New Brunswick College of Pharmacists
Ordre des pharmaciens du Nouveau-Brunswick

GUIDANCE FOR PRESCRIBING IN ACCORDANCE WITH A RESEARCH OR PILOT PROTOCOL

Acknowledgement

The New Brunswick College of Pharmacists gratefully acknowledges the Nova Scotia Pharmacy Regulator for their invaluable contribution in developing the original documents *Prescribing in Accordance with a Research or Pilot Protocol, Approach to Scope of Pharmacist Prescribing,* and the *Review of Scope of Practice Framework*. Their willingness to share these resources has been instrumental in creating a framework suited to New Brunswick practice.

Introduction

The New Brunswick College of Pharmacists (NBCP) has developed a framework that enables pharmacists to prescribe medications within approved research or pilot projects. This initiative supports the evolution of pharmacy practice through innovation and research, while also enabling pharmacy practice research that serves the public interest by ensuring pharmacists are able to apply the full extent of their knowledge and skills to meet patient health needs. In doing so, it advances the College's mandate to protect and promote the health and wellbeing of New Brunswickers.

The College ensures that any expansion in pharmacists' prescribing authority is guided by comprehensive oversight and systematic evaluation, prioritizing public health and safety while delivering measurable benefits to patients and the healthcare system. This document provides research teams with clear guidance on eligibility requirements, submission procedures, and reporting obligations necessary to conduct prescribing-related research under NBCP authorization. This authority is established under Section 21.3 (f) of the Regulation. The authority also supports the NBCP in exploring safeguards to determine under what circumstances a pharmacy practitioner may prescribe for a condition or within a specific practice arrangement, which is currently being studied.

Eligible Research and Pilot Protocols

The research or pilot protocol must fulfill one of the following criteria to be authorized under prescribing pursuant to a Council-approved research or pilot project, in accordance with Section 21.3 (f) of the regulation.

- Approval from a Research Ethics Board (REB) that complies with the Tri-Council Policy Statement (TCPS)[1]: or
- Collaboration with New Brunswick's Regional Health Authorities, the Department of Health, DataNB or other provincially recognized healthcare entities

[1] https://ethics.gc.ca/eng/tcps2-eptc2_2022_introducing-presentation.html

- Projects will be deemed ineligible if they are funded by individuals or institutions with undisclosed conflicts of interest, including corporations or for-profit companies lacking transparency agreements.

Inter-Provincial Collaboration Protocols

The NBCP council may approve temporary scope expansions for New Brunswick pharmacists to engage in research approved by the Nova Scotia Pharmacy Regulator (NSPR) and the Pharmacy Association of Nova Scotia (PANS), provided the following conditions are met:

- The organization submitting the proposal must have received formal approval from the NSPR and must submit the complete approved proposal to NBCP.
- The NBCP Council will assess the proposal for alignment with New Brunswick's practice environment and will provide written authorization before participation.
- New Brunswick pharmacists participating in the project must meet all education or training requirements as outlined by the organization submitting the proposal.
- All reporting requirements outlined in this framework must be fully met throughout the project's duration.
- NBCP council may consider a permanent scope expansion as appropriate.

Pharmacist Qualifications and Training

Pharmacists participating in research or pilot projects must demonstrate competencies relevant to the prescribing activity. Additional recommended training may include:

- Certification in research ethics.
- Training on informed consent and conflict of interest management.
- Specialized training aligned with the specific scope and requirements of the research or pilot project.

Submission and Approval Process

1. Initial project discussion with NBCP's Deputy Registrar and Director of Practice and Quality Assurance ideally before REB or health authority approval to explore the project teams and NBCP's timelines for submission and review and to initiate initial project discussions.
2. The project team submits a brief overview (max. 5 pages) of the proposed research or pilot project to be conducted that includes:

   - the rationale and public interest(s) that will be served by the new prescribing practice to be studied;
   - an overview of existing research (if applicable) that has explored pharmacist prescribing for the condition or practice arrangement in another jurisdiction;
   - an initial assessment of pharmacist entry-to-practice competencies that enables pharmacists to competently prescribe for the condition or within the practice arrangement, as well as any additional training/education that will be provided to pharmacists before and/or during the project;
   - an initial assessment of potential health system barriers to implementing the proposed pharmacist prescribing and proposed solutions;
   - an overview of safeguards that will be in place during the project to mitigate risk of patient harm;
   - the research methods/methodology(ies) to be used (including evaluation metrics);
   - a description of the project team; and
   - any collaborative agreements or arrangements required with other healthcare providers or health systems.
   - a commitment to identify, collect, and report on patient/pharmacist/system experience or outcome data

   The NBCP Council will use this overview in deciding whether to provide support in principle for the initiative, allowing it to proceed for review by an institutional REB, the

Department of Health, a Regional Health Authority, DataNB or other provincially recognized healthcare entity.

3. Once the research or pilot project has been approved by an institutional REB, the Department of Health, a Regional Health Authority, DataNB or other provincially recognized healthcare entity, the project team must confirm with the NBCP in writing that:

    - the protocol has been approved by an institutional REB, the Department of Health, a Regional Health Authority, DataNB or other provincially recognized healthcare entity; and
    - the project team will provide the NBCP with a final project report based on the evaluation and reporting metrics outlined in the NBCP Review of Scope of Practice Framework (see "Project Report Submission" below).

4. The project team provides an up-to-date list of participating pharmacies/pharmacists to the NBCP, including advising the NBCP when pharmacies/pharmacists are added or removed (to ensure that the NBCP is aware of prescribing activity and can provide appropriate oversight of activities).

NOTE: Pharmacist prescribing for the condition or within the practice setting/arrangement can only commence once the project team has received an approval letter from the NBCP.

Reporting Requirements

The *Review of Scope of Practice Framework* and the *Approach to Scope of Pharmacists Prescribing* outline the key criteria NBCP will consider when evaluating potential changes to pharmacists' scope of practice. These frameworks are intended to support research and pilot project teams, as well as guide NBCP Council discussions, by highlighting important evaluation criteria and identifying the types of information and data that may be relevant when considering broader prescribing authority.

- The final project report submitted to NBCP must comprehensively address the questions outlined in the *Review of Scope of Practice Framework* (to the project team's best ability). This includes:
  - whether the prescribing authority studied is in the public's interest, including any competing public interests that may have been identified during the project;
  - Whether or not pharmacist entry-to-practice competencies supports this new authority and whether additional training is required to attain competency (including if foundational competence supports attaining the advanced competency and whether education/training programs already exist);
  - The extent of collaboration with other healthcare providers required and what conditions might apply;
  - any system-level barriers identified (e.g., ability to order labs, communication with other members of the patient's care team, referrals) that need to be addressed prior to broadly enabling authority;
  - safeguards that are needed to protect the public and promote optimal care; and
  - any future or planned strategies for research or pilot project scale up or health system implementation (if applicable).

- The project teams must confirm to NBCP that it:
  1. Commits to identify, collect, and report on patient/pharmacist/system experience or outcome data that demonstrate the:
     - acceptability of the prescribing activity among patients, pharmacy professionals, and other members of the patient's care team (as appropriate);
     - uptake frequency and patterns of prescribing activity by pharmacy professionals.
     - impact of more broadly enabling the prescribing authority on the public and healthcare system.
  2. Agrees to share all outcome data collected with the NBCP without bias (i.e., both positive and negative outcomes).