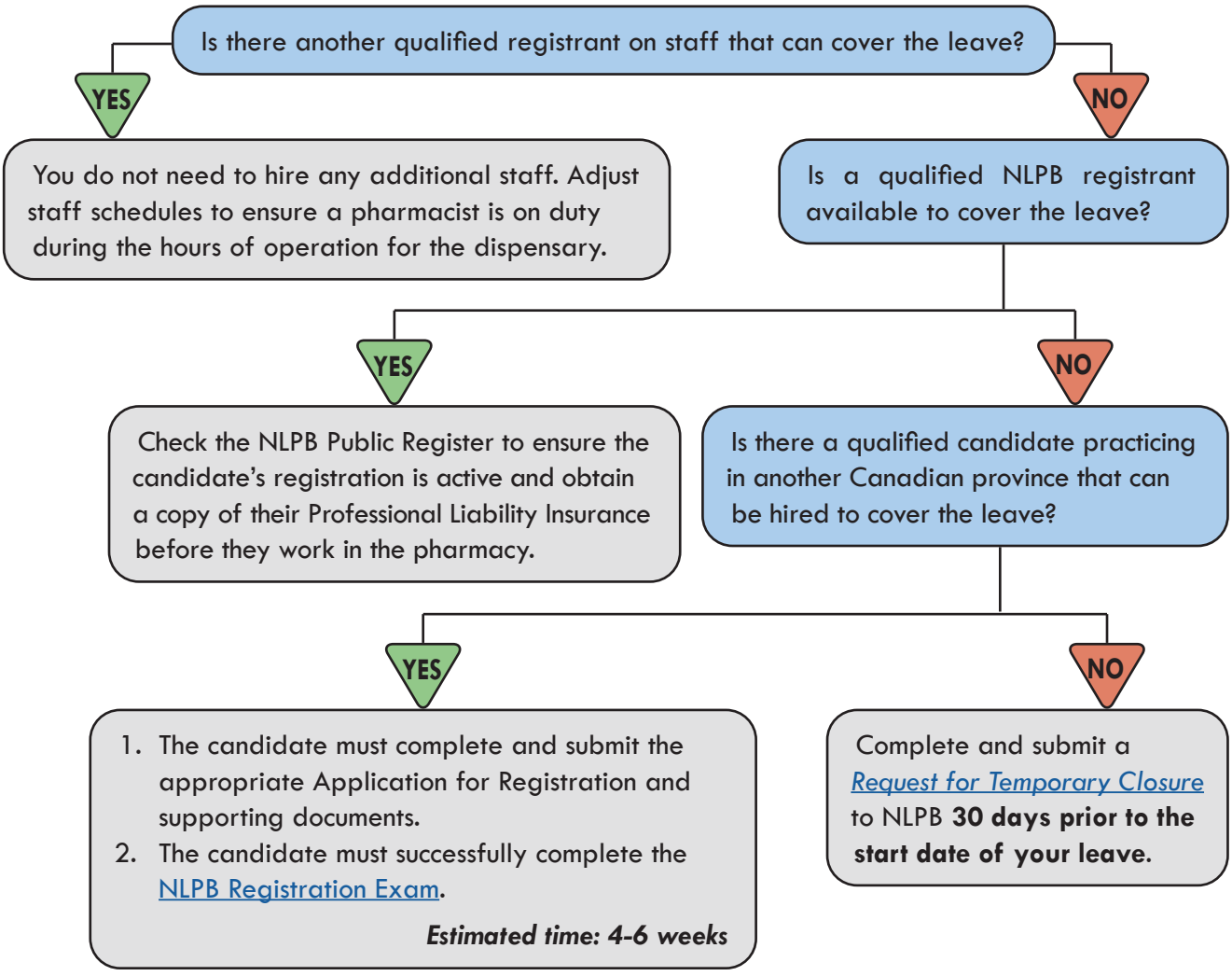
RESPONSIBILITIES OF A PHARMACIST-IN-CHARGE — MANAGING LEAVE

Managing Pharmacist Relief

A pharmacy cannot operate without the oversight of a pharmacist and sufficient staff. Therefore, it may be necessary to hire additional temporary staff to cover the pharmacy staff leave. If hiring pharmacists or pharmacy technicians from other Canadian provinces to cover staff leave, ensure there is sufficient time to have them complete the registration process. Relief pharmacists and pharmacy technicians should not be relied on for coverage until their registration is confirmed. The registration process for a pharmacist or pharmacy technician practicing within another Canadian province can take 4-6 weeks to complete. For a detailed view of the process of covering short term leave, refer to Chart B: Process for Pharmacist or Pharmacy Technician Leave Relief below.

When managing staff leave, the pharmacist-in-charge's main priority should always be continuity of care for the pharmacy's patients. If any changes to pharmacy hours of operation and/or services should result from a staff shortage, or for any other reason, it is their duty to ensure patients are informed and that their needs will be addressed during the disruption. NLPB should also be informed of the change in pharmacy operation at the earliest opportunity.

CHART B: Process for Pharmacist or Pharmacy Technician Leave Relief



COMPLAINTS AND DISCIPLINE UPDATE

Failure to Perform Adequate Assessment in Relation to Refill Requests

While two parents were in the midst of sorting out custody and parenting of their child, one parent (the Complainant) filed an allegation against a pharmacist, alleging that the pharmacist had been dispensing too much of a controlled substance that was prescribed to the child to the other parent. The child's patient profile printout showed multiple early refills that resulted in nearly double the amount of tablets being dispensed over a nine month period. The pharmacist acknowledged the early refills and indicated that they were primarily provided at times when the other parent stated that they had not received all of the child's medication back from the Complainant when the child returned from their care. The pharmacist attempted to reach the prescriber on a number of occasions but did not receive any direct communication in reply from the prescriber.

The Complaints Authorization Committee found reasonable grounds to believe that the pharmacist had breached the following responsibilities: to assess patient adherence issues prior to dispensing, to consult with other health care professionals when appropriate, to consider how inappropriate use of medication can negatively impact the general public, and to take appropriate measures to mitigate potential public risks that may arise from his decisions. The Complaints Authorization Committee counselled the pharmacist to consider both the safety of his patients and public safety, and to consider intervening sooner in circumstances where family disputes are interfering with a patient's regular refill schedule. The pharmacist was also counselled to consider other means to correct the problem, such as ensuring a conversation with the prescriber occurs or contacting the police or child protective services when it becomes apparent that there are regular questions arising about whether a child is receiving their medication.

LESSONS LEARNED

Regardless of whether the patient has presented a prescription for a new medication, a new prescription for ongoing therapy, or has requested a refill, no medication should be released to the patient without a pharmacist completing a clinical assessment and consulting with the patient or their agent, as required.

When assessing refill requests for appropriateness, pharmacists are expected to review relevant patient information to ensure:

- there are no significant drug interactions, contraindications, or adverse effects;
- the medication is still required;
- the patient is adherent with taking the medication as prescribed for their health condition;
- the dose and instructions for use of the medication are correct; and
- that the patient is receiving appropriate monitoring for this medication and disease.

If after completing this assessment, the pharmacist determines that the patient's request for a refill poses a potential risk to the patient or that there are medication adherence issues, they are expected to:

- adapt the prescription as necessary, in accordance with appropriate legislation and standards;
- contact the prescriber to discuss the issue and/or recommend changes to the drug therapy; and/or
- refuse to dispense the medication.

Further to this, in accordance with the Code of Ethics, registrants have a societal obligation to

- recognize how the inappropriate use of medication can negatively impact patients, the general public, and the health care system, and participate in activities that prevent such harms whenever possible; and
- take appropriate measures to mitigate potential public risks that may arise from their practice decisions.

COMPLAINTS AND DISCIPLINE UPDATE

Breach of Code of Ethics in Relation to Advertising and Inducements

An allegation was filed alleging that a pharmacy had violated NLPB's advertising guidelines with respect to an advertisement posted through various social and other media by a third-party company that the pharmacy had a contract with. The allegation was forwarded to both the staff pharmacist who had provided quotations for the advertisement and to the pharmacist in charge.

The Complaints Authorization Committee determined that there were reasonable grounds to believe that the advertisement violated the NLPB's advertising and inducement guidelines as it contained: comparative statements implying superiority over other pharmacies, endorsements, and inducements to encourage the transfer of prescriptions to that pharmacy.

The Complaints Authorization Committee counselled the staff pharmacist and pharmacist in charge to ensure the advertisement was removed and to be more cautious in the future about attaching their name or the pharmacy's name to an advertisement.

The Complaints Authorization Committee also counselled the parties that regardless of who sponsors an advertisement, it must comply with all NLPB requirements.

LESSONS LEARNED

Registrants are expected to practice in accordance with the Code of Ethics, which states that:

- registrants do not participate in advertising or promotion that is outside of the boundaries of the law or that diminishes the dignity and honour of the profession; and
- registrants do not offer inducements to any person or entity that are conditional on or related to a patient obtaining medications or services from the registrant.

The Code of Ethics Interpretation Guide related to Advertising & Promotion goes on to state that advertisements and promotions communications MUST NOT:

- contain comparative statements, or claim or imply superiority over other pharmacies or registrants; or
- encourage the transfer of prescriptions by offering the receipt of a gift, discount or other inducement associated with filling prescriptions or receiving professional services.

PROFESSIONALISM ON SOCIAL MEDIA

The requirement to abide by all federal, provincial, and NLPB legislation, standards, and guidelines, along with expectations of professional and ethical conduct, are the same for registrants whether they are interacting with others in person or through social media and whether they are interacting in a personal or professional context.

Registrants are reminded to review and abide by the NLPB Registrant Use of Social Media Policy when interacting on social media platforms. Inappropriate use of social media may result in disciplinary action from the NLPB, disciplinary action from the registrant's employer, an investigation by the Office of the Information and Privacy Commissioner, civil liability, or prosecution.

Any registrant who is aware of any activity by another registrant that is in violation of these requirements has a duty to report, as outlined in section 58 of the *Pharmacy Act, 2012*.

CONTINUOUS QUALITY & SAFETY IMPROVEMENT – PRACTICE SITE ASSESSMENTS

Public health restrictions and the additional strain on the healthcare system due to the COVID-19 pandemic have contributed to a delay in the scheduling of NLPB practice site assessments (PSAs). However, as NLPB has moved forward in scheduling PSAs, practice site assessors have faced additional challenges with pharmacists-in-charge (PICs) committing to carving out the time in their schedule to carry out the assessment. While we understand that pharmacy professionals are busy managing day-to-day practice issues, NLPB staff are required to carry out PSAs as part of NLPB's Quality Assurance (QA) program, and PICs are required to participate. Continuous improvement of quality and safety in pharmacy practice must remain a shared goal of both NLPB and pharmacy professionals, and PSAs are key to ensuring that goal is reached.

A Legislative Requirement

Section 52(1) of the *Pharmacy Act, 2012* states:

52. (1) The board shall establish and maintain a quality assurance program to promote high standards of practice within the pharmacy profession.

Per the legislation, the QA program must be designed to promote continuing competence and quality improvement.

The QA program consists of four main categories:

- registrant;
- practice site;
- practice support tools; and
- legislative and regulatory support.

Within the practice site category, NLPB has developed practice site assessment programs for community and hospital pharmacies in order to promote regulatory standards and facilitate quality improvement processes.

Community Pharmacy PSAs: Getting Back on Track

NLPB has been carrying out practice site assessments in community pharmacies since 2014. The QA program has a set target to assess a pharmacy at least every 3-5 years, as well as to perform assessments upon pharmacy opening, renovation, or relocation. Since 2020, circumstances have made it difficult to meet this target, as the focus of both registrants and NLPB had to shift to the issues related to the COVID-19 pandemic. However, as the province adjusts to a new normal of living with COVID-19, NLPB is compelled to shift back to its core business lines and meet its regulatory obligation to carry out QA activities.

As indicated in the Fall 2021 issue of The Apothecary, NLPB recently implemented a new virtual method of conducting assessments, to address the challenges the COVID-19 pandemic will continue to present to scheduling and conducting community pharmacy PSAs. This process allows assessments to be completed remotely, adding more flexibility to scheduling for PICs and enabling NLPB to resume the pre-pandemic frequency of conducting assessments.

When a pharmacy is selected for a PSA, the PIC will receive an email, indicating an assessment date. As such, it is important that PICs ensure the preferred email address in the pharmacy profile of NLPB's member portal is accurate, and that it is being checked regularly. The NLPB assessor will then consult with the PIC directly to determine the assessment start time. It is important to note, that although NLPB does its best to work with the PIC to accommodate their schedule, participation is mandatory. Assessments are usually scheduled four weeks in advance to give the PIC sufficient notice to prepare. PICs are asked to confirm their assessment time as soon as possible and only request to reschedule if necessary (i.e. unexpected staff shortages, illness, etc.).

Patient Safety: A Shared Goal

Through the PSA program, NLPB aims to enhance patient outcomes by working with registrants to increase adherence to federal and provincial legislation, Standards of Practice, and the Code of Ethics. NLPB's mandate is to protect the public; however, patient safety is a shared goal with registrants, as we collectively aim to improve the safety and quality of pharmacy practice and meet patients' health care needs.

NLPB thanks pharmacy professionals for their commitment and cooperation towards meeting this shared goal.

NEWFOUNDLAND & LABRADOR PHARMACY BOARD

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